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The Perilous Process of Protecting Process
Patents from Infringing Importations

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I. INTRODUCTION

Inventors of new, useful, and nonobvious products and processes may obtain United States patent protection for their inventions.¹ Armed with patents, inventors have the exclusive right to make, use, or sell their inventions, or to perform their processes within the territory of the United States. According to section 271(a) of the Patent Act, with limited exceptions, "whoever without authority makes, uses or sells any patented invention, *within the United States* during the term of the patent therefor, infringes the patent."²

Perceiving a possible geographical limitation in the territorial reach of United States patents, would-be infringers perform patented processes outside the United States and import the resulting products domestically, thus infringing patented processes without penalty. Until recently, United States process patent holders could only hope to exclude infringing importations from entering the United States.³

The Process Patent Amendments Act of 1988⁴ ("Process Patent

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1. Patent Act, 35 U.S.C. § 101 (1988). Section 101 of the Patent Act provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements [of the Patent Act]." *Id.*

2. *Id.* § 271(a) (1988) (emphasis added); see also *id.* § 154 (1988) (contents and terms of a patent).

3. See *infra* notes 40-99 and accompanying text.

4. Pub. L. No. 100-418, §§ 9001-9007, 1988 U.S.C.A.N. (102 Stat.) 1107, 1563-67 (codified at 35 U.S.C. §§ 154, 271, 287, 295); see also Glenn E.J. Murphy, Comment, *The Process Patent Amendments Act of 1988*, 9 J.L. & COM. 267 (1989).

Act”), enacted as part of the Omnibus Trade and Competitiveness Act of 1988,⁵ remedied this situation by expanding the rights of process patent holders. This new law enables process patentees to “exclude others from using or selling throughout the United States, or importing into the United States, products made by that [patented] process.”⁶ The Process Patent Act also creates a judicial cause of action for process patent infringement. This new cause of action provides monetary damages to process patent holders for the importation, sale, or use of infringing products manufactured abroad through processes protected by United States patents.⁷ In theory, the expansive reach of the Process Patent Act effectively affords process patent holders protection beyond the borders of the United States. Thus, since 1989, would-be patent infringers have been prohibited from performing patented processes in both the United States and abroad when intended for importation into the United States.⁸

This Article begins with a brief discussion of the types of processes eligible for patent protection.⁹ Next, it evaluates the remedies available for process patent infringements. In particular, this Article compares the merits of the new in personam judicial proceedings available for process patent infringements under the Process Patent Act with in rem exclusion orders available through the United States International Trade Commission under the Tariff Act of 1930.¹⁰ This Article then provides a brief overview of the Process Patent Act, and analyzes issues of statutory construction raised in the first two years of its existence. The 1991 federal district court case of *Allegheny Lud-*

5. Pub. L. No. 100-418, 1988 U.S.C.A.N. (102 Stat.) 1107 (codified in scattered sections of 19 and 35 U.S.C.); see also PRACTICING LAW INSTITUTE, *THE NEW TRADE LAW: OMNIBUS TRADE AND COMPETITIVENESS ACT OF 1988* (1988); Terry L. Clark, *The Future of Patent-Based Investigations Under Section 337 After the Omnibus Trade and Competitiveness Act of 1988*, 38 AM. U. L. REV. 1149, 1156 (1989); Mark Modak-Truran, Comment, *Section 337 and GATT in the Akzo Controversy: A Pre- and Post-Omnibus Trade and Competitiveness Act Analysis*, 22 INTELL. PROP. L. REV. 189, 192 (1990).

6. Omnibus Trade and Competitiveness Act § 9002, 102 Stat. 1107, 1563 (1988) (amending 35 U.S.C. § 154).

7. 35 U.S.C. § 271(g) (1988).

8. The Process Patent Act entered into effect on February 23, 1989. See Omnibus Trade and Competitiveness Act § 9006; *Bristol-Myers Co. v. Erbamont Inc.*, 723 F. Supp. 1038, 1039 n.6 (D. Del. 1989), *dismissed*, 734 F. Supp. 661 (D. Del.), and *aff'd without opinion*, 918 F.2d 186 (Fed. Cir. 1990).

9. See *infra* notes 14-39 and accompanying text.

10. 35 U.S.C. § 271(g); 19 U.S.C. § 1337 (1988); see *infra* notes 40-105 and accompanying text.

*lum Corp. v. Nippon Steel Corp.*¹¹ raises questions as to whether the Process Patent Act, enacted in the context of comprehensive amendments to the customs laws of the United States, may be interpreted without reference to the customs laws.¹² Finally, this Article identifies a new, expanded liability of importers, who face unexpected perils for "importing" infringing items, even when the "imported" merchandise never enters United States customs territory, and suggests that, for purposes of United States patent law, "importation" should not occur until merchandise actually enters the customs territory of the United States.¹³

II. PROCESS PATENTS

As defined by the Patent Act, the term "process" refers to "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."¹⁴ The United States Supreme Court interprets a process as "an act, or a series of acts, performed upon the subject-matter or to be transformed and reduced to a different state or thing."¹⁵ Therefore, "process" is equivalent to a "method,"¹⁶ and a "process patent" is a "patent on the way an item is produced."¹⁷

Because the United States Patent and Trademark Office grants patents based on how an item is produced, the ultimate product need not be something new, useful, or nonobvious. If the product *is* new, useful, and nonobvious, however, the inventor may secure a patent on both the inventive process and the ultimate invention.¹⁸ Thus, patented processes may be "either a way of getting to something inven-

11. 765 F. Supp. 224 (E.D. Pa. 1991), *reconsideration granted in part, denied in part*, 1991 U.S. Dist. LEXIS 2821 (E.D. Pa. 1991).

12. See *infra* notes 106-38 and accompanying text. The problem may be one of federal district court insulation from customs laws that, at the trial court level, are within the exclusive jurisdiction of the United States Court of International Trade.

13. See *infra* notes 139-83 and accompanying text.

14. 35 U.S.C. § 100(b) (1988).

15. *Cochrane v. Deener*, 94 U.S. 780, 788 (1876); see also *Diamond v. Diehr*, 450 U.S. 175, 182-84 (1980) (quoting *Cochrane*, 94 U.S. at 787-88); *Corn Prods. Ref. Co. v. FTC*, 324 U.S. 726, 744 (1945). A "process" has also been defined as a "means to an end." ARTHUR R. MILLER & MICHAEL H. DAVIS, *INTELLECTUAL PROPERTY: PATENTS, TRADEMARKS AND COPYRIGHT IN A NUTSHELL* 21 (2d ed. 1990).

16. *In re Bergy*, 596 F.2d 952, 965 (Fed. Cir.), *vacated sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028, and *aff'd*, 447 U.S. 303 (1980).

17. U.S. CUSTOMS SERVICE, *Patent Surveys, Process Patents and Exclusion Orders, in CUSTOMS DIRECTIVE* 2300-06 1 (Nov. 21, 1989).

18. 35 U.S.C. §§ 101-104 (1988).

tive or they may be an inventive way of getting to something already known.”¹⁹ It is important to note, however, that processes, like machines, manufactures, and compositions of matter, are subject to the general rules of patentability.²⁰ Accordingly, to secure a process patent, the process must be a new, useful, and nonobvious way of doing something,²¹ and must be more specific than “the very idea of how to do something.”²²

Chemical processes are a common subject of process patents.²³ Inventors of new drugs created from chemical processes often seek to patent not only the drugs themselves, but the way in which they are produced, in order to secure “double” patent protection.²⁴ This is important because, if later proceedings determine that a patented drug is an obvious derivative of an earlier medication, the patent on the drug will be held invalid.²⁵ However, if the inventor also patented the chemical process that led to the drug’s creation, the patent covering the inventive process may still provide substantial protection.²⁶

If a process is particularly abstract, however, it may not be pat-

19. MILLER & DAVIS, *supra* note 15, at 21.

20. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 483 (1974).

21. 35 U.S.C. §§ 101-04; MILLER & DAVIS, *supra* note 15, at 24.

22. MILLER & DAVIS, *supra* note 15, at 25. Professors Miller and Davis explain process patents with the example of pressing pants:

If a pants-presser, for instance, were claimed as new, the idea of pressing pants obviously could not be patented. A particular way of inserting creases, however, might be patentable because, as a way of producing creases, the patent would cover the process and not the very idea of creases.

Thus, the patentability of the result or product of a process is not relevant to the patentability of the process. Clearly, pressed pants, the product of the process, could not be patented. Pressed pants, though useful, are neither novel nor nonobvious. But an ingenious way of producing creases certainly might qualify if it were novel, useful, and nonobvious.

Id.

