University of Minnesota Law School
Scholarship Repository

Minnesota Law Review

1991

Amgen, Inc. v. United States International Trade Commission: Designer Genes Don't Fit

Ann Sturtz Viksnins

Follow this and additional works at: https://scholarship.law.umn.edu/mlr

 Part of the Law Commons

Recommended Citation

Viksnins, Ann Sturtz, "Amgen, Inc. v. United States International Trade Commission: Designer Genes Don't Fit" (1991). *Minnesota Law Review*. 842.
https://scholarship.law.umn.edu/mlr/842

This Article is brought to you for free and open access by the University of Minnesota Law School. It has been accepted for inclusion in Minnesota Law Review collection by an authorized administrator of the Scholarship Repository. For more information, please contact lenzx009@umn.edu.

Comment

Amgen, Inc. v. United States International Trade Commission: Designer Genes Don't Fit

Ann Sturtz Viksnins

Amgen, Inc. ("Amgen")[1] holds a United States patent to certain genetically-altered cells[2] that produce unusually large amounts[3] of a hormone called erythropoietin ("EPO").[4] In a complaint filed with the United States International Trade Commission ("ITC"),[5] Amgen alleged that Chugai Pharmaceu-

1. Amgen, Inc. is a biotechnology company located in Thousand Oaks, California. Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1738 (D. Mass. 1989), *aff'd in part and rev'd in part*, 927 F.2d 1200 (Fed. Cir. 1991).

2. U.S. Patent No. 4,703,008 ("the '008 patent"). Amgen was the first to clone the gene for human erythropoietin, doing so in October, 1983. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1738. Inventor Dr. Fu-Kuen Lin obtained and cloned the amino acid sequence for erythropoietin, and Amgen filed a patent application in the United States Patent and Trademark Office on December 13, 1983. *Id.*

3. These genetically-altered cells do not have the natural feedback mechanisms found in human cells which allow genetically altered cells to produce erythropoietin at much higher rates than normal human cells. *In re* Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) 1906, 1908 (U.S. Int'l Trade Comm'n 1989), *aff'd*, 902 F.2d 1532 (Fed. Cir. 1990).

4. EPO is a kidney-made hormone which controls the production of erythrocytes, commonly known as red blood cells. ALEXANDER P. SPENCE & ELLIOTT B. MASON, HUMAN ANATOMY AND PHYSIOLOGY 468 (1979). A small amount of the erythropoietin hormone circulates in the blood to maintain the proper number of red blood cells so that cells receive enough oxygen. *Id.* at 469. If the number of red blood cells becomes too low, a person becomes anemic and tires very easily because his or her organs are not receiving enough oxygen. *Id.* EPO increases the rate of production of red blood cells, and thus relieves the symptoms of fatigue in anemic patients. *Id.* Sales of erythropoietin in the United States by pharmaceutical companies approached $200 million in 1990, and the market for the drug in the United States alone may eventually reach the billions of dollars. Donna K. H. Walters, *Two Proposed Laws Bitterly Divide Biotech Industry*, L.A. TIMES, June 3, 1990, Business Section, at 1.

5. The ITC, established under the Tariff Act of 1930, is a federal administrative agency which investigates and adjudicates complaints of unfair trade practices. *See* 19 U.S.C. § 1330 (1988) (organization of the ITC); *id.* § 1331 (general powers of the ITC); *id.* § 1332 (investigations by the ITC); *id.* § 1337 (investigation by ITC of unfair practices in import trade).

tical Co. of Japan and its American subsidiary, Chugai Pharma U.S.A., Inc. (collectively "Chugai") engaged in unfair trade practices, in violation of section 337 of the Tariff Act,[6] by importing and selling recombinant erythropoietin ("rEPO")[7] made using genetically-altered cells covered by Amgen's patent.[8] The ITC's Administrative Law Judge determined that Chugai did not violate section 337 because Amgen's patent did not cover the process for producing rEPO.[9]

In *Amgen, Inc. v. United States International Trade Commission*,[10] the Federal Circuit[11] affirmed, concluding that 1988 Amendments to the Tariff Act did not prohibit the importation of end-products made abroad using a patented intermediate product.[12] According to the *Amgen* court, Chugai did not violate section 337 of the Tariff Act because neither the product imported by Chugai (rEPO) nor the process by which it was made (cloning) were patented.[13]

---

6. 19 U.S.C. § 1337 (1988).

7. The chemical structure of naturally made and recombinantly made EPO is functionally the same. *Certain Recombinant Erythropoietin*, 10 U.S.P.Q.2d (BNA) at 1908. The only difference is the method by which they are made. Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 103-04 (D. Mass. 1989), *aff'd in part and rev'd in part*, 927 F.2d 1200 (Fed. Cir. 1991). Chugai licensed the rights to a patent, U.S. Patent No. 4,677,195 ("the '195 patent"), covering both a nonrecombinant method for purifying EPO and compositions of highly purified EPO. *Id.* at 96. Natural EPO is made by means of the purification method taught by the '195 patent, and rEPO is made by means of the recombinant method taught by Amgen's '008 patent, which requires the use of Amgen's patented DNA sequences, vectors, and host cells. *Id.* at 97.

8. *Certain Recombinant Erythropoietin*, 10 U.S.P.Q.2d (BNA) at 1907.

9. *Id.* at 1910. Upon further review, a panel of the ITC dismissed Amgen's complaint on jurisdictional grounds. *Id.* at 1911.

10. 902 F.2d 1532 (Fed. Cir. 1990).

11. The Federal Circuit exercises exclusive appellate jurisdiction over patent and trademark decisions of the United States District Courts, 28 U.S.C. § 1295(a)(1) (1988), the Board of Patent Appeals and Interferences, *id.* § 1295(a)(4)(A), the Commissioner of Patents and Trademarks, *id.* § 1295 (a)(4)(B), and the Trademark Trial and Appeal Board, *id.* § 1295(a)(4)(B). The Federal Circuit also has direct appellate jurisdiction over ITC rulings relating to unfair trade practices involving § 337 of the Tariff Act. *Id.* § 1295(a)(6). *See generally* Robert D. Wallick & Neil R. Ellis, *The United States Court of Appeals for the Federal Circuit: At the Leading Edge of High Technology Issues*, 36 AM. U. L. REV. 801 (1987) (discussing the scope of the Federal Circuit's jurisdiction); Rochelle Cooper-Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1 (1989) (discussing the Federal Circuit's patent jurisdiction).

12. 902 F.2d at 1540.

13. *Id.* Contrary to the determination of the ITC panel, the Federal Circuit held that the ITC had subject matter jurisdiction over Amgen's complaint. *Id.* at 1536.

The *Amgen* court's interpretation of the Tariff Act has broad implications for the biotechnology industry.[14] Most im-

14. Traditionally, commentators have defined biotechnology as the "willful harnessing of life forms for human use." APPLICATION OF BIOTECHNOLOGY: ENVIRONMENTAL AND POLICY ISSUES 3 (John R. Fowle III ed., 1987) [hereinafter APPLICATION]. Under this broad definition, people have utilized biotechnology for thousands of years through domestication of crops and animals, and through the production of fermentation products like cheese, wine, and beer. *Id.* at 3; *see also* OFFICE OF TECHNOLOGY ASSESSMENT, GENETIC TECHNOLOGY: A NEW FRONTIER 47-56, 107-14 (1982) [hereinafter GENETIC TECHNOLOGY] (describing modern fermentation technologies and the food processing industry).

According to more current definitions, the term "biotechnology" means "the commercialization of the tools of molecular biology, mainly [recombinant] DNA and hybridoma or cell fusion technologies." APPLICATION, *supra*, at 3. It includes a variety of technologies "linked only by their association with life or life-processes." Thomas G. Wiseman, *Biotechnology Patent Application Examination, in* TRENDS IN BIOTECHNOLOGY AND CHEMICAL PATENT PRACTICE 31, 36 (PLI Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series No. 286, 1989). *See generally* Linda S. Watrud, *The Biological Revolution: Tools and Products of Biotechnology, in* APPLICATION, *supra*, at 11-29 (historical perspective on the development of modern molecular biology). This Comment utilizes the more modern definition of biotechnology as the commercialization of various aspects of molecular biology.

Modern biotechnology has great potential for creating new industrial products and applications, for generating advances in medicine, and for improving modern agriculture. *See* PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY 1-5 (1991) [hereinafter COMPETITIVENESS]; Eric Christensen, Note, *Genetic Ark: A Proposal to Preserve Genetic Diversity for Future Generations*, 40 STAN. L. REV. 279, 289 (1987); 136 CONG. REC. S3107-08 (daily ed. Mar. 22, 1990) (remarks of Sen. DeConcini). For example, one researcher genetically engineered a strain of bacteria which could assist in cleaning up oil spills by breaking crude oil down into its multiple components. *See* Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980); Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. 183, 264-65 (1987) (describing potential for creating new products and processes but noting need for regulation of biotechnology research and the release of genetically engineered organisms into the environment); Christensen, *supra*, at 289-90 (examining the need for regulation of the industry in order to maintain genetic diversity).