23. See, e.g., *Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532 (Fed. Cir. 1990) (patent contained claims directed toward recombinant DNA sequences, vectors, and host cells used to produce recombinant erythropoietin); *Bristol-Myers Co. v. Erbamoto Inc.*, 723 F. Supp. 1038 (D. Del. 1989), *dismissed*, 734 F. Supp. 661 (D. Del.), and *aff'd without opinion*, 918 F.2d 186 (Fed. Cir. 1990) (process to prepare doxorubicin, a well-known drug used in the chemotherapeutic treatment of cancer).

24. See, e.g., *In re Pleuddemann*, 910 F.2d 823, 827 (Fed. Cir. 1990); MILLER & DAVIS, *supra* note 15, at 25.

25. See 35 U.S.C. § 103. According to 35 U.S.C. § 103:

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Id.

26. MILLER & DAVIS, *supra* note 15, at 25-26.

entable.²⁷ For example, in *Gottschalk v. Benson*,²⁸ the United States Supreme Court held that an abstract mathematical process of converting information from binary-coded numbers to digital numbers was unpatentable.²⁹ Further, abstract processes may be barred from patentability if they are too similar to non-patentable subject matters, such as mental steps, business methods, laws or principles of nature, or ideas.³⁰ In addition, just as naturally occurring products are not patentable, "a process may not be patentable because, although the inventor was the first to articulate the methodology, it is so basic as to be held, in a sense, naturally occurring."³¹ That is, a formula, program, or method may be deemed to be "out there all along, just like a mineral in the earth that the inventor merely found but did not invent."³²

However, a process is not unpatentable simply because it includes a law of nature or a mathematical algorithm.³³ As the Supreme Court stated in *Diamond v. Diehr*,³⁴ "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."³⁵ Nonetheless, a clear distinction does not always exist between patentable processes and unpatentable principles.³⁶

Prior to the Process Patent Act, courts found that, once a patent issues on the inventive process, the patent holder's power extends only to those products made by the patented process.³⁷ Therefore, a process patent left the field "open to ingenious men [and women] to in-

27. *Id.* at 26.

28. 409 U.S. 63 (1972).

29. *Id.*; see MILLER & DAVIS, *supra* note 15, at 26; Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer-Related Inventions*, 39 EMORY L.J. 1025 (1990).

30. See *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *In re Grams*, 888 F.2d 835, 837 (Fed. Cir. 1989); Application of Sarkar, 588 F.2d 1330, 1335-36 (C.C.P.A. 1978); Application of Chatfield, 545 F.2d 152, 157 (C.C.P.A. 1976), *cert. denied sub nom.* Dan v. Noll, 434 U.S. 875 (1977); MILLER & DAVIS, *supra* note 15, at 26.

31. MILLER & DAVIS, *supra* note 15, at 26.

32. *Id.*

33. *Diamond*, 450 U.S. at 187-88; *Parker v. Flook*, 437 U.S. 584, 590 (1978); *In re Grams*, 888 F.2d at 838; see also *Claim with Algorithm is Unpatentable Under § 101*, 39 PAT. TRADE-MARK & COPYRIGHT J. 23 (BNA) (Nov. 9, 1989).

34. 450 U.S. 175 (1981).

35. *Id.* at 187-88.

36. *Parker*, 437 U.S. at 589.

37. See, e.g., *United States v. Studiengesellschaft Kohle, G.m.b.H.*, 670 F.2d 1122, 1127 (D.C. Cir. 1981) (citing *Merrill v. Yeomans*, 94 U.S. 568 (1876)).

vent and to employ other processes.”³⁸ This principle led courts to find that the “sale of a product made by a patented process does not itself infringe the patent; it is the unauthorized use of the process that infringes the patent.”³⁹

III. REMEDIES FOR PROCESS PATENT INFRINGEMENTS

A. Introduction

1. Pre-1988 Remedies for Process Patent Infringements

Prior to the Process Patent Act, a process patent holder could seek infringement relief only through an import exclusion order issued by the United States International Trade Commission (“ITC”).⁴⁰ Process patents had been protected by former section 337a of the Tariff Act of 1930, which the Omnibus Trade and Competitiveness Act of 1988 repealed.⁴¹ Prior to the Omnibus Trade and Competitiveness Act, section 337a declared that imported goods made by a process patented in the United States would be treated as if a United States product patent existed for the resulting product.⁴² Thus, a United States process patent holder could block the importation and sale of goods made abroad by its patented process, even though the patent holder could cite to no actual “infringement” of its process patent under United States law.⁴³

2. Post-1988 Remedies for Process Patent Infringements

Process patents are now protected under an amended section 337 of the Tariff Act of 1930.⁴⁴ Section 337 allows the ITC to order the United States Customs Service to exclude future importations of in-

38. *Id.* at 1122, 1127-28 (quoting ALBERT H. WALKER, PATENTS § 23, at 140 (2d ed. 1964)).

39. *Id.* (citing *Koratron Co. v. Lion Uniform, Inc.*, 449 F.2d 337, 338 (9th Cir. 1971); *In re Amtorg Trading Corp.*, 75 F.2d 826 (C.C.P.A. 1935), *cert. denied sub nom.* *International Agric. Corp. v. Amtorg Trading Corp.*, 296 U.S. 576 (1935) (noting that former § 337a (now 19 U.S.C. § 337) subjects the importation of products covered by a United States process patent to the same administrative sanctions as products covered by a product patent)).

40. *See, e.g.*, Wilbur L. Fugate, *Antitrust Aspects of International Patent and Technology Licensing*, 5 J.L. & COM. 433, 441 (1985).

41. Tariff Act of 1930, Pub. L. No. 76-515, 54 Stat. 724 (1930), amended by Omnibus Trade and Competitiveness Act § 1342(c); *see also* *Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532, 1540 n.13 (Fed. Cir. 1990).

42. Murphy, *supra* note 4, at 288-89.

43. *Id.* at 289 (citing James M. Johnstone, *Impact of the Drug Price Competition and Patent Term Restoration Act of 1984 on the Generic Industry—Business Considerations and Potential Legal Issues*, 40 FOOD DRUG COSM. L.J. 339, 343 (1985)).

44. 19 U.S.C. § 1337 (1988).

fringing products.⁴⁵ However, section 337 does not empower the ITC to grant any monetary relief to United States process patent holders in the event of infringement.⁴⁶

The new process patent protection law contained in section 271(g) of the Process Patent Act grants federal district courts the power to award monetary damages to process patent holders in the event an infringer imports, sells, or uses articles manufactured abroad by a patented process.⁴⁷ This judicial cause of action for process patent infringement is not intended to eliminate other available legal remedies,⁴⁸ such as exclusion orders from the ITC under section 337 of the Tariff Act.⁴⁹

B. Tariff Act Section 337 Administrative Proceedings Before the United States International Trade Commission

Process patent rights are enforceable against imported products through ITC administrative proceedings. Under the provisions of section 337 of the Tariff Act, the ITC can issue exclusion orders for merchandise imported through unfair trade practices,⁵⁰ for infringements of product and process patents,⁵¹ and for violations of other intellectual property rights, including trademark,⁵² copyright,⁵³ and

45. *Id.* § 1337(d). Section 1337(d) provides:

If the [ITC] determines . . . that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless . . . it finds that such articles should not be excluded from entry.

Id.

46. *Id.* § 1337.

47. 35 U.S.C. §§ 271(g), 284 (1988). According to section 271(g), "Whoever without authority imports into the United States or 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 . . ." *Id.* § 271(g). Further, according to section 284, "Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." *Id.* § 284.

48. The Process Patent Act provides that the Act "shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law." Omnibus Trade and Competitiveness Act § 9006(c); see also U.S. CUSTOMS SERVICE, *supra* note 17, at 2.

49. 19 U.S.C. § 1337.

50. *Id.* § 1337(a)(1)(A). Section 1337(a)(1)(A) prohibits "unfair methods of competition and unfair acts in the importation of articles . . . into the United States." *Id.*

51. *Id.* § 1337(a)(1)(B). Section 1337(a)(1)(B) prohibits "[t]he importation into the United States . . . 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." *Id.*

52. *Id.* § 1337(a)(1)(C). Section 1337(a)(1)(C) prohibits "[t]he importation into the

mask work registrations.⁵⁴ Although the Tariff Act also addresses alleged violations of "trade secrets" not otherwise protectable under federal law,⁵⁵ section 337 is most often invoked to enforce patent rights.⁵⁶ Administrative proceedings under section 337 are in rem,⁵⁷ and the ITC confiscates all infringing articles.⁵⁸

1. Scope of Section 337

Section 337 of the Tariff Act prohibits unfair methods of competition in the importation or sale of articles if the effect of such methods destroys, substantially injures, or prevents the establishment of an efficient and economical United States industry, or restrains or monopolizes trade and commerce in the United States.⁵⁹ Further, section 337 prohibits the importation, sale for importation, and sale within the United States after importation of articles that either infringe a valid and enforceable United States patent or copyright or "are made,

United States . . . of articles that infringe a valid and enforceable United States trademark registered under the Trademark Act of 1946." *Id.*; see also William M. Borchard, *Trademark Piracy at Home and Abroad*, WALL ST. J., May 7, 1991, at A22. Further, a Senate Bill was introduced on April 23, 1991, to prohibit the importation or sale within the United States of goods manufactured outside the United States bearing a trademark that is identical or confusingly similar to a United States registered trademark owned by, or exclusively licensed to, a citizen, corporation, or other entity created in the United States, unless the owner or exclusive licensee consents to the sale or importation. See S. 894, 102d Cong., 1st Sess. (1991).

53. 19 U.S.C. § 1337(a)(1)(D). Section 1337(a)(1)(B)(i) protects against articles that infringe "a valid and enforceable United States copyright registered under title 17" of the United States Code. *Id.* § 1337(a)(1)(B)(i).

54. *Id.* § 1337(a)(1)(D). Section 1337(a)(1)(D) prohibits "[t]he importation into the United States . . . of a semiconductor chip product in a manner that constitutes infringement of a mask work registered under chapter 9 of title 17" of the United States Code. *Id.*; see also U.S. CUSTOMS SERVICE, U.S. CUSTOMS PROTECTION OF INTELLECTUAL PROPERTY RIGHTS (1989).

Mask works are electronic circuitry products, such as integrated circuits and semiconductor chips. See 17 U.S.C. §§ 901-904 (1988); 19 C.F.R. § 12.39(d) (1990); Charles R. McManis, *International Protection for Semiconductor Chip Designs and the Standard of Judicial Review of Presidential Proclamations Issued Pursuant to the Semiconductor Chip Protection Act of 1984*, 22 GEO. WASH. J. INT'L L. & ECON. 331, 343 (1988).

55. U.S. CUSTOMS SERVICE, *supra* note 54.

56. See 3 HAROLD I. LORING, MICHAEL P. MAXWELL & MARK E. WOJCIK, *International Trade*, in NEW YORK PRACTICE GUIDE: BUSINESS & COMMERCIAL § 22.16(4)(a) (1991); see also Clark, *supra* note 5, at 1156; Modak-Truran, *supra* note 5, at 192.

57. "In rem" is "[a] technical term used to designate proceedings or actions instituted against the thing, in contradistinction to personal actions, which are said to be *in personam*." BLACK'S LAW DICTIONARY 793-94 (6th ed. 1990).

58. 19 U.S.C. § 1337(b)-(g).

59. *Id.* § 1337(a)(1)(A); 19 C.F.R. § 12.39(a); see generally DONALD K. DUVALL, FEDERAL UNFAIR COMPETITION ACTIONS: PRACTICE AND PROCEDURE UNDER SECTION 337 OF THE TARIFF ACT OF 1930 (1990).

produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.”⁶⁰

This section 337 exclusion for process patents is available only if an industry in the United States “relating to the articles protected by the patent . . . exists or is in the process of being established.”⁶¹ An industry “exists” if there is a significant United States investment in plants and equipment, significant employment of United States labor or capital, or a substantial United States investment in the exploitation of the patent, including engineering, research and development, and licensing.⁶²

2. Procedures of Section 337

When the ITC receives a proper complaint of process patent infringement under section 337, an administrative law judge holds a preliminary hearing to determine whether the imported articles violate the process patent.⁶³ After this initial determination, the ITC may adopt the administrative law judge’s report, in whole or in part,⁶⁴ or it may determine, irrespective of the administrative law judge’s report, that a possible violation of section 337 exists.⁶⁵ In either case, the ITC’s determination takes effect the day it is published in the *Federal Register*.⁶⁶

The ITC then sends its determination to the United States president, who has sixty days to reject it for policy reasons.⁶⁷ If the president rejects the ITC’s determination, the process patent holder and alleged infringer are not entitled to appeal, and the investigation ends.⁶⁸ If the president does not reject the determination during the sixty-day period, the determination is final and appealable the day following the close of the period.⁶⁹ The determination may be effective

60. 19 U.S.C. § 1337(a)(1)(B); see *supra* note 51 and accompanying text.

61. 19 U.S.C. § 1337(a)(2).

62. *Id.* § 1337(a)(3).

63. 19 C.F.R. §§ 210.41, 210.53 (1990); Clark, *supra* note 5, at 1155.

64. 19 C.F.R. § 12.39(a); Clark, *supra* note 5, at 1155.

65. 19 C.F.R. §§ 12.39(a), 210.56 (1990); LORING ET AL., *supra* note 56, at 22-197; Clark, *supra* note 5, at 1155.

66. 19 U.S.C. §§ 1337(j)(1)(A), 1337(j)(3); 19 C.F.R. § 12.39(a); H.R. REP. NO. 576, 100th Cong., 2d Sess. 639 (1986), reprinted in 1988 U.S.C.A.N. 1547, 1672; LORING ET AL., *supra* note 56, at 22-197.

67. 19 U.S.C. § 1337(j); 19 C.F.R. § 12.39(a); DUVALL, *supra* note 59, at 460-73.

68. *Duracell, Inc. v. United States Int’l Trade Comm’n*, 778 F.2d 1578 (Fed. Cir. 1985); Clark, *supra* note 5, at 1155.

69. 19 C.F.R. § 12.39(a); LORING ET AL., *supra* note 56, at 22-197 to 22-198; Clark, *supra* note 5, at 1155.

earlier if the president notifies the ITC of his approval before the close of the sixty-day period.⁷⁰ Once the ITC's determination is final, the United States Customs Service will deny entry to all merchandise covered by an ITC exclusion order, or seize the merchandise subject to a seizure order.⁷¹

3. International Trade Commission Orders

The types of orders available from the ITC include (1) orders to cease and desist; (2) orders for temporary exclusion; and (3) orders for permanent exclusion.⁷² The penalty for violation of an ITC cease and desist order has increased from \$10,000 or the value of the excluded goods to \$100,000 or twice the value of the excluded goods.⁷³ In addition, an ITC exclusion order, such as that concerning crystalline cefadroxil monohydrate,⁷⁴ can be a general exclusion of all infringing products or a limited exclusion of products from only certain importers.⁷⁵ Limited exclusion orders may result in patent holders expending a great deal of time and money embroiled in section 337 litigation before the ITC, but achieving only pyrrhic victories against a single infringing importer.

Litigants may appeal final ITC exclusion orders directly to the United States Court of Appeals for the Federal Circuit⁷⁶ and ultimately, by writ of certiorari, to the United States Supreme Court.⁷⁷ In contrast to ITC determinations for other international trade laws,⁷⁸ process patent exclusion orders are not subject to intervening appeal

70. 19 C.F.R. § 12.39(a); LORING ET AL., *supra* note 56, at 22-198; Clark, *supra* note 5, at 1155.

71. 19 C.F.R. § 12.39(b); H.R. CONF. REP. NO. 576, 100th Cong., 2d Sess. 639 (1987), reprinted in 1988 U.S.C.C.A.N. 1547, 1672; U.S. CUSTOMS SERVICE, *supra* note 17, at 3.

72. 19 U.S.C. § 1337(f); JEROME GILSON, TRADEMARK PROTECTION AND PRACTICE 8-349 (1989); LORING ET AL., *supra* note 56, at 22-198.

73. 19 U.S.C. § 1337(f)(2); Omnibus Trade and Competitiveness Act § 1342(a)(4)(B); Murphy, *supra* note 4, at 291-92.

74. U.S. Int'l Trade Comm'n, *Commission Opinion on the Issue Under Review, and on Remedy, the Public Interest, and Bonding*, Inv. No. 337-TA-293, at 25 (Mar. 1990).

75. LORING ET AL., *supra* note 56, at 22-198.

76. 28 U.S.C. § 1295(a)(6) (1988); DUVALL, *supra* note 59, at 476; Clark, *supra* note 5, at 1155.

77. 28 U.S.C. § 1254 (1988); Clark, *supra* note 5, at 1155.