Biotechnology has fostered advances in the diagnosis and treatment of disease. *See, e.g.*, G. J. V. NOSSAL, RESHAPING LIFE: KEY ISSUES IN GENETIC ENGINEERING 54-58, 60-62 (1985) (explaining role of biotechnology in diagnosing certain blood diseases and AIDS); *id.* at 43-45, 50-51 (discussing how biotechnology produces rare but important proteins in clotting factors for hemophiliacs and insulin for diabetics).

Biotechnology also offers improvements in agriculture. For example, scientists have developed a biological insecticide which is considered to be safer than chemical treatment. George Gunset, *Peoria Lab Readies Biological Weapons Against Bugs*, CHI. TRIB., May 25, 1990, at 1.

Because of the great potential of biotechnology, investment in the industry is increasing. *See* Joan Hamilton, *The Gene Jockeys Are Finally Seeing Some Green*, BUSINESS WEEK, July 2, 1990, at 77. "Presently, the biotechnol-

portant biotechnological end-products cannot be patented because they can be found in nature, albeit in very small quantities.[15] Further, the processes for making these biotechnological end-products are sufficiently well known and thus not patentable.[16] Biotechnology advancements receive patent protection only for the intermediate products used in the production of the end-products, such as the genetically altered cells covered by Amgen's patent.[17]

Utilizing patented intermediate products in the United States to make a particular end-product is actionable under a general patent infringement statute, but the statute does not provide damages for the importation of end-products made with patented intermediate products.[18] Moreover, because of the *Amgen* court's narrow interpretation of the Tariff Act, a holder of a United States patent cannot prevent foreign companies from importing into the United States end-products made abroad using patented intermediates.[19] Thus, foreign biotechnology companies enjoy a significant competitive advantage over domestic companies.[20]

This Comment argues that the *Amgen* court's literal interpretation of section 337 of the Tariff Act reflects neither the legislative intent of the 1988 Amendments nor sound public policy.[21] Part I of this Comment outlines principles of patent

---

ogy industry produces billions of dollars annually for our Nation's economy. President Bush recognized the importance this field has on our economic growth by designating biotechnology research as a funding priority in his proposed budget." 136 CONG. REC. S3108 (daily ed. Mar. 22, 1990) (statement of Sen. DeConcini). For a further introduction to genetic engineering and the biotechnology industry, see COMPETITIVENESS, *supra*, at 1-5; *In re* O'Farrell, 853 F.2d 894, 895-99 (Fed. Cir. 1988); John M. Czarnetzky, Note, *Altering Nature's Blueprints for Profit: Patenting Multicellular Animals*, 74 VA. L. REV. 1327, 1330-34 (1988).

15. Naturally occurring substances do not have the requisite "novelty" required under the patent laws and thus are not patentable. 35 U.S.C. § 102 (1988).

16. To obtain a patent, an inventor must prove that his or her invention is not "obvious." 35 U.S.C. § 103 (1988). Biotechnology companies have difficulty obtaining process patents because much of the manufacturing of the end-products is performed by bacterial or animal cells. The inventive part of biotechnology is genetically altering the cells so that they produce the desired end-product. The method of genetically altering the cells, "cloning," is well known and practiced in the field and therefore does not meet the requirement of non-obviousness.

17. *See infra* notes 61-71 and accompanying text.

18. *See* 35 U.S.C. § 271 (1988).

19. *See infra* note 98 and accompanying text.

20. *See infra* note 148.

21. *See infra* notes 107-25 and accompanying text.

law and the Omnibus Trade and Tariff Act of 1988 as applied to biotechnology. Part II addresses the Federal Circuit's reasoning and holding in *Amgen*. Part III analyzes the implications of the *Amgen* holding for the biotechnology industry and proposes various alternatives for mending the hole in the net of patent protection available to biotechnology companies in the United States. To combat the *Amgen* court's interpretation, this Comment recommends statutory changes.

I. BASIC PATENT LAW AS APPLIED TO BIOTECHNOLOGY

The Constitution gives Congress the power to grant patents to inventors in order to encourage and reward creativity and new research.[22] The patent gives the owner the "right to exclude others from making, using, or selling the invention throughout the United States,"[23] and, if the invention is a process, the "right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process."[24]

22. The U.S. Constitution grants Congress the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8; *see also* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974) (patent as an incentive to inventors to risk cost of time, research, and development to develop new products and processes); Graham v. John Deere Co., 383 U.S. 1, 9 (1966) (patent as a reward and "inducement to bring forth new knowledge"); Universal Oil Products Co. v. Globe Oil & Refining Co., 322 U.S. 471, 484 (1944) (patent as a reward for invention and as encouragement for disclosure).

The major type of patent, the "utility" patent, has a lifespan of 17 years. 35 U.S.C. § 154 (1988). The notion of a time-limited patent strikes a careful balance between the general American distaste for monopolies and a desire to encourage innovation by excluding others from practicing one's invention. *Graham*, 383 U.S. at 10-11. Society benefits from the public disclosure, as well as from the introduction of new products and processes of manufacture, while the inventor benefits from the limited exclusionary rights. *Kewanee Oil*, 416 U.S. at 480-81.

23. 35 U.S.C. § 154 (1988).

24. *Id.* A patent grants the right to exclude others from practicing that invention. The patent does not necessarily allow the patent holder to practice his or her own invention. *See* 4 DONALD S. CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 16.02(1) (1991). If the practice of one's own invention would require the infringment of another's patent, then permission, generally in the form of a license, is required from the other patent owner. ROBERT GOLDSCHEIDER, TECHNOLOGY MANAGEMENT § 16.01 (1988).

A. ACQUIRING PATENT RIGHTS

The U.S. patent laws define the scope of patent protection to include "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[25] There are three legal requirements for a patent: novelty,[26] utility,[27] and non-obviousness.[28] The U.S. Patent and Trademark Office ("PTO") issues a patent to an inventor only if all three requirements are met.[29]

Every patent application contains two distinct parts: the "specification" and the "claims." The specification details how the invention works and instructs how best to use the invention.[30] The claims provide "the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention."[31]

---

25. 35 U.S.C. § 101 (1988). According to the U.S. Supreme Court, § 101 allows the patenting of "anything under the sun that is made by man[kind]," provided it fulfills the statutory requirements. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (citing S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess. 6 (1952)).

However, § 101 does not permit patenting of the laws of nature, physical phenomena or abstract ideas. *See* Parker v. Flook, 437 U.S. 584, 589-91 (1978) (algorithm or mathematical formula not patentable); Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (scientific truth, mathematical formula, abstract principles, or phenomena of nature not patentable); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("patents cannot issue for the discovery of the phenomena of nature"); O'Reilly v. Morse, 56 U.S. 62, 116 (1854) (scientific principle not patentable); Le Roy v. Tatham, 55 U.S. 156, 174-75 (1852) (same). Thus, Watson and Crick's discovery that DNA is the blueprint for life, Darwin's discovery of a new species of turtle, and Newton's discovery of the law of gravity are not patentable, nor are pure mathematical formulas like $2+2=4$, or $E=mc^2$. *See Chakrabarty*, 447 U.S. at 309.

26. 35 U.S.C. § 102 (1988).

27. *Id.* § 101.

28. *Id.* § 103.

29. *See id.* § 101-03.

30. *Id.* § 112. The disclosure must teach how to best use the invention. *In re* Bundy, 642 F.2d 430, 434-35 (C.C.P.A. 1981).

31. Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). A patent contains one or more claims which define the scope of the invention. The U.S. Patent Office permits only certain types of patent claims: "product," "process," and "product-by-process." Product patent claims cover only the thing itself. *See, e.g.*, Scripps Clinic & Research Found. v. Genentech, Inc., 231 U.S.P.Q. (BNA) 978, 979 (N.D. Cal. 1986) (protein necessary to clot blood is a product which may be patented); Application of Larsen, 292 F.2d 531, 533 (C.C.P.A. 1961) (patent application for a certain organic compound), *cert. denied*, 370 U.S. 936 (1962); *see also* Czarnetzky, *supra* note 14, at 1355-61 (discussing patenting of animals as product patents).

Process patents, unlike product patents, cover only the method by which the thing was made. *See, e.g.*, Sealed Air Corp. v. U.S. Int'l Trade Comm'n, 645

Although the specification is essential to understanding and learning to use the invention, the claims actually determine the legal scope of the patent.[32]

Although not a biotechnology case, *In re Durden*[33] addresses whether the Patent and Trademark Office may issue a patent for a process that would be considered obvious except that "either or both the specific starting material employed and the product obtained [were] novel and unobvious."[34] Durden had been granted patents for a chemical end-product and its novel starting material, but the Patent Office rejected Durden's process claims of making the end-products from the starting materials.[35] Relying on *In re Albertson*,[36] the Federal Circuit affirmed the Patent Office's rejection. *Albertson* holds that a process is not patentable simply because the starting material and end-product are novel and nonobvious.[37] Consequently, the Federal Circuit rejected Durden's process claims as obvious because another inventor had already described the *process* in a patent, even though Durden used a different starting material and created a different end-product.[38] Thus, *In re Durden* stands for the proposition that the existence of a patentable starting material or end-product does not make an obvious process non-obvious.