78. The ITC also makes "material injury" determinations in antidumping and countervailing duty proceedings. See, e.g., Lawrence M. Friedman & Mark E. Wojcik, *Computer Software as Articles of Commerce in International Trade: The Surprising Study of Singapore's Software Subsidies*, 4 SOFTWARE L.J. 301 (1991); William B.T. Mock, Jr., *Cumulation of Import Statistics in Injury Investigations Before the International Trade Commission*, 7 Nw. J. INT'L L. & BUS. 433, 435-39 (1986).

to the United States Court of International Trade.⁷⁹

If the ITC finds a violation of section 337, or has reason to believe that a violation may exist, the ITC may direct the United States Customs Service to exclude from entry into the United States the articles imported by the violator or suspected violator.⁸⁰ If the ITC so directs, the exclusion order will remain in effect until the ITC determines that the conditions that led to the exclusion order no longer exist, or until the president rejects the ITC's determination for policy reasons.⁸¹

In some cases, "excluded" articles may be imported under bond until the ITC's exclusion order is final.⁸² However, once the ITC's order is final, the United States Customs Service will refuse entry to all articles covered by the exclusion order.⁸³ The only exception is for articles imported by the federal government for its own use.⁸⁴

C. *Tariff Act Section 337 and the General Agreement on Tariffs and Trade*

While it may appear that section 337 of the Tariff Act of 1930 effectively prohibits the importation of products found to infringe valid United States patents, a dispute resolution panel, established under the General Agreement on Tariffs and Trade⁸⁵ ("GATT"), found that section 337 is inconsistent with the United States' obliga-

79. See 28 U.S.C. § 1581(c) (1988); LORING ET AL., *supra* note 56, at 22-198.

80. Procedurally, United States Customs Headquarters will notify regional commissioners and area, district, and port directors of exclusion orders and bonding requirements. Headquarters will also notify the field when the exclusion order becomes final. Once an order is final, the Customs Service's area or district directors will notify local enforcement offices of any shipments of products covered by the exclusion order. The Customs Service will then provide written notice to the importer of the denial of entry for its infringing products. The Customs Service will also transmit a copy of this notice to the Office of Trade Operations at Customs Headquarters. 19 C.F.R. § 12.39(b)(1); U.S. CUSTOMS SERVICE, *supra* note 17, at 3; LORING ET AL., *supra* note 56, at 22-198 to 22-199.

81. 19 C.F.R. § 12.39(b)(1); H.R. CONF. REP. NO. 576, 100th Cong., 2d Sess. 637-38 (1987), *reprinted in* 1988 U.S.C.C.A.N. 1547, 1670-71; LORING ET AL., *supra* note 56, at 22-198 to 22-199.

82. LORING ET AL., *supra* note 56, at 22-199. The ITC establishes the amount of such bonds. 19 U.S.C. § 1337(e)(1); 19 C.F.R. § 12.39(b)(2).

83. 19 C.F.R. § 12.39(b)(2); LORING ET AL., *supra* note 56, at 22-199.

84. ITC exclusion orders do not apply to articles imported by and for the United States government, nor to articles imported for the United States government with its authorization or consent. 19 C.F.R. § 12.39(c); H.R. CONF. REP. NO. 576, 100th Cong., 2d Sess. 638 (1987), *reprinted in* 1988 U.S.C.C.A.N. 1547, 1671; LORING ET AL., *supra* note 56, at 22-200.

85. General Agreement on Tariffs and Trade: Technical Barriers to Trade, *done* Apr. 12, 1979, art. 14, § 14.13, 31 U.S.T. 405, 427, 1186 U.N.T.S. 276, 298.

tions under the GATT.⁸⁶ The GATT panel determined that ITC proceedings under section 337 discriminate against foreign goods, and thus violate the GATT in four respects: (1) section 337 proceedings in the ITC must proceed to termination under fixed time limits, while infringement proceedings in the district courts have no such time limits; (2) alleged infringers cannot raise counterclaims in section 337 proceedings, while counterclaims can be raised in district court proceedings; (3) United States patent holders may elect to proceed in a district court or before the ITC, but there is no choice of forum for enforcing United States patents against domestic products; and (4) importers may have to defend their products simultaneously before both the ITC and a federal district court.⁸⁷

In response to the GATT panel report, the United States Trade Representative ("USTR") proposed five methods of reforming patent enforcement procedures under United States law.⁸⁸

86. LORING ET AL., *supra* note 56, at 22-198.

87. Committee on Patents, Association of the Bar of the City of New York, *Recommendations Addressing Proposed Amendments to Section 337 of the Tariff Act of 1930*, 46 RECORD OF THE ASS'N OF THE BAR OF THE CITY OF NEW YORK 149-50 (Mar. 1991) [hereinafter Committee on Patents].

88. In Revisions to U.S. Patent Enforcement Procedures; Section 337: Request for Public Comments, 55 Fed. Reg. 3503 (1990), the USTR proposed the following five reforms:

(1) Congress could create a specialized trial-level patent court empowered to hear all patent-related litigation and amend section 337 to provide that patent-based complaints be brought before the new court. Congress could grant this patent court the authority to issue limited and general exclusion orders, temporary exclusion orders (TEOs) and temporary cease and desist orders (TCDs). These authorities would be in addition to the powers exercised by other Article III courts.

(2) Congress could create a new division of the U.S.C.I.T. [United States Court of International Trade] which would have jurisdiction over section 337 patent-based actions and collateral claims (patent litigation not involving imports would continue to be heard in the district courts). The new division of the U.S.C.I.T. could have the authority to issue limited and general exclusion orders, TEOs, and TCDs and exercise all other Article III authorities. Rules would provide for consolidation of related court actions such as declaratory judgments requests into a single proceeding.

(3) Congress could provide for transfer of patent-based section 337 cases to a specialized division of the U.S.C.I.T. or to designated [federal] district courts at the request of the respondents in a section 337 action. Further amendments to section 337 could provide a procedure whereby the patent owner could obtain damages from the court after [an ITC] patent-based section 337 proceeding, without a *de novo* hearing by the court on patent infringement issues. Rules on consolidation of actions would also be part of this approach.

(4) Congress could enact a variation on the transfer approach described above that would permit transfer of a patent-based section 337 action to a court after the [ITC] conducts a hearing on preliminary relief. The portion of the proceeding heard before the United States International Trade Commission would be subject to statutory deadlines and presidential review. Rules on obtaining damages and consolidation of court actions would be the same as those described above.

Various groups studied the USTR proposals, including the Committee on Patents of the New York City Bar Association ("Committee on Patents").⁸⁹ The Committee on Patents recommended that the GATT panel's objections be met by providing a mechanism by which respondents could remove a section 337 proceeding from the ITC to a federal district court of the complainant's choosing, either before or after a determination with respect to preliminary relief.⁹⁰ Upon transfer, the federal district court should be empowered to grant temporary, permanent, and general exclusion orders.⁹¹ The complainant should also be allowed to withdraw a section 337 complaint and substitute a complaint that includes "the full panoply of remedies available to patentees."⁹² The Committee on Patents urged Congress to retain section 337 proceedings before the ITC, but to modify those procedures the GATT panel found most objectionable to respondents.⁹³ The Committee on Patents specifically recommended enlarging the time limits for section 337 actions and empowering the ITC to hear counterclaims related to the transactions under review.⁹⁴

The Committee on Patents noted that its proposal for the ITC to consider counterclaims might raise constitutional issues, in light of the United States Supreme Court decision in *Northern Pipeline Construction Co. v. Marathon Pipe Line Co.*⁹⁵ In *Northern Pipeline Construction Co.*, the Supreme Court invalidated a section of the Bankruptcy Act requiring litigants involved in actions with bankrupt parties to submit traditional state-law claims to a non-Article III tribunal.⁹⁶ The Committee on Patents also perceived a potential constitutional due process violation if Congress were to adopt its proposal to provide district courts with the power to issue general exclusion

(5) Congress could amend section 337 to provide for transfer of patent-based section 337 cases to court for a hearing on those issues that cannot be adjudicated by the [ITC], e.g., damage claims and counterclaims. Transfer would occur after the United States International Trade Commission determined whether there is a violation of section 337 in the importation of goods that infringe a valid and enforceable U.S. patent and decided whether to issue a TEO or TCD order.

Id. at 3503-04.

89. The Section of Patent, Trademark, and Copyright Law of the American Bar Association also studied the USTR proposals. See SECTION OF PATENT, TRADEMARK, AND COPYRIGHT LAW, AMERICAN BAR ASS'N, 1990 SUMMARY OF PROCEEDINGS 86-90 (1991).

90. Committee on Patents, *supra* note 87, at 150.

91. *Id.*

92. *Id.* at 150-51.

93. *Id.* at 159.

94. *Id.* at 159-60.

95. 458 U.S. 50 (1982).

96. *Id.*; Committee on Patents, *supra* note 87, at 158.

orders.⁹⁷ However, there is no constitutional right to import merchandise into the United States.⁹⁸

In sum, section 337 administrative proceedings before the ITC are subject to future legislative amendments. The USTR and private groups have proposed modifications to section 337,⁹⁹ but the statute remains unamended. In addition, it is unlikely that any eventual amendment to section 337 will be retroactive, or that it will otherwise affect investigations then pending before the ITC. Further, amendments to section 337 may be subject to constitutional challenges. For the foreseeable future, therefore, section 337 remains a viable tool for process patent holders to protect their inventive processes from infringing importations.