F.2d 976, 983 (C.C.P.A. 1981) (applicant claimed a process patent for the manufacturing of multicellular plastic film).

Product-by-process claims are another form of product claims. Product-by-process claims cover only the product made, not the process by which it is made. *In re* Bridgeford, 357 F.2d 679, 682 (C.C.P.A. 1966). "A product may be defined by the process of making it if the English language is inadequate to describe the invention." Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379, 1386 (N.D. Cal. 1987) (product-by-process patent for a blood clotting factor).

32. McGill, Inc. v. John Zink Co., 736 F.2d 666, 672 (Fed. Cir.) ("In order to determine what is patented, the threshold requirement is to examine the language of the claims at issue."), *cert. denied*, 469 U.S. 1037 (1984); Genentech, Inc. v. Wellcome Found., 14 U.S.P.Q.2d (BNA) 1363, 1367 (D. Del. 1990).

33. 763 F.2d 1406 (Fed. Cir. 1985).

34. *Id.* at 1408.

35. *Id.* at 1407.

36. 332 F.2d 379 (C.C.P.A. 1964).

37. *Id.* at 382.

38. *Durden*, 763 F.2d at 1409. The *Durden* court addressed only the issue of whether process claims can be patented. The court did not face the issue of whether to prohibit the importation of end-products made using Durden's patented starting materials—the issue which later arose in *Amgen*.

B. PROTECTING PATENT RIGHTS

1. Action for Infringement

Once an inventor acquires a patent, she may preclude others from making, using, or selling the invention.[39] The primary mechanism for protecting these rights is an action for infringement.[40] Section 271 of title 35 protects patent owners by prohibiting others from making, using or selling products that infringe on their patented invention.[41] This statute covers all products patented in the United States, whether made in the United States or abroad.[42] Where the product is manufactured is irrelevant. Once the product is in the United States, it is sub-

39. *See supra* notes 22-24 and accompanying text.

40. 35 U.S.C. § 281 (1988) (authorizing action for infringement of patent). If an entity prevails in its patent infringement suit, it may recover treble damages, *id.* § 284, and attorney's fees, *id.* § 285. *See also* Great Northern Corp. v. Davis Core & Pad Co., 782 F.2d 159, 167 (Fed. Cir. 1986) (treble damages); Kori Corp. v. Wilco Marsh Buggies & Draglines, Inc., 761 F.2d 649, 656-57 (Fed. Cir.) (double damages), *cert. denied*, 474 U.S. 902 (1985); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1547-48 (Fed. Cir. 1984) (treble damages and attorneys' fees); Underwater Devices, Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1390 (Fed. Cir. 1983) (treble damages).

41. Section 271 of title 35 provides:

> (a) [W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.
>
> (b) Whoever actively induces infringement of a patent shall be liable as an infringer.
>
> (c) Whoever sells a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271 (1988).

In addition to literal infringement, a person or corporation may be liable for infringement according to the doctrine of equivalents. Under the doctrine of equivalents, the court may find infringement if the device "perform[s] substantially the same overall work to achieve substantially the same overall result by substantially the same means." Johnston v. IVAC Corp., 885 F.2d 1574, 1581 (Fed. Cir. 1989) (citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1949)).

There are some limits to the doctrine of equivalents, such as "prosecution history estoppel." Hormone Research Found. v. Genentech, Inc., 904 F.2d 1558, 1564 (Fed. Cir. 1990), *cert. denied*, 111 S. Ct. 1434 (1991). If the Patent Office requires a patent owner to limit a claim during the patent application process, the patent owner cannot later argue that the claim is broader in order to establish an infringement claim. *Id.*

42. *See* 35 U.S.C. § 271 (1988).

ject to the United States patent laws.[43]

Further, section 271(g) of title 35 protects process patent owners by establishing liability for importers of products made using a process patent.[44] Although section 271 cannot prohibit foreign entities from making products or using processes in their own countries that are patented in the United States, it does subject them to potential infringement liability once their products enter the United States.[45] A significant gap in the protection offered by section 271(g) is that it does not address whether a person or corporation is liable for infringement if the end-product imported into the United States was manufactured using a patented intermediate product.

2. The Tariff Act of 1930 as Amended in 1988

Other than infringement actions brought pursuant to section 271, the Tariff Act of 1930 provides the principal means of protection for American companies against unfair use of patented products or processes by foreign entities.[46] Section 337 of the Tariff Act allows the International Trade Commission to issue exclusionary orders that prevent products that infringe on United States patents from entering the United States.[47] Ex-

43. *See id.* § 271(a).

44. Section 271(g) of title 35 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.

Id. § 271(g).

45. *See id.* § 271.

46. The purpose of the Tariff Act of 1930 (and its predecessor, the Tariff Act of 1922) was "to provide an adequate remedy for domestic industries against unfair methods of competition and unfair acts instigated by foreign concerns operating beyond the *in personam* jurisdiction of domestic courts." Sealed Air Corp. v. U.S. Int'l Trade Comm'n, 645 F.2d 976, 985 (C.C.P.A. 1981).

47. 19 U.S.C. § 1337(e) (1988). Section 337(d) of the Tariff Act of 1930, as amended, authorizes the ITC to issue exclusionary orders as a remedy for U.S. patent owners against unfair methods of competition by foreign corporations. *Sealed Air Corp.*, 645 F.2d at 985. The United States Customs Service may block the importation of products that would clearly infringe on a valid American patent. Exclusionary orders pursuant to § 337(d) are an example of the ITC exercising powers delegated to it by Congress pursuant to the power of Congress to regulate foreign commerce. *See* U.S. CONST. art. I, § 8, cl. 3; *In re* Chain Door Locks, 191 U.S.P.Q. (BNA) 272, 272 (U.S. Int'l Trade Comm'n 1976).

In contrast, patent infringement proceedings "are on a party by party basis, involving private rights, and are not part of the international trade laws of the United States." *The Sixth Annual Judicial Conference of the United*

clusionary orders are the most effective means of protecting American patent rights, especially for small businesses that cannot afford cumbersome and costly infringement litigation.[48]

The Omnibus Trade and Competitiveness Act of 1988 ("Omnibus Act")[49] significantly amended the Tariff Act of 1930. Congress intended for the amendments to open foreign markets to United States goods, improve the competitiveness of American firms, and reform the area of intellectual property.[50]

States Court of Appeals for the Federal Circuit, 122 F.R.D. 281, 315 (1988) (statement of David Foster, former assistant general counsel of the ITC, and international trade counsel for the Senate Finance Committee). Unfair trade practices proceedings, however, permit a person to seek an exclusionary order, an extraordinary remedy not otherwise available under federal law. *Id.* at 315-16.

48. United States patent law has no extraterritorial effect. Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 531 (1972). Therefore, exclusionary orders to ban the importation of products are one of only two alternatives for U.S. patentees to exclude others from using their products or processes. The other possible way to protect a product or process is to obtain a patent in a foreign country and litigate abroad in the event of unauthorized use. *See* Judson Vickers, Note, *Congress Attacks Process Patent Piracy—But Who Walks the Plank?*, 14 BROOKLYN J. INT'L L. 615, 616-17 (1988). This latter option of obtaining foreign patent protection can be expensive and laborious. *Id.* at 617. Further, not all countries have patent protection laws, or their laws may not be as stringent as those in the United States. Judith H. Bello & Alan F. Holmer, *The GATT Uruguay Round: Its Significance for U.S. Bilateral Trade with Korea and Taiwan*, 11 MICH. J. INT'L L. 307, 312 (1990). Some observers suggest that certain countries, such as Argentina, Brazil, South Korea, and Taiwan, have purposely weak patent protection or refuse to enforce their patent laws in order to capitalize on foreign knowledge and thereby develop their own countries economically. Calvin Sims, *Wounded by Patent Piracy*, N.Y. TIMES, May 13, 1987, at D1. Finally, some countries permit companies to make insignificant changes in the patented product and consider it no longer infringing under local patent laws. *Industry Representatives Urge Change in Competitiveness Policy at ITC Hearing*, 41 PAT. TRADEMARK & COPYRIGHT J. 273, 273 (1991). For example, in Japan, major patents originally worth $200 million to $300 million in sales have been pending eight years or more; the patents may not be worth much when they finally issue because Japan permits companies to make slight changes in the product without violating Japanese patent law. *Id.*

49. Pub. L. No. 100-418, 102 Stat. 1107 (1988); H.R. CONF. REP. NO. 576, 100th Cong., 2d Sess. 516-17 (1988).

50. "We need this legislation to stop the piracy of American intellectual property," Senator Frank R. Lautenberg (D-NJ) declared, noting that such losses to American business were estimated at $40 billion per year in a recent ITC study. 134 CONG. REC. S10713 (daily ed. Aug. 3, 1988). Further, Senator DeConcini, a principal author of the Senate bill, stated that one of the principles behind the 1988 Omnibus Act was that "no one should be allowed to import a product manufactured off-shore that would constitute patent infringement if it was manufactured in the U.S." News release from Sen. DeConcini (Mar. 22, 1990) (on file with the *Minnesota Law Review*).

With regard to the latter, Congress recognized that the Tariff Act needed "a more effective remedy for the protection of United States intellectual property rights."[51]

The 1988 Amendments strengthened one of the Act's principal protections of American industry: section 337(a).[52] This section prohibits the importation of goods that infringe on a valid United States product patent or that were made by means of a valid United States process patent. As amended, the section prohibits the importation into the United States, the sale for importation, or the sale within the United States after importation of articles that (i) infringe on a valid and enforceable United States patent or (ii) are made, or made by means of, a process covered by a valid and enforceable United States patent.[53]

The 1988 amendments to section 337 eliminated the requirement that the party claiming an unlawful trade practice by a foreign competitor show that the domestic industry affected by the importation was being operated economically and efficiently prior to the importation of the particular product.[54] Elimination of this requirement makes it easier for domestic entities to obtain exclusionary orders.

---

51. *See* Pub. L. No. 100-418, § 1341(b), 102 Stat. at 1212. The amendments to § 337 of the Tariff Act of 1930, according to its sponsor, Senator Lautenberg, "remove hurdles that stand in the way of an innovator's ability to get protection from the [ITC]." 134 CONG. REC. S4906-07 (daily ed. Apr. 27, 1988).

52. Section 337 of the Tariff Act is codified at 19 U.S.C. § 1337 (1988).

53. 19 U.S.C. § 1337(a) (1988). The 1988 amendments repealed the former version of § 337(a) of the Tariff Act. Pub. L. No. 100-418, § 1342(c), 102 Stat. at 1215-16. The earlier statute had provided:

> The importation hereafter for use, sale, or exchange of a product made, produced, processed, or mined under or by means of a process covered; by the claims of any unexpired valid United States letters patent, whether issued heretofore or hereafter, shall have the same status for the purposes of section 337 of the Tariff Act of 1930 [19 U.S.C. § 1337] as the importation of any product or article covered by the claims of any unexpired valid United States letters patent.

Act of July 2, 1940, ch. 515, 54 Stat. 724 (repealed 1988).

54. The former § 337(a) provided that the importation of infringing articles would be considered an unfair method of competition only if the petitioner established that the importation would "destroy or substantially injure an industry, efficiently and economically operated, in the United States." Tariff Act of 1930, ch. 497, § 337(a), 46 Stat. 590, 703 (1930) (prior to 1988 amendments). The 1988 Amendment eliminated this requirement; it was designed to enable "independent inventor[s] and small businesses, particularly in the emerging biotechnology industry, to produce their product and seek relief under § 337 [19 U.S.C. § 1337]." 134 CONG. REC. S10713 (daily ed. Aug. 3, 1988).

C. PROTECTING BIOTECHNOLOGY PATENT RIGHTS

Congress was concerned about the biotechnology industry when it debated the Omnibus Act. It recognized that product and process patents had become increasingly important to the biotechnology industry,[55] that the biotechnology industry was particularly susceptible to patent infringement,[56] and that greater process patent protection was needed.[57] It further recognized that stronger patent laws could greatly help the American biotechnology industry[58] and bring United States patent protection laws in line with those of Japan and almost all of the Western European countries.[59] Indeed, the Conference Committee addressed a problem closely analogous to the one litigated in the *Amgen* case, stating in its report: "It should be noted that many of the 'products' produced by patented processes are themselves 'used' in the manufacture of another product which is introduced into commerce."[60]

---

55. *See supra* note 31 (introducing product and process patents generally). Examples of biotechnology product patents include a strain of genetically engineered bacteria which breaks down crude oil, Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980), and a genetically engineered mouse useful in studying different cancer treatments, U.S. Patent No. 4,736,866.

Examples of biotechnology process patents include a method of DNA cloning in bacteria, U.S. Patent No. 4,237,224, and a method of DNA cloning in animal cells, U.S. Patent No. 4,339,216.

56. H.R. CONF. REP. NO. 576, 100th Cong., 2d Sess. 516-17 (1988).

57. *See* 134 CONG. REC. S4859-62 (daily ed. Apr. 27, 1988) (statement of Senator DeConcini).

58. For example, Senator DeConcini has stated the following:

> American scientists invented genetic engineering and America is currently the world leader in biotechnology research. However, because of the rapid advancements in this promising field, our patent and trade laws have failed to keep pace. Instead of providing incentives and the path to progress, the Patent Code and trade laws have become impediments to the commercialization of biotechnology research. We cannot sit idly by watching another American industry succumb to foreign competitors.

136 CONG. REC. S3107-08 (daily ed. Mar. 22, 1990) (statement of Sen. DeConcini).

59. 134 CONG. REC. S4859-62 (daily ed. Apr. 27, 1988) (statement of Sen. DeConcini).

60. H.R. CONF. REP. NO. 576, 100th Cong., 2d Sess. 516-17 (1988). The Conference Committee's discussion of the lack of patent protection for end-products relying on patented intermediates included the following:

> Consider a process patent held on a method for preparing a plasmid or other vector. The use of the plasmid or vector to insert a new gene into a living cell, instructing the cell to produce an important human protein (such as insulin or interferon) which will then be separated from the fermentation mash, purified, and packaged into single dosage forms, is a commercial use and is ineligible for the limited protection granted to non-commercial uses. *The field of biotechnology is*

The Committee did not take the next step, however, and direct that patented intermediate products also receive protection under the Tariff Act. Either inadvertently, or because of an unstated objection to protecting intermediate products, Congress left a gap in the net of the patent protection laws. That gap was the subject of Amgen's appeal to the Federal Circuit.

II. *AMGEN, INC. V. U.S. INTERNATIONAL TRADE COMMISSION*

Amgen owned the '008 patent,[61] a product patent[62] covering certain DNA sequences,[63] vectors[64] and host cells[65] used to

---

particularly susceptible to commercial "users" without sales. For example, a patent may cover a process for producing a microorganism using recombinant DNA technology. The microorganism is then used to produce a particular commercial end-product of great value. *The bill's provisions limiting remedies against users are not intended to apply to such commercial uses.*

Id. (emphasis added).

61. *See supra* note 2 (discussing Amgen's patent).

62. *See supra* note 31 (describing product, process, and product-by-process patents).

63. Inside every living cell is at least one chromosome. The chromosome is the basic hereditary material of all organisms. WILLIAM T. KEETON, BIOLOGICAL SCIENCE 99 (3d ed. 1980). Bacteria have only one chromosome, *id.* at 120; humans have 46, SPENCE & MASON, *supra* note 4, at 63. The genetic information in the chromosome is made of deoxyribonucleic acid, commonly known as DNA. LUBERT STRYER, BIOCHEMISTRY 559 (2d ed. 1981). DNA molecules are divided into individual regions called "genes" which regulate activity in the cell. KARL DRLICA, UNDERSTANDING DNA AND GENE CLONING: A GUIDE FOR THE CURIOUS 4 (1984). Genes are the blueprints for proteins used by cells. *Id.* The genes encode the exact chemical structure for the proteins. *Id.* This genetic code is very simple and made up of only four "letters": A, C, G, and T, corresponding to four different chemicals. STRYER, *supra*, at 560. A DNA sequence is a combination of these letters in a particular order directing the cell to make a specific protein. *Id.* at 565. In *Amgen*, the DNA sequence told the cell to make rEPO. Amgen, Inc. v. U.S. Int'l Trade Comm'n, 902 F.2d 1532, 1533 (Fed. Cir. 1990).