D. The Paris Convention for the Protection of Industrial Property

Possible international protection for process patents may be found within the framework of the Paris Convention for the Protection of Industrial Property¹⁰⁰ ("Paris Convention"), which provides an international system of industrial property protection.¹⁰¹ Approximately one hundred nations, including the United States, are members of the Paris Convention.¹⁰² The Stockholm revision of the Paris Convention, to which the United States is bound, addresses the rights of process patent holders as against importers of products manufactured abroad through domestically-patented processes.¹⁰³ The relevant provision of the Paris Convention, and its application to United States process patents, is analyzed as follows:

Article 5 *quater* grants a process patentee of [a] member nation equal rights under that nation's law as between domestically pro-

97. Committee on Patents, *supra* note 87, at 156-57.

98. See *Ganadera Indus., S.A. v. Block*, 727 F.2d 1156, 1160 (D.C. Cir. 1984); see also *Arjay Assocs., Inc. v. Bush*, 891 F.2d 894, 896-97 (Fed. Cir. 1989); *American Ass'n of Exporters and Importers v. United States*, 751 F.2d 1239, 1250 (Fed. Cir. 1985).

99. For a discussion of these proposed modifications, see *supra* notes 88-98 and accompanying text.

100. International Convention for the Protection of Industrial Property, Mar. 20, 1883, 25 Stat. 1372, 161 T.S. 409, as revised at Brussels on Dec. 14, 1900, 32 Stat. 1936, 189 T.S. 134; Washington on June 2, 1911, 38 Stat. 1645, 213 T.S. 405; the Hague Convention on Nov. 6, 1925, 47 Stat. 1789, 74 L.N.T.S. 289; London on June 2, 1934, 53 Stat. 1748, 192 L.N.T.S. 17; Lisbon on Oct. 31, 1958, 13 U.S.T. 1, 828 U.N.T.S. 107; Stockholm on July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

101. *Id.*

102. Murphy, *supra* note 4, at 280-81 (citing 2J JOHN P. SINNOT, WORLD PATENT LAW AND PRACTICE 42 (1988)).

103. *Id.*

duced or imported products of the patented process. Thus, it appears that Article 5 *quater* extends the application of U.S. patent law to infringing acts beyond the borders of the United States or its territories. In 1927, a [f]ederal [d]istrict court held that patents are within Congress' treaty-making power, that treaties involving patents controlled over prior inconsistent statutes, and that such treaties were self-executing absent specific provisions for an executory treaty. The Supreme Court confirmed that the Paris Convention is self-executing and its provisions are immediately applicable by the Patent Office or [f]ederal courts. However, since the adoption of Article 5 *quater* by the Senate in 1967, no [f]ederal court has applied its provisions in an infringement action. Thus, while it appears that [f]ederal courts would be willing to enforce Article 5 *quater*, no U.S. process patentees have opted to take that chance.¹⁰⁴

Thus, while the Paris Convention may protect United States process patent holders against infringing importations, its provisions remain untested for process patent infringement litigation.

In addition to this untested protection, the Paris Convention offers a process by which nations, but not individuals or companies, can appear before the International Court of Justice with any disputes concerning the application or interpretation of the Paris Convention.¹⁰⁵

E. The Process Patent Amendments Act

1. Overview of the Process Patent Amendments Act

Congress enacted the Process Patent Act to remedy a perceived infirmity in then-existing United States patent law.¹⁰⁶ Proponents of the Process Patent Act claimed that the prior patent law inadequately protected domestic process patent holders against harmful use of their patented technology by foreign manufacturers.¹⁰⁷ Process patent holders claimed that technology piracy decreased competitiveness and incentives to innovate by preventing recovery of research and development costs ordinarily derived from an exclusive patent grant.¹⁰⁸

104. *Id.* at 281-82 (citations omitted).

105. *Id.* at 282.

106. Omnibus Trade and Competitiveness Act §§ 9001-9007.

107. Murphy, *supra* note 4, at 267 (citing *General Oversight Hearings on Patent and Trademark Issues Before the Subcomm. on Patents, Trademarks and Copyrights of the Senate Comm. on the Judiciary*, 100th Cong., 1st Sess. 2 (1987) (statement of Sen. DeConcini, Chairman)).

108. *Id.* (citing *General Oversight Hearings on Patent and Trademark Issues Before the Subcomm. on Patents, Trademarks and Copyrights of the Senate Comm. on the Judiciary*,

Because of their large capital investments in research and development, pioneer drug companies strongly supported passage of the Process Patent Act.¹⁰⁹ However, the generic drug industry, which imports significant amounts of foreign-produced pharmaceuticals in bulk and finished forms, vigorously opposed the Process Patent Act because its passage would terminate the flow of relatively inexpensive products.¹¹⁰

The Process Patent Act identifies an "infringer" as any unauthorized importer of a product made by a process patented in the United States.¹¹¹ Under this Act, process patent holders may file causes of action for monetary damages and injunctive relief in federal district court, instead of in the United States Court of International Trade or with the ITC.¹¹² This new right of action is in addition to any remedies otherwise available to process patent holders under other provisions of law.¹¹³ Section 271(g) of the Process Patent Act provides:

Whoever without authority *imports* into the United States or 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*, sale, or use of the product occurs during the term of such process patent. . . . 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 is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product. 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.¹¹⁴

2. Statutory Construction of the Process Patent Amendments Act

The Process Patent Act, as summarized by the Eastern District

100th Cong., 1st Sess. 47-48 (1987) (statement of Donald W. Banner, President of Intellectual Property Owners, Inc.).

109. *Id.* (citing James M. Gould, *Protecting Owners of U.S. Process Patents from the Importation of Pharmaceuticals Made Abroad by Use of the Patent Process: Current Options, Proposed Legislation, and a GATT Solution*, 42 FOOD DRUG COSM. L.J. 346, 347 (1987)).

110. *Id.* (citing 4 INT'L TRADE REP. 138 (BNA) (Feb. 4, 1987)).

111. U.S. CUSTOMS SERVICE, *supra* note 17, at 2.

112. *Id.*; LORING ET AL., *supra* note 56, at 22-196.

113. *See supra* notes 48-49 and accompanying text.

114. 35 U.S.C. § 271(g) (emphasis added).

Court of Pennsylvania in *Allegheny Ludlum Corp. v. Nippon Steel Corp.*,¹¹⁵ “allows United States process patent holders to sue *foreign companies* who manufacture products using the process described in the United States patent and then ship the goods for sale into the United States.”¹¹⁶ In spite of the court’s statement, however, the statute does not limit potential defendants to foreign companies. Domestic importers can also be sued under section 271(g).

The new provisions of the Process Patent Act implemented several changes. First, the Process Patent Act grants patent holders the right to prohibit the use, sale, or importation of products made by a process patented in the United States.¹¹⁷ Further, the statute defining infringement now includes any unauthorized sale, use, or importation of products resulting from United States patented processes.¹¹⁸

Second, the Process Patent Act provides that in an infringement action based on such unauthorized importation, sale, or use, a “conditional” presumption exists that the product was made by the patented process.¹¹⁹ The presumption is conditional in that before it applies, a court must determine that (1) a “substantial likelihood” exists that the product was made by the patented process; and (2) the patent holder made a reasonable effort to determine the actual process used to manufacture the product.¹²⁰ If a court finds that both conditions exist, the burden of establishing that the suspect product was *not* made by the patented process “shall be on the party asserting that it was not so made.”¹²¹ While the proof necessary to sustain this burden is readily available to foreign manufacturers and producers, it may be elusive to importers, distributors, and export trading companies because foreign manufacturers may not be willing to disclose the methods used in their production processes.

Third, the Process Patent Act contains a “grandfather clause” which provides that the new cause of action created by the Process Patent Act does not apply to entities already engaged in “substantial

115. 765 F. Supp. 224 (E.D. Pa. 1991), *reconsideration granted in part, denied in part*, 1991 U.S. Dist. LEXIS 2821 (E.D. Pa. Mar. 7, 1991).

116. *Id.* at 225 (emphasis added).

117. Omnibus Trade and Competitiveness Act § 9002, *revising* 35 U.S.C. § 154; Murphy, *supra* note 4, at 291.

118. Omnibus Trade and Competitiveness Act § 9003, *revising* 35 U.S.C. § 271; Murphy, *supra* note 4, at 291.

119. 35 U.S.C. § 295 (1988).