64. Vectors are pieces of DNA found in a cell that are not a part of the cell's chromosome, and are not essential to the maintenance of the cell. STRYER, *supra* note 63, at 755-56. One of the most common vectors used by scientists are "plasmids." BENJAMIN LEWIN, GENES 301 (1983). Vectors are very useful because scientists can manipulate this DNA without harming the cell's normal processes. STRYER, *supra* note 63, at 755-56. For example, scientists can cut an insulin gene out of a human chromosome, paste it into the vector, and place the vector into a bacterial cell. *Id.* at 766; Ann M. Sturtz, Fine Structure Restriction Endonuclease Mapping of Molecularly Cloned Cottontail Rabbit Papillomavirus DNA from Rabbit Tumors 10-12, 19-20 (June 1986) (unpublished M.S. thesis, University of Minnesota, on file in the University of Minnesota Medical School Library). The bacteria can then make all of its own proteins needed to live and make human insulin. *See* STRYER, *supra* note 63, at 765-66.

make rEPO.[66] The '008 patent does not cover EPO or rEPO,[67] nor the process of making rEPO,[68] because EPO is a naturally occurring product[69] and because the cloning process used to make rEPO fails to satisfy the non-obviousness requirement of the patent laws.[70] The '008 patent grants Amgen the right to exclude all others from using these DNA sequences, vectors, and host cells as the "machinery" to produce the commercially important rEPO in the United States.[71] Chugai imported rEPO into the United States. It made rEPO using host cells that the '008 patent covered.[72] Chugai did not actually import the host cells covered by Amgen's '008 patent, but merely used them in Japan in the process of making its rEPO.[73]

---

65. Host cells are the recipients of the vectors. DRLICA, *supra* note 63, at 7-8. After introducing the vector into the host cell, scientists grow the cell containing the vector in a rich broth until the single original host cell has grown and divided many millions of times. *Id.* at 8. Since all the cells in the broth started from a single "parent" host cell, all the cells in the broth will be identical. *See id.* They will all contain the same vector and will all produce the same proteins. This culture of identical cells is what is called a "clone." *Id.*

66. *See supra* note 7 (describing rEPO).

67. *See supra* note 25 and accompanying text (suggesting why Amgen cannot own the product claims to rEPO, a naturally occurring protein).

68. *See supra* note 31 and accompanying text (discussing process patents generally). Amgen originally included the process claim for making rEPO via recombinant DNA methods in its patent application, but the Patent and Trademark Office (PTO) examiner would not allow this claim to issue. *Amgen*, 902 F.2d at 1534 n.1. According to the PTO examiner, this claim was merely the application of a known (i.e., "obvious" and thus not meeting the patentability requirement of 35 U.S.C. § 103) process to new starting materials to produce a new product, and thus not patentable. *Id.*

69. *See supra* notes 25-26 and accompanying text (describing naturally occurring substances and the novelty requirement for a patent).

70. *See supra* note 28 and accompanying text (noting the non-obviousness requirement of a patent).

71. *Amgen*, 902 F.2d at 1533-34. A civil action for infringement is a remedy available to a patent owner. *See supra* notes 40-43 and accompanying text (discussing remedies for patent infringement).

72. *In re* Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) 1906, 1908 (U.S. Int'l Trade Comm'n 1989), *aff'd*, 902 F.2d 1532 (Fed. Cir. 1990). The ITC determined that Chugai made its imported rEPO by the host cell method rather than by utilizing a completely different nonrecombinant purification method licensed from another company, Genetics Institute, Incorporated. *Id.*

73. Because Chugai's activities occur outside the jurisdiction of the United States patent protection laws, its manufacturing process cannot constitute patent infringement. Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 531 (1972). United States patent laws have no extraterritorial effect. *Id.* "To the degree that the inventor needs protection in markets other than those of this country, . . . [he must] seek it abroad through patents secured in countries where his goods are being used." *Id.*; *see also Certain Recombinant Erythro-*

Amgen filed a complaint with the ITC,[74] principally alleging[75] that this importation of rEPO made using its host cells

poietin, 10 U.S.P.Q.2d (BNA) at 1908; *supra* note 48 (discussing jurisdiction of federal courts under the U.S. patent laws).

74. The ITC has authority to hear only unfair trade practices claims; it does not have jurisdiction over infringement claims. *See* 19 U.S.C. § 1337(c) (1988) ("The Commission shall determine . . . whether or not there is a violation of this section [unfair practices in import trade]."); 35 U.S.C. § 281 (1988) ("A patentee shall have remedy by civil action for infringement of his patent."); 28 U.S.C. § 1338 (1988) (granting district courts original and exclusive jurisdiction over civil actions arising under any Act of Congress relating to patents, such as 35 U.S.C. § 281 (1988)). Amgen did initiate a concurrent civil action for infringement in federal district court. Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1337, 1337-38 (U.S. Int'l Trade Comm'n 1989), *aff'd in part and rev'd in part*, 927 F.2d 1200 (Fed. Cir. 1991).

75. Chugai also challenged on appeal whether the ITC had subject matter jurisdiction over Amgen's complaint, and whether the Federal Circuit had appellate jurisdiction over the Commission's dismissal of the complaint. Amgen, Inc. v. U.S. Int'l Trade Comm'n, 902 F.2d 1532, 1535 (Fed. Cir. 1990). The ITC's Administrative Law Judge held that the ITC had jurisdiction over the complaint, *id.* at 1534-35, but the full Commission disagreed and dismissed the case for lack of subject matter jurisdiction, *id.* at 1535. Amgen appealed the Commission's dismissal to the Federal Circuit. *Id.*

The Federal Circuit held that the Commission had subject matter jurisdiction over Amgen's complaint. *Id.* at 1536. According to the Federal Circuit, whether the ITC has subject matter jurisdiction depends on the test established by the Supreme Court in Bell v. Hood, 327 U.S. 678 (1946). In *Bell*, the Court examined whether the complaint on its face sought relief that the tribunal was empowered to grant. 327 U.S. at 682. If the tribunal had statutory authorization to order such relief, then it had subject matter jurisdiction to hear the claim. *Amgen*, 902 F.2d at 1536 (citing *Bell*).

The Federal Circuit applied the *Bell* analysis and determined that the Commission had jurisdiction over the complaint because on its face it alleged an unfair trade practice and because Congress had authorized the ITC to hear such allegations and to grant appropriate relief. The court found irrelevant, for jurisdictional purposes, that Amgen could not ultimately prevail on the merits because the alleged complaint was not frivolous and was not brought merely for the purpose of obtaining jurisdiction in a particular forum. *Id.* at 1536-37.

The Federal Circuit also discussed whether it had appellate jurisdiction over the Commission's dismissal of the complaint on the stated grounds of a lack of subject matter jurisdiction. *Id.* at 1535. The Federal Circuit's authority to review the Commission's decisions arises out of § 1337(c) of title 19 of the U.S. Code, which states: "Any person adversely affected by a *final determination* of the Commission . . . may appeal such determination . . . to the United States Court of Appeals for the Federal Circuit." 19 U.S.C. § 1337(c) (1988) (emphasis added). The issue in this regard was whether a dismissal for lack of subject matter jurisdiction which never reached the merits was a "final determination." *Amgen*, 902 F.2d at 1535.

The Federal Circuit held that it did have appellate jurisdiction, reasoning that § 1337(c) provided judicial review of "both positive and negative determinations" by the Commission. *Id.* Otherwise, the Commission could "effec-

was an unfair trade practice violating the Tariff Act.[76] The ITC dismissed the case and Amgen appealed to the Federal Circuit.

Because the Tariff Act prohibits the entry of either patented end-products or products made by using a patented process, and not end-products manufactured using a patented product,[77] Amgen needed to convince the court that its host cells were a type of process that made rEPO. Amgen argued that its host cell[78] claims were different from traditional process claims. It proposed that the claims "were unique 'hybrid' claims covering both product (cells) and intracellular processes (thousands of chemical processes that take place within a living cell)."[79] According to Amgen, the host cell is not only a patented product, but also inherently a type of process because it produces a desired end-product.[80] Amgen further argued that Congress's intent in passing the Omnibus Act was to broaden the protection of the Tariff Act to prohibit the importation of end-products made using a patented intermediate product.[81] Thus, Amgen argued that the host cells should receive protection under the section of the Tariff Act[82] that covers process claims.[83]

The Federal Circuit affirmed the ITC's dismissal because none of Amgen's claims in the '008 patent covered the process Chugai used to make rEPO in Japan.[84] The court rejected Amgen's argument that the host cell claims were anything but regular product claims.[85] It stated: "A host cell claim does not 'cover' intracellular processes any more or less than a claim to a

---

tively shield all negative determinations from judicial review simply by labelling the determination as a dismissal for lack of jurisdiction." *Id.*

76. Amgen alleged Chugai violated 19 U.S.C. § 1337(a)(1)(B)(ii) (1988). *Id.* Amgen filed its complaint with the ITC in January, 1988, prior to the passage of the Omnibus Act. However, because the Omnibus Act expressly stated that it applied to all pending actions, the court held that the statute with the Omnibus Act amendments governed the action. 902 F.2d at 1534.

77. *See supra* notes 46-54 and accompanying text (describing coverage of the Tariff Act).

78. *See supra* note 65 (describing host cells).

79. *In re* Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d 1906, 1908 (U.S. Int'l Trade Comm'n 1989), *aff'd*, 902 F.2d 1532 (Fed. Cir. 1990).

80. *Amgen*, 902 F.2d at 1537-38; *see also supra* note 65 (describing host cells and how they produce the desired end-product).

81. 902 F.2d at 1539.

82. 19 U.S.C. § 1337(a)(1)(B)(ii) (1988).

83. 902 F.2d at 1537.

84. *Id.* at 1540; *see supra* notes 61-71 and accompanying text (discussing the scope of Amgen's patent).

85. 902 F.2d at 1537.

machine 'covers' the process performed by that machine."[86] Thus, Amgen could not claim any process patent protection.

Furthermore, the court held that Amgen could not claim product patent protection because the Tariff Act did not extend such protection to intermediate products used in foreign countries.[87] The Tariff Act could protect Amgen's product patent claims only if it were to prohibit the importation of articles made abroad by a process utilizing a product covered by a United States patent.[88] However, the Tariff Act contains no such language.[89]

In arriving at this conclusion, the court first looked to the plain meaning of the statutory language of section 337 of the Tariff Act.[90] It read the statutory language and concluded that the statute's reference to "a process covered by the claims of a . . . patent"[91] meant that the section covered only traditional process claims and not products used in a process.[92]

The court then examined the legislative history of the amended Tariff Act.[93] The court reasoned that Congress could have changed the statute to include products used in a process, but instead enacted legislation covering only regular process patents.[94] The court concluded that Congress did not intend to expand the Tariff Act's protection of processes to cover intermediate products because it did not alter this key language of the Tariff Act in the 1988 amendment.[95]

The court also reasoned that there was no indication that "former section [337(a)] was intended to prohibit the importation of goods made by a process which merely used abroad a

---

86. *Id.* at 1538 (footnote omitted).

87. *Id.* at 1540; *see also supra* note 73 (applying *Deepsouth*'s holding to Chugai's activities in Japan).

88. 902 F.2d at 1538.

89. *See supra* notes 49-54 and accompanying text (discussing the Tariff Act as amended in 1988).

90. As in all questions of statutory construction, we look first to the plain meaning of the statutory language, and then to other extrinsic aids such as legislative history, rules of statutory construction, and the construction placed on the statute by the agency which administers it, the ultimate objective being to discern, if possible, the intent of Congress.

902 F.2d at 1538 (citing Johns-Manville Corp. v. United States, 855 F.2d 1556, 1559 (Fed. Cir. 1988)).

91. 19 U.S.C. § 1337(a)(1)(B)(ii) (1988).

92. 902 F.2d at 1538.

93. *Id.* at 1538-40.

94. *Id.*

95. *Id.*

product, apparatus, or material patented in this country."[96] The court assumed that Congress was not aware of the problem its amendments created.[97] Therefore, the court concluded, Congress could not have intended the Tariff Act to forbid importation of products made using a patented intermediate product.[98] The court recognized that present statutes did not protect certain biotechnological patent claims, but concluded that remedying the problem was a task for Congress to address.[99]

III. IMPLICATIONS OF THE FEDERAL CIRCUIT'S INTERPRETATION

A. *AMGEN*'S FAILURE TO CLOSE THE GAP IN THE TARIFF ACT

The Federal Circuit's interpretation of section 337 does not reflect the congressional purpose behind the Tariff Act's 1988 amendments,[100] or sound public policy concerning the importation of goods into the United States. The Federal Circuit's interpretation undermines one of the major purposes of the Omnibus Trade Act: to increase the competitiveness of United States industry.[101] Congress found that section 337 of the Tariff Act did not adequately protect United States patent owners from having their patented products used by foreign companies without permission.[102] Congress explicitly stated that the purpose of the amendments to section 337 was to "make [the Act] a more effective remedy for the protection of United States intellectual property rights."[103]

The Federal Circuit's interpretation of section 337 leaves a conspicuous gap in patent protection. Congress wanted to close

96. *Id.* at 1539.

97. *Id.* at 1540.

98. *Id.*

99. The court stated: "[I]t is a task for Congress, which can explore its impact and side effects, and not for this court." *Id.*

100. Congress amended the Patent Code and § 337 of the 1930 Tariff Act in 1988 to prevent offshore process patent infringement. 136 CONG. REC. S3107 (daily ed. Mar. 22, 1990). As the Act's sponsor noted two years after passage: "In that important piece of legislation, Congress adopted the principle that no one should be allowed to import a product manufactured offshore that would constitute patent infringement if it had been manufactured in the United States." *Id.* (statement of Sen. DeConcini).

101. *See* H.R. CONF. REP. NO. 576, 100th Cong., 2d Sess. 516-17 (1988).

102. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, § 1341(a)(2), 102 Stat. 1107, 1212 (1988).

103. *Id.* § 1341(b), 102 Stat. at 1212.

that gap.[104] *Amgen* allows foreign companies to import and sell certain products that would infringe a United States patent if made in the United States.[105] Rather than narrowing the terms of the statute, the court should have interpreted the statute's reference to processes "covered by the claims of a . . . patent"[106] to include all patent protection provided in domestic operation. This interpretation would be more consistent with the purpose and spirit of the Omnibus Act.

Not only is the *Amgen* result contrary to the purpose of the Omnibus Act of 1988, it also fails to reflect sound public policy. Biotechnology suffers an inherent disadvantage in trade protection; many of its commercial products can never be patented as products[107] because they are necessarily identical to naturally occurring substances.[108] These commercially useful end-products cannot be protected directly. They may be protected indirectly, however, by patent protection for intermediate products.[109] The Federal Circuit's reading of the Tariff Act[110] failed to take into account the unique nature of the biotechnology industry and congressional recognition that biotechnology has tremendous potential that should be encouraged.[111]

Patent rights constitute one of the foundations for the profitable development of innovations.[112] Current uncertainties in patent rights for biotechnological innovations, however, continue to hamper the industry.[113] The *Amgen* court treated biotechnology as if it were a generic field, subject to patent law rules developed for other scientific and technical fields. Biotechnology is unlike most other fields; its end-products cannot be patented.[114] The continued application of *Durden* and

104. "[T]he language of the bill as interpreted did not mirror our intent." 136 CONG. REC. S3107 (daily ed. Mar. 22, 1990) (statement of Sen. DeConcini introducing Senate Bill 2326).

105. *See supra* notes 39-45 and accompanying text (describing action for infringement).

106. 35 U.S.C. § 1337(a)(1)(B)(ii) (1988).

107. *See supra* note 31 (discussing product patents generally).

108. *See supra* note 15 and accompanying text (asserting that naturally occurring substances cannot be patented).

109. *See supra* notes 16-17 and accompanying text (discussing the patenting of intermediate products).

110. *See supra* text accompanying notes 84-87 (describing the holding of *Amgen*).

111. *See supra* note 14 (discussing the utility and diverse applications of the biotechnology industry).

112. COMPETITIVENESS, *supra* note 14, at 16-17.

113. *Id.* at 18.

114. *See supra* note 15 and accompanying text.

Amgen in the biotechnology area could deny protection to innovations that can be protected only through process patents.[115] If Congress overturned *Durden* and *Amgen*, patenting these processes would permit the patent holders to block the importation of products produced by the use of patented intermediate materials.[116]

B. CONGRESSIONALLY PROPOSED SOLUTIONS TO THE PROBLEMS LINGERING AFTER *AMGEN*

The troublesome result in *Amgen* has not escaped legislative attention. Congress has considered three possible amendments which address the Tariff Act's lack of protection for intermediate products.

Congress first considered an amendment that would expand the definition of non-obviousness[117] to allow the patenting of a process that uses a patented product.[118] In effect, this would permit a "process-by-product" patent.[119] Under the proposal, an applicant for a patent on a particular product may include in her claim a process which necessarily uses that product. As long as the product is new, the process using the product will be considered non-obvious and patentable along with the product.

Second, Congress considered expanding the definition of

115. COMPETITIVENESS, *supra* note 14, at 18.

116. *Id.*

117. *See supra* note 28 (acknowledging the 35 U.S.C. § 103 non-obviousness patentability requirement).

118. In particular, Congress considered the following amendment to allow for the patenting of these types of processes:

> When a process of making or using a machine, manufacture, or composition of matter is sought to be patented in the same application as such machine, manufacture, or composition of matter, such process shall not be considered as obvious under this section if such machine, manufacture, or composition of matter is novel under section 102 and nonobvious under this section. If the patentability of such process depends upon such machine, manufacture, or composition of matter, then a single patent shall issue on the application.

S. 654, 102d Cong., 1st Sess. (1991); *see also* 137 CONG. REC. E946 (daily ed. Mar. 14, 1991) (Biotechnology Patent Protection Act introduced in the House by Rep. Richard Boucher).

The Bill, introduced in the 102d Congress, varied in text from that introduced in the 101st Congress, but not in purpose: "A process of making a product shall not be considered obvious under this section if an essential material used in the process is novel under [35 U.S.C.] section 102 and otherwise nonobvious under [35 U.S.C.] section 103." S. 2326, 101st Cong., 2d Sess. § 1 (1990).