120. *Id.*

121. *Id.*

and continuous sales of [a] product.”¹²² This clause was construed for the first time in *Allegheny Ludlum Corp.*, where Allegheny sued Nippon Steel for process patent infringement under section 271(g) of the Process Patent Act.¹²³ Allegheny accused Nippon of importing high-permeability silicon steel manufactured in Japan by a process that allegedly infringed Allegheny’s Patent 3,855,018 (“’018 patent”).¹²⁴ Nippon moved for partial summary judgment, claiming that the grandfather clause of the Process Patent Act protected Nippon from its alleged infringement of Allegheny’s ’018 patent.¹²⁵ The Eastern District Court of Pennsylvania denied Nippon’s motion, holding that the grandfather clause was “only to be used to *protect domestic companies and interests* during the transition from enactment of the law to the time that these companies were able to obtain new sources of the product.”¹²⁶

The court interpreted the legislative history of the Process Patent Act to mean that “the target of the statute was the foreign manufacturer.”¹²⁷ The court pointed out that the original proposed Process Patent Act would not have abridged or affected the rights of any entity to continue to use, sell, or import any specific product “already in substantial and continuous commercial production . . . or for which substantial preparation for production was made to the extent equitable for the protection of investments made or business commenced before that date.”¹²⁸ The court compared this early language to the adopted language of the Process Patent Act, which limits application of the grandfather clause to those products “in substantial and contin-

122. *Id.* § 271. Section 271 provides that the Process Patent Act

shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1988, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This [grandfather clause] shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a process patent enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered.

Id. (emphasis added); see also *Allegheny Ludlum Corp.*, 765 F. Supp. at 224.

123. *Allegheny Ludlum Corp.*, 765 F. Supp. at 224.

124. *Id.*

125. *Id.*

126. *Id.* at 226 (emphasis added).

127. *Id.*

128. *Allegheny Ludlum Corp.*, 765 F. Supp. at 226.

uous sale or use by such person in the United States.”¹²⁹ The court found that the legislative history of this restriction evidenced Congress’ intent “to protect persons in the United States, not the foreign manufacturer of the goods.”¹³⁰ The court also cited a Senate Report which stated:

[T]he primary target of the U.S. process patentholder will naturally be the manufacturer, who is practicing the process and importing the resulting goods in the United States. . . . In any case, the Committee does not expect or intend the bill to be used to sue purchasers of the product, when the infringing manufacturer can be sued instead.¹³¹

Thus, the court held, the first portion of the grandfather clause applies only to entities in the United States who are not alleged to be infringing manufacturers.¹³² Accordingly, the clause could not protect Nippon who *was* an allegedly infringing manufacturer.¹³³

Nippon also argued that another provision of the grandfather clause, which concerned the extent of equitable protection available for “commercial investments made or business commenced in the United States before such date,” applied to its case.¹³⁴ Although Nippon claimed no direct protection under this clause, it asserted that its customers would be harmed if the court awarded damages against Nippon.¹³⁵

To decide this issue, the court weighed the objectives of the Process Patent Act as a whole against the specific interests of the grandfather clause:

The Act’s purpose is to protect United States process patentholders against the infringements of foreign manufacturers who avoid lia-

129. *Id.*

130. *Id.* The court also cited testimony of Donald W. Banner, President of Intellectual Property Owners, Inc., to “explain” the reasoning behind the change in wording:

Maximum incentives for patent owners to manufacture in the United States would be achieved by deleting the [original wording quoted above]. We see no compelling reason to allow foreign manufacturers who are currently taking a free ride on the R&D investments of U.S. process patent owners to be allowed to continue to do so. If the second sentence is retained, the phrase “commercial production” should be changed to [the wording adopted by Congress].

Id. (citing *Process Patents, 1985: Hearing Before the Subcomm. on Patents, Trademarks and Copyrights of the Senate Comm. on the Judiciary, 99th Cong., 1st Sess. 57 (1985)*).

131. *Id.* (citing S. REP. NO. 83, 100th Cong., 1st Sess. 39, 47 (1987)).

132. *Id.*

133. *Allegheny Ludlum Corp.*, 765 F. Supp. at 226.

134. *Id.*

135. *Id.*

bility by applying the process in other countries and selling the subject goods in the United States. The grandfather clause's purpose is to help the United States companies shift from these often cheaper, foreign-produced goods to goods produced under the auspices of the Act. Nippon asks me not to apply the Act to them because they may have to raise the price of the steel they sell. This price increase will then allegedly harm domestic businesses.¹³⁶

Based on this analysis, the court rejected Nippon's argument that the potential for economic harm to its United States customers should protect the alleged foreign infringer under the grandfather clause:

First, Nippon has already contracted with its American purchasers through June, 1991, so that the only prices that may be affected are those from July, 1991 to November, 1991 (the patent expires in December, 1991). Second, Nippon has made no showing that this potential price increase will harm the domestic businesses in a manner that would outweigh the benefit of the purpose of the entire Act (protecting the domestic patentholders). Third, Nippon has not shown that it would even have to increase its prices to the domestic purchasers for these last few months of the patent's life. Therefore, I can see little reason to allow Nippon to slip through prosecution for alleged infringement of a patent by applying a clause that purports to protect interests in the United States only. Nippon has not shown that the domestic interests at issue in the "equitable" clause would be harmed, or at least adversely affected in such a way as to allow Nippon to avoid liability for alleged patent infringement.¹³⁷

The court's refusal to apply the grandfather clause in *Allegheny Ludlum Corp.* properly recognized that the "harm" to Nippon's customers was only a potential increase in the cost of steel. However, the court's analysis of the grandfather clause was unduly influenced by notions of domestic industry and United States interests. The narrow focus of the analysis ignores the possibility, indeed often the probability, that United States process patents are owned by entities outside the United States.¹³⁸ Courts should apply the protections of the grandfather clause in a fair and equitable manner to all those with legitimate expectations of completing specific business transactions in

136. *Id.*

137. *Id.*

138. For example, the process patent at issue in *Bristol-Myers Co. v. Erbamont Inc.*, 723 F. Supp. 1038 (D. Del. 1989), *dismissed*, 734 F. Supp. 661 (D. Del.), and *aff'd without opinion*, 918 F.2d 186 (Fed. Cir. 1990), was issued to *Societa Farmaceutici Italia*. *Id.* at 1039.

the United States commenced before enactment of the Process Patent Act.

The *Allegheny Ludlum Corp.* decision was not the first to construe the scope of Process Patent Act section 271(g). An earlier case, *Bristol-Myers Co. v. Erbamont Inc.*,¹³⁹ illuminates some of the problems that will undoubtedly arise in the judiciary's construction of the statute and in importers' attempts to avoid its reach. In *Bristol-Myers Co.*, the District Court of Delaware considered the question of what constitutes an "importation." This question required a determination of whether the goods at issue were "imported" before the effective date of Process Patent Act section 271(g).¹⁴⁰ The case arose when Bristol-Myers sought a declaratory judgment against Erbamont and other defendants to invalidate and render unenforceable United States Patent 3,803,124 (" '124 patent"), which defined and claimed a process to prepare doxorubicin hydrochloride ("doxorubicin HCL"), a drug used in the chemotherapeutic treatment of cancer.¹⁴¹ Erbamont filed a counterclaim against Bristol-Myers under section 271(g) of the Process Patent Act for alleged infringement of the '124 patent.¹⁴²

In December 1987, Bristol-Myers filed an abbreviated new drug application ("ANDA") with the Food and Drug Administration ("FDA"), seeking approval to import and sell doxorubicin HCL.¹⁴³ Bristol-Myers indicated in its ANDA that bulk doxorubicin HCL would be manufactured in Japan, in accordance with a process approved by the FDA.¹⁴⁴ The FDA approved the doxorubicin HCL ANDA on April 13, 1989.¹⁴⁵

While the FDA was in the process of reviewing the doxorubicin HCL ANDA, the Japanese manufacturer sent Bristol-Myers two shipments of bulk doxorubicin HCL, weighing thirteen kilograms in total.¹⁴⁶ The Japanese manufacturer sent both shipments to Bristol-Myers' finishing facilities in Mayaguez, Puerto Rico, Foreign Trade

139. 723 F. Supp. 1038 (D. Del. 1989), *dismissed*, 734 F. Supp. 661 (D. Del.), and *aff'd without opinion*, 918 F.2d 186 (Fed. Cir. 1990).

140. *Id.* Section 271(g) entered into effect on February 23, 1989. See Omnibus Trade and Competitiveness Act § 9006.

141. *Bristol-Myers Co.*, 723 F. Supp. at 1039.

142. *Id.* at 1038.

143. *Id.* at 1039.

144. *Id.*

145. *Id.*

146. *Bristol-Myers Co.*, 723 F. Supp. at 1039. The Japanese manufacturer produced the bulk doxorubicin HCL by a process the FDA had previously approved. *Id.* at n.5.