119. In *In re Durden*, the U.S. Patent and Trademark Office rejected Durden's "process-by-product" claim. 763 F.2d 1406, 1407 (Fed. Cir. 1985); *see also supra* notes 33-38 and accompanying text.

infringing activity. A proposed amendment to section 271 of the patent laws creates liability for anyone who:

> without authority imports into the United States or sells or uses within the United States a product which is made by using an essential biotechnological material (as defined under section 154(b)) which is patented in the United States . . . if the importation, sale, or use of the product occurs during the term of such patent.[120]

Third, Congress considered amending the Tariff Act to prohibit the importation of end-products using patented intermediate products.[121] This proposal excludes from American markets end-products manufactured from patented intermediate products, just as current law prohibits the importation of products manufactured by means of patented processes and products.[122] The proposal singles out biotechnological materials for protection.[123]

---

120. S. 2326, 101st Cong., 2d Sess. § 2(b)(1) (1990).

121. *See* H.R. 3957, 101st Cong., 2d Sess. (1990); 139 CONG. REC. E207 (daily ed. Feb. 7, 1990) (statement of Rep. Moorhead); H.R. 5664, 101st Cong., 2d Sess. (1990); 136 CONG. REC. E2909 (daily ed. Sept. 19, 1990) (statement of Rep. Boucher); S. 2326, 101st Cong., 2d Sess. (1990); 136 CONG. REC. S3107 (daily ed. Mar. 22, 1990) (statement of Sen. DeConcini).

122. *See* H.R. 3957, 101st Cong., 2d Sess. (1990); 139 CONG. REC. E207 (daily ed. Feb. 7, 1990) (statement of Rep. Moorhead); H.R. 5664, 101st Cong., 2d Sess. (1990); 136 CONG. REC. E2909 (daily ed. Sept. 19, 1990) (statement of Rep. Boucher); S. 2326, 101st Cong., 2d Sess. (1990); 136 CONG. REC. S3107 (daily ed. Mar. 22, 1990) (statement of Sen. DeConcini).

123. Both Houses of Congress considered bills that would prohibit the importation of articles that "are made, produced, or processed under, or by means of, the use of an essential biotechnological material [as defined under section 154(b) of title 35 of the U.S. Code] covered by a valid and enforceable United States Patent." H.R. 3957, 101st Cong., 2d Sess. (1990) (introduced Feb. 7, 1990); *see also* H.R. 5664, 101st Cong., 2d Sess. (1990) (introduced Sept. 18, 1990); S. 2326, 101st Cong., 2d Sess. (1990) (introduced Mar. 22, 1990).

Discussion in the House of Representatives identified the hole in the patent statutes:

> I was an original author of the process patent amendments of the 1988 trade bill. Those amendments were designed to prevent the importation of foreign products into the United States when the manufacture of such products within the United States would violate our patent laws. But in light of developing technology, those amendments have not proved fully adequate. So this new bill, which is clearly within the spirit of the 1988 amendments, allows us to finish some unfinished business.

136 CONG. REC. E207 (daily ed. Feb. 7, 1990) (statement of Rep. Moorhead); *see also* 136 CONG. REC. E213 (daily ed. Feb. 7, 1990) (statement of Rep. Boucher) ("Technological advancement has outpaced the government's ability to pass laws which provide sufficient proprietary protection for biotechnology inventions.").

C. ALTERNATIVE APPROACHES TO THE *AMGEN* PROBLEM

This Comment contends that even though the three congressional proposals offer some protection for intermediate product patents held by the biotechnology industry, each has negative ramifications.

1. Amend 35 U.S.C. Section 103 to Expand the Definition of Non-obviousness

The proposed amendment to section 103 of title 35 expanding the definition of non-obviousness would overturn the corresponding holdings in *Durden* and *Amgen*.[124] These cases held that the use of a novel starting material in combination with a known process was not eligible for a process patent.[125] Congress's remedy would permit intermediate product patent owners to gain process patent protection. The proposed amendment has the advantage of granting the ITC the authority to issue exclusionary orders[126] protecting intermediate patent owners without actually amending the Tariff Act.[127]

The Tariff Act already prohibits the importation of products that infringe upon a United States patent or products made using a patented process.[128] If end-products made using intermediate products were covered by the original product patent, the existing terms of the Tariff Act would prohibit their importation because their use in a process would present a valid process patent claim.

With this definitional change, however, Congress would take a much larger step than is necessary. The proposal would transform well-known, "obvious" processes under current patent standards into "non-obvious" processes simply to overturn *Durden* and *Amgen*. This proposal defeats the primary purpose

124. *See supra* notes 33-38, 84-89 and accompanying text (giving the holdings of *Durden* and *Amgen*).

125. *See supra* notes 33-38, 84-89 and accompanying text.

126. *See supra* note 47 (discussing ITC exclusionary orders).

127. This allows Congress to circumvent a concern about linking patent reform with General Agreement on Tariffs and Trade ("GATT") negotiations. *See infra* note 144 (discussing GATT). The House of Representatives and the Bush Administration favored this option. *See* H.R. 5664, 101st Cong., 2d Sess. (1990); 136 CONG. REC. E2909 (Sept. 19, 1990) (statement of Rep. Boucher) (referring to a letter from the General Counsel of the Department of Commerce on July 5, 1990, to the House of Representatives setting forth the Administration's views); *Legislation: House Panel Examines Biotech Patent Legislation*, 40 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 999, at 463 (Sept. 27, 1990).

128. *See supra* notes 46-48 and accompanying text (discussing the Tariff Act).

of a non-obviousness standard. The granting of patents is designed to encourage innovation,[129] not to award those who can somehow lay a proprietary claim to a product or process already known in the scientific or technical community.[130]

Legislative tinkering with the definition of non-obviousness for one particular industry threatens the basic structure of the patent laws. The entire patent law scheme depends upon consistent, objective determinations of non-obviousness based on the expertise of the United States Patent Office.[131] A decision to alter definitional requirements not only would undermine confidence in the objectivity of the patent system, but also would discourage experimentation and innovation in areas other than the narrow areas covered by the congressionally altered definition of non-obviousness.[132] Inventors would be more inclined to work in areas where there was a possibility of acquiring a patent than in non-patentable areas.[133] If an inventor is unsure whether she will be able to patent her technology, she may prefer to keep it secret or not go through the expensive and time-consuming process of pursing a patent application. This defeats the constitutional goal of encouraging the useful arts through patents.[134] Predictability, fairness and incentives for innovation would suffer.

2. Amend 35 U.S.C. Section 271 to Expand the Definition of Infringing Activity

The proposal to expand the definition of infringing activity to include products made using a patented biological material recognizes the serious patent difficulties in the biotechnology industry.[135] Congress, however, should not focus exclusively on

129. *See supra* note 22 (discussing patents as a reward for ingenuity).

130. "Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available." Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

131. *Id.* at 18-19.

132. *See id.* at 10 (discussing Congress' reluctance to change the statutory requirements for patentability).

133. *See id.* at 9 (noting that Thomas Jefferson, as Secretary of State and thus in charge of the U.S. patent system, believed that "[o]nly inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly").

134. *See supra* notes 22-24 and accompanying text (discussing constitutional grant of patent rights).

135. *See supra* notes 14-17 and accompanying text (discussing the biotechnology industry's unique patent concerns).

biotechnology.[136] Problems for intermediate products may arise in other industries as well. For example, one of the cases that Congress would overturn with this broader amendment is *In re Durden*, a case concerned with a chemical—not a biotechnological—patent claim.[137] A congressional amendment limited to biotechnology would not remedy the chemical situation in *Durden*. Moreover, amending the definition of infringement in a particular industry seems to invite further definitional changes for other industries. One consequence of such changes would be a patchwork definition of infringement that would vary from one industry to another.

Further, merely bolstering the infringement statute does not adequately protect many patent holders. The infringement statute and the Tariff Act serve two different purposes. The infringement statute allows a patent owner to recover damages for economic harm suffered because of the infringing activity once the infringing product is imported into the United States.[138] The Tariff Act provides a mechanism to prevent the importation of such products in the first place.[139] If intermediate patent owners can prohibit the entry of infringing end-products into the United States, they do not need to rely on costly, lengthy infringement actions to vindicate their intellectual property rights.[140] The recovery of damages in an infringement action provides some relief to patent holders but is not, and should not be, the primary method of policing unfair trade practices.[141]

---

136. *See* 136 CONG. REC. E2909 (daily ed. Sept. 19, 1990) (statement of Rep. Boucher) (referring to a letter from the General Counsel of the Department of Commerce on July 5, 1990, to the House of Representatives criticizing this proposal as industry-specific).

137. 763 F.2d 1406 (Fed. Cir. 1985). For a discussion of the *Durden* case, see *supra* notes 33-38 and accompanying text. The *Durden* court would not permit the patenting of chemical process claims even though the original starting materials and the end-products were new. *Durden*, 763 F.2d at 1411.

138. *See supra* notes 39-45 and accompanying text (discussing infringement claims).

139. *See supra* notes 46-48 and accompanying text (discussing Tariff Act claims).

140. Congress placed a stringent one-year time requirement on all ITC actions. 19 U.S.C. § 1337(b)(1) (1988); *see also* text accompanying note 48 (noting the cost of patent infringement litigation).