Zone 7.¹⁴⁷ The shipments arrived at the foreign trade zone in September 1988 and mid-February 1989.¹⁴⁸ The bulk chemical "apparently was warehoused in the custody of the United States Customs Service" when section 271(g) of the Process Patent Act entered into effect on February 23, 1989.¹⁴⁹ However, Bristol-Myers did not withdraw any of the thirteen kilograms of bulk doxorubicin HCL from the foreign trade zone until *after* February 23, 1989.¹⁵⁰ On May 1, 1989, Bristol-Myers withdrew 1.257 of the 13 kilograms for entry into the United States,¹⁵¹ and the United States Customs Service assessed duties on the portion withdrawn that day.¹⁵²

Erbamont premised its counterclaim for process patent infringement, under section 271(g) of the Process Patent Act, on Bristol-Myers' storage of the thirteen kilograms of bulk doxorubicin HCL in the foreign trade zone.¹⁵³ In defense, Bristol-Myers argued that it had "imported" the chemical before section 271(g) became effective, so it could not be liable as an infringer under that section.¹⁵⁴ Thus, the heart of the controversy revolved around the meaning of the terms "importation" and "import" in section 271(g) of the Process Patent Act.¹⁵⁵ The court framed the issue as a simple choice: "If Bristol-Myers 'imported' the 13 kilograms before the effective date of § 271(g) (February 23, 1989), then Erbamont has no cause of action under this statute. If, however, the 13 kilograms were not 'imported' until after February 23, 1989, Erbamont could still maintain its action under § 271(g)."¹⁵⁶

Erbamont argued that the terms "importation" and "import"

147. *Id.* at 1039.

148. *Id.* Further, according to the court:

All 13 kilograms of the doxorubicin hydrochloride had entered the Mayaguez facility prior to the FDA's approval of the Bristol-Myers ANDA. This bulk doxorubicin hydrochloride is currently being processed at the Mayaguez facility into individual vials of lyophilized injectable preparations of powdered doxorubicin hydrochloride. Bristol-Myers has indicated that sales of these vials containing individual lyophilized doses of doxorubicin hydrochloride will begin in the near future as permitted by the terms of Bristol-Myers' recently approved ANDA.

Id. at 1040.

149. *Id.* at 1039. However, this "appearance" is not necessarily correct. See *infra* section IV and accompanying notes.

150. *Bristol-Myers Co.*, 723 F. Supp. at 1039.

151. *Id.* at 1040.

152. *Id.*

153. *Id.*

154. *Id.*

155. *Bristol-Myers Co.*, 723 F. Supp. at 1042.

156. *Id.*

meant that the allegedly infringing goods “must have lawfully entered into United States commerce as opposed to being in custody of Customs officials.”¹⁵⁷ Bristol-Myers argued to the contrary, contending that “once the alleged infringing goods entered into the territory of the United States . . . this constituted ‘importation’ under the relevant provisions of the Act.”¹⁵⁸

To resolve this dispute, the court essentially relied on the *Black’s Law Dictionary* definition of “importation” and agreed with the contention of Bristol-Myers.¹⁵⁹ *Black’s Law Dictionary* defines “importation” as “[t]he act of bringing goods and merchandise into a country from a foreign country.”¹⁶⁰ As support for the accuracy of this definition, *Black’s Law Dictionary* cites the United States Supreme Court decision in *Cunard Steamship Co. v. Mellon*,¹⁶¹ which held that importation is the act of “bringing an article into a country from the outside. If there be an actual bringing in it is importation regardless of the mode in which it is effected. Entry through a custom house is not the essence of the act.”¹⁶²

The *Bristol-Myers Co.* court recited that the process of statutory interpretation begins with the language of the statute itself, and that judicial inquiry terminates at this point only when the terms of the statute are unambiguous and no special circumstances exist.¹⁶³ With these fundamental rules, the court held that the terms “importation” and “import” in section 271(g) of the Process Patent Act had to be given “their plain [and] ordinary meaning of bringing goods into the United States from another country.”¹⁶⁴ Accordingly, the court found that the bulk doxorubicin HCL “was imported—brought into the United States—prior to the effective date of the statute.”¹⁶⁵ The court further held that, under the “plain meaning” of the term “importation,” Bristol-Myers’ receipt of the bulk chemicals in the foreign

157. *Id.* Erbamont’s claim may have been improperly characterized. If the chemical was in a foreign trade zone, it would have simply been outside the customs territory of the United States, not necessarily “in the custody” of United States Customs Service officials.

158. *Id.*

159. *Id.*

160. BLACK’S LAW DICTIONARY 680 (6th ed. 1990).

161. 262 U.S. 100 (1923).

162. *Id.* at 122. The *Bristol-Myers Co.* court also cited *Canton R.R. v. Rogan*, 340 U.S. 511, 515 (1951) (“to import means to bring into the country”). See *Bristol-Myers Co.*, 723 F. Supp. at 1043.

163. *Bristol-Myers Co.*, 723 F. Supp. at 1042.

164. *Id.* at 1044.

165. *Id.*

trade zone before the effective date of the statute placed it outside the reach of section 271(g).¹⁶⁶

The *Bristol-Myers Co.* court did not discuss the unique status of foreign trade zones. Rather, the court erroneously interpreted the phrase "Mayaguez facility" to refer to the city where the foreign trade zone is located, rather than to refer to the foreign trade zone itself. The customs territory of the United States includes Puerto Rico.¹⁶⁷ However, for revenue purposes, foreign trade zones are considered to be outside the customs territory of the United States.¹⁶⁸ Further, products inside foreign trade zones cannot be freely sold or distributed outside of the zone, and activities allowed in foreign trade zones are severely limited.¹⁶⁹

Congress authorized the creation of foreign trade zones in the Foreign Trade Zones Act of 1934.¹⁷⁰ The Foreign Trade Zones Act, as amended,¹⁷¹ authorizes the Foreign Trade Zones Board to establish foreign trade zones.¹⁷² Merchandise may be brought into such zones for any purpose set forth in the statute "without being subject to the customs laws of the United States"¹⁷³ since it is effectively outside the general stream of United States commerce.

The thirteen kilograms of bulk doxorubicin HCL at issue in *Bristol-Myers Co.* were not imported into the customs territory of the United States, but were sent to a foreign trade zone.¹⁷⁴ After section 271(g) of the Process Patent Act went into effect, Bristol-Myers withdrew 1.257 of the 13 kilograms for entry into the United States, and the United States Customs Service assessed duties on the withdrawn chemical that day.¹⁷⁵ The *Bristol-Myers Co.* court should have found

166. *Id.* at 1043.

167. U.S. INT'L TRADE COMM'N, PUB. NO. 2333, HARMONIZED TARIFF SCHEDULE 1 gen. n.2 (1991).

168. See 19 U.S.C. § 81c (1988); *Nissan Motor Mfg. Corp. v. United States*, 884 F.2d 1375 (Fed. Cir. 1989); Dennis J. Curram, *Foreign-Trade Zones Expedite and Encourage Foreign Commerce*, GLOBAL TRADE, Sept. 1988, at 10; Marshall V. Miller, *There Is a Reason for FTZs' Startling Growth: It Makes Good Business Sense*, GLOBAL TRADE, Sept. 1988, at 14.

169. See 15 C.F.R. § 400.01 (1990); *Nissan Motor Mfg. Corp. v. United States*, 12 Ct. Int'l Trade 737, 738 (1988), *aff'd*, 884 F.2d 1375 (Fed. Cir. 1989).

170. June 18, 1934, ch. 590, § 39, 48 Stat. 999 (codified as amended at 19 U.S.C. § 81c); *Nissan Motor Mfg. Corp. v. United States*, 884 F.2d 1375 (Fed. Cir. 1989); see also Donald E. deKieffer & George W. Thompson, *Political and Policy Dimensions of Foreign Trade Zones: Expansion or Beginning of the End?*, 18 VAND. J. TRANSNAT'L L. 481, 492 (1985).

171. 19 U.S.C. §§ 81(a)-(u) (1988).

172. *Id.*

173. *Nissan Motor Mfg. Corp.*, 884 F.2d at 1375 (citing 19 U.S.C. § 81c).

174. *Bristol-Myers Co.*, 723 F. Supp. at 1039.

175. *Id.* at 1040-41.

that entry of the 1.257 kilograms of bulk doxorubicin HCL into the customs territory of the United States constituted an infringing "importation" because this portion of the doxorubicin HCL entered the United States *after* the enactment of section 271(g) of the Process Patent Act.

IV. RECOMMENDATIONS FOR DEFINING "IMPORTATION" UNDER THE PROCESS PATENT AMENDMENTS ACT

An "importation" for purposes of process patent infringement should be a formal, identifiable process. The execution of a formal customs entry is the ideal moment to establish a legal importation for purposes of process patent infringement. The name of the importer, a possible future defendant, is provided on the customs entry form, and related documents, such as invoices and bills of lading, are presented upon importation. This entry should constitute the official act of "importation." The same information is also available for paperless entries on the automated commercial system.

Merchandise stored in a foreign trade zone or bonded customs warehouse should not be subject to process patent infringement claims.¹⁷⁶ This proposed interpretation of section 271(g) is limited to the storage of protected merchandise, and does not extend to the use of protected merchandise to manufacture other products. For example, an importer may be uncertain of whether a pending importation infringes a United States process patent.¹⁷⁷ In an exercise of good faith, the importer might not formally enter the merchandise, but choose to store it in a foreign trade zone or bonded customs warehouse to avoid formal entry into the United States. If the method of making the product is found to infringe a valid United States process patent, the importer could then re-export the product, without incurring any liability for process patent infringement. Theoretically, the importer could return the infringing merchandise to the foreign manufacturer for a refund or credit, or ship the infringing merchandise to a third country where there is no patent infringement. The importer could also decide to destroy the merchandise rather than defend a suit for patent infringement.

Under this scenario, the importer should not be held liable for

176. Storage is distinguished from consumption of the merchandise in the foreign trade zone. See *Nissan Motor Mfg. Corp.*, 884 F.2d at 1377.

177. For instance, the importer may question whether the term of a process patent has expired.

making an infringing importation, because the merchandise was stored in a place where it could be neither sold nor distributed to others. The merchandise never entered the customs territory of the United States. The *Bristol-Myers Co. v. Erbamont Inc.* decision removes this protection by holding that the term "importation" in section 271(g) of the Process Patent Act must be accorded its "plain meaning."

Interestingly, a later decision by the *same court* used the word "import," but cautioned that "[t]he Court does not use the term 'import' in the context of § 271(g)."¹⁷⁸ How could this be if the prior decision held that the term "import" must be given its plain meaning?

Although it amended the Patent Act under title 35 of the United States Code, the Process Patent Act was part of the Omnibus Trade and Competitiveness Act.¹⁷⁹ The Omnibus Trade and Competitiveness Act was itself a major piece of legislation, affecting nearly every aspect of importing to the United States. Therefore, in future cases, the analysis of the "legislative history" of the Process Patent Act should consider section 271(g) in the context of the other, contemporaneous amendments to the customs and international trade laws. The massive and comprehensive nature of the Omnibus Trade and Competitiveness Act presents a "special circumstance" for courts to look beyond the plain meaning of technical terms, such as "importation." Thus, at a minimum, the *Bristol-Myers Co.* court should have considered whether the term "importation," as used in the Process Patent Act, encompasses deliveries to sites outside the customs territory of the United States where merchandise cannot be freely distributed or sold.¹⁸⁰

The Process Patent Act establishes a means for United States process patent holders to claim monetary damages for infringing importations. Now, consistent with domestic process laws applicable to patent litigation, process patent holders are entitled to damages adequate to compensate the pecuniary losses sustained due to infringing importations.¹⁸¹ Although they are difficult to quantify, these dam-

178. *Bristol-Myers Co. v. Erbamont Inc.*, 734 F. Supp. 661, 662 n.3 (D. Del.), *aff'd without opinion*, 918 F.2d 186 (Fed. Cir. 1990).

179. *See supra* notes 4-5 and accompanying text.

180. This proposal does not extend to consumption in foreign trade zones of merchandise covered by a valid process patent. *See Nissan Motor Mfg. Corp. v. United States*, 884 F.2d 1375 (Fed. Cir. 1989).

181. *See* 35 U.S.C. § 284 (1988); *General Motors Corp. v. Devex Corp.*, 461 U.S. 648 (1983), *aff'g* 749 F.2d 1020 (Fed. Cir.); *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d

ages generally constitute the difference between the patent holder's condition after the infringement and what the patent holder's condition would have been absent the infringing importation.¹⁸² However, in no event should a damage award be less than reasonable royalties.¹⁸³

In typical domestic patent litigation, the patent holder and its infringer are the only suppliers in the market, and the patent holder seeks to recover profits lost through every sale made by the infringer.¹⁸⁴ However, the definition of the "market" significantly swells where imports are included. Allegedly infringing imports are often sold in the country of production as well as other countries beyond the United States. Sales outside the United States may not violate any foreign patent laws if the United States patent holder does not own a valid process patent for that foreign country.¹⁸⁵ The calculation of "lost profits" attributable solely to United States sales will only complicate litigation under section 271(g) of the Process Patent Act. Indeed, many novel issues will arise as cases develop from each new application of the Process Patent Act.

1573 (Fed. Cir. 1989), *cert. denied*, 110 S.Ct. 725 (1990); *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320 (Fed. Cir. 1987); *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1064 (Fed. Cir. 1983).

182. See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964) (citing *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 536, 552 (1886)); *Lam, Inc.*, 718 F.2d at 1064 (citing *Aro Mfg. Co.*, 377 U.S. at 507).

183. *State Indus., Inc.*, 883 F.2d at 1577 (citing *Seattle Box Co. v. Industrial Crating & Packing Inc.*, 756 F.2d 1574, 1581 (Fed. Cir. 1985)).

184. *Id.* (citing *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 672 (Fed. Cir. 1988); *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1543 (Fed. Cir. 1987); *Lam, Inc.*, 718 F.2d at 1065).

185. Foreign patent laws generally require a patent to be "worked" in the granting country. For process patents, this usually requires that the process be performed in the granting country. Thus, working requirements may act as a disincentive to patent abroad, since often new technology is neither capable of immediate practical application nor economic exploitation, especially in countries lacking the resources to develop the technology. Further, the failure to work the patent may result in compulsory licensing or forfeiture of the patent. Therefore, while process patent protection is theoretically available, it may provide only temporary protection until sanctions for failure to work the patent are imposed, or it may force economically unsound foreign investment decisions. See *Murphy*, *supra* note 4, at 287.

Further, foreign patents are often costly and difficult to obtain. Foreign patenting requires specially skilled counsel, extensive paperwork, and costly technical translations. In addition, foreign countries often demand high maintenance fees after payment of the initial filing fee, and litigation to defend foreign patents involves costs for special counsel, translations, and logistical expenses. See *id.* at 288.

V. CONCLUSION

The Process Patent Act expanded the scope of patent rights to include the prohibition of unauthorized uses, sales, and imports of products made by processes patented in the United States.¹⁸⁶ Further, the Process Patent Act strengthened the definition of infringement to encompass any unauthorized sale, use, or importation of the products of United States-patented processes.¹⁸⁷ The Process Patent Act also eased the patent holder's burden of proof by establishing a presumption that products are made by the patented process.¹⁸⁸

The Process Patent Act will undoubtedly reduce access to United States import markets, "which are the fruits of intellectual property piracy."¹⁸⁹ This reduced access should, in turn, decrease the United States' trade deficit.¹⁹⁰ However, the amount of such trade deficit reduction directly related to the Process Patent Act will be measurable only in intangible terms. Even so, the legislative history of the Process Patent Act indicates that it was enacted for reasons other than the reduction of the United States' trade deficit.

Litigation under section 271(g) of the Process Patent Act may be the more desirable method of enforcing United States process patent rights, because it lacks the time pressures and perceived procedural unfairness identified by the GATT panel's analysis before the ITC of Tariff Act section 337 proceedings. There is, of course, no finding that section 271(g) of the Process Patent Act violates the United States' obligations under the GATT, nor are any proceedings underway to declare section 271(g) violative of the GATT. The procedural protections and equality of treatment generally available in federal district court should effectively address the concerns raised by the GATT panel in its analysis of section 337.

From the standpoint of a United States process patent holder—a party who may or may not be located in the United States—the new

186. Omnibus Trade and Competitiveness Act § 9002 (amending 35 U.S.C. § 154); Murphy, *supra* note 4, at 291.

187. Omnibus Trade and Competitiveness Act § 9003 (amending 35 U.S.C. § 271); Murphy, *supra* note 4, at 291.

188. Omnibus Trade and Competitiveness Act § 9005 (amending 35 U.S.C. § 295). As discussed *supra* at the text accompanying notes 119 and 120, this presumption is conditional because for it to apply, a court must find a "substantial likelihood" that the product was made by the patented process, and conclude that the patent holder "made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine." *Id.*

189. Murphy, *supra* note 4, at 298.

190. *See id.*

in personam judicial proceedings under section 271(g) of the Process Patent Act are in many ways superior to the in rem exclusion orders available from the ITC under section 337 of the Tariff Act. From the standpoint of an importer, however, section 271(g) of the Process Patent Act presents unexpected perils, because liability for “importing” infringing items may attach in future cases, even when the “imported” merchandise never enters the customs territory of the United States. Hopefully, these perils will be mitigated in future decisions that interpret the scope and proper applications of the Process Patent Act.