141. If Congress does decide to amend the infringement statute, a better modification than the current congressional proposal would extend infringement liability to persons or entities that import, sell or use within the United States a product made from an essential material (such as an intermediate product) which is already patented in the United States. Merely eliminating the term "biotechnological" from the currently proposed congressional amend-

3. Amend the Tariff Act to Prohibit the Importation of End-Products Made by Using Patented Intermediates

The proposed amendment to the Tariff Act is the best of the three proposals, although it should be redrafted.

a. Prohibit The Importation of End-products

Congress should amend the Tariff Act to prohibit the importation of end-products made by using patented intermediates. Foreign enterprises should not have a competitive advantage over American enterprises.

Congress should ban the importation of all articles made; produced; or processed under, or by means of, *all* patented intermediates—not just patented biotechnological intermediates. Congress simply cannot predict future innovations that may develop in all industries. It should not require all industries to suffer the same serious injuries as the biotechnology industry before it acts.

The ban would extend protection to end-products using patented intermediates in a manner that is not industry specific and that can accommodate problems not yet identified. Congress could thus address the general problem in a single law that protects new technologies from their inception, rather than leaving new technologies unprotected during their critical inception period.[142]

---

ment would accomplish this result. Deleting the reference to biotechnological material would better serve the needs of domestic patent protection laws. Although *Amgen* concerned a biotechnological patent, other industries may also suffer in the international economy because the only patent protection available to them are intermediate product patents. By amending the statutory definition of infringing activity without specific reference to the biotechnology industry, Congress would avoid having to amend the Act every time a new industry, or an emerging portion of an existing industry, needed patent protection for something more than its intermediate-product patents.

142. Congress should amend § 337(a)(1)(B) of the Tariff Act to include the following as an unlawful activity:

> (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 . . . (iii) are made, produced, or processed under, or by means of, the use of an essential material, as defined by section 154 of title 35, United States Code, covered by a valid and enforceable United States patent.

This additional language would prohibit the importation of materials made using a patented intermediate product. The current statute only prohibits the importation of patented end-products materials or materials that are made using a patented process. 19 U.S.C. § 1337(a)(1)(B) (1988).

b. Ramifications for International Trade

International political repercussions need to be examined whenever changes to the Tariff Act are proposed. The Bush Administration is concerned about changing the Tariff Act[143] because the trading nations of the world are involved in a round of negotiations concerning the General Agreement on Tariffs and Trade ("GATT").[144] Participants in this round of negotiations[145] are considering including patents and other forms of intellectual property within the GATT.[146] The private

143. *See* H.R. 5664, 101st Cong., 2d Sess. (1990); 136 CONG. REC. E2909-10 (daily ed. Sept. 19, 1990) (statement of Rep. Boucher) (referring to a letter from the General Counsel of the Department of Commerce on July 5, 1990, to the House of Representatives setting forth the Administration's views). The Administration is concerned that an amendment to § 337 would create dissent by GATT-participating nations. *See id.* at E2909.

144. General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A3, 55 U.N.T.S. 187 ("GATT"). One hundred seven contracting parties are currently participating in the GATT talks. Karen Tumulty, *Nothing Short of a Miracle Needed at Trade Talks*, L.A. TIMES, June 2, 1991, at D6.

145. This round of talks, the "Uruguay Round" of GATT, began in September, 1986 and is the eighth round of multilateral trade negotiations of GATT. Bello & Holmer, *supra* note 48, at 309-10. The Uruguay Round of GATT negotiations broke off in December, 1990 in Brussels when the 12-nation European Community ("EC") rejected a demand by the United States and other agricultural-exporting countries that it significantly lower its farm subsidies. Tumulty, *supra* note 144, at D6. The talks resumed in February, 1991 when the EC stated that it was willing to at least discuss cutting farm subsidies. *Id.*

146. Robert W. Kastenmeier & David Beier, *International Trade and Intellectual Property: Promise, Risks, and Reality*, 22 VAND. J. TRANSNAT'L L. 285, 285-86 (1989). Representative Kastenmeier is the Chair of the Subcommittee on Courts, Intellectual Property and the Administration of Justice for the House Committee on the Judiciary. The negotiating goals of the round are the following:

> In order to reduce the distortations [sic] and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines.
>
> Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT.
>
> These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organization and elsewhere to deal with these matters.

Punta del Este Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations, Sept. 1986, at 7-8, *reprinted in* A. Jane Bradley, *Intellectual Property Rights, Investment, and Trade in Services in the Uruguay Round: Laying the Foundations*, 23 STAN. J. INT'L L. 57, 95 (1987).

The United States's goal for the Uruguay Round "is to achieve clearer,

sector in the United States, Europe, and Japan supports the effort to include intellectual property protection in the GATT.[147]

Because the purpose of GATT is to place all foreign and domestic corporations on an even playing field,[148] changes to the Tariff Act should not impair the GATT negotiations. GATT prohibits nations from giving their domestic corpora-

---

more enforceable rules [protecting] intellectual property." Bello & Holmer, *supra* note 48, at 313; Kastenmeier & Beier, *supra*, at 290-91.

147. Kastenmeier & Beier, *supra* note 146, at 287. The United States in particular is concerned about protecting its intellectual property rights as the percentage of American exports with a high intellectual property content (such as pharmaceuticals, chemicals, books, movies, and computers) has increased to more than 25% of all United States exports. *Intellectual Property, Domestic Productivity, and Trade: Oversight Hearings Before the Subcommittee on Courts, Intellectual Property and Administration of Justice of the House Committee on the Judiciary*, 101st Cong., 1st Sess. 2 (1989). As of March, 1988, the royalties received by American industries from the licensing of intellectual property exceeded eight billion dollars per year, more than six times the amount paid to foreign firms. 3 U.S. DEPARTMENT OF COMMERCE, SURVEY OF CURRENT BUSINESS 54-59 (1988) (Table 10). Between $43 billion and $61 billion is lost each year by the United States because of inadequate protection of intellectual property rights around the world. U.S. INTERNATIONAL TRADE COMMISSION, FOREIGN PROTECTION OF INTELLECTUAL PROPERTY RIGHTS AND THE EFFECT ON U.S. INDUSTRY AND TRADE H3 (1988). "The United States is losing the competitive edge gained from the research, development, innovation, and creativity that flourish when investment in creative development is rewarded with exclusive rights that enable the establishment of a foothold in foreign markets." Bello & Holmer, *supra* note 48, at 312.

148. Article 3 of GATT addresses the application of internal taxes and regulations, guaranteeing that foreign goods will be given equal treatment with domestic products:

> 2. The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution, or use.

GATT, Oct. 30, 1947, part II, art. III, 61 Stat. A3, A18, 55 U.N.T.S. 187, 202.

Foreign goods are now receiving better treatment than domestic products in the United States. American corporations may not use Amgen's host cells without Amgen's permission because of the United States product patent covering the host cells. Foreign corporations, however, may use them under current law because the host cells are not themselves imported into the United States. Only the products made by the host cells are imported.

GATT permits the regulation of imports which harm a domestic industry. If a product is imported into a country which abides by the GATT regulations, and that importation causes or threatens injury to the domestic corporations producing that product, the country may take steps to remedy the situation. GATT, Oct. 30, 1947, part II, art. XIX, § (1)(a), 61 Stat. A3, A58-59. Thus, the United States would not violate GATT by altering the Tariff Act to permit exclusionary orders against products made by a process which would infringe a U.S. patent if made in the same manner in the United States.

tions an advantage over foreign corporations. However, the changes to the Tariff Act would not give United States corporations a competitive advantage.[149] Rather, the changes would eliminate the advantage foreign corporations currently enjoy by requiring that all corporations respect United States patent rights.[150]

Even if the Tariff Act is not in full compliance with GATT, Congress should pass the proposed amendment. The United

149. The purpose of the proposals is not to give American companies special protection against foreign competition, but to allow them to compete on a level playing field. 136 CONG. REC. E207 (daily ed. Feb. 7, 1990).

150. U.S. patent holders should not be left worse off than inventors in other countries. 136 CONG. REC. E2910 (daily ed. Sept. 19, 1990) (statement of Rep. Boucher).

In 1987 the EC filed a complaint with a GATT panel claiming that § 337 of the Tariff Act is incompatible with GATT rules on non-discrimination and national treatment under Article 3 of GATT trade rules. *See EC Endorses Panel's Ruling That Section 337 Violates GATT Non-Discrimination Rules*, 37 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 961, at 302 (Dec. 28, 1989).

The EC alleged that § 337 of the Tariff Act discriminated against foreign companies because it gave the ITC jurisdiction over imported, but not domestic, products. *See European Community Files Complaint Alleging Section 337 Violates GATT*, 33 PAT. TRADEMARK & COPYRIGHT J. (BNA) 526, 526 (1987). The GATT council adopted a finding in early 1991 that § 337 is inconsistent with GATT. *See* Lloyd Day et al., *Bartering Away American Biotechnology: The Coming Erosion of U.S. Patent Protection, in* 137 CONG. REC. E1201-03 (daily ed. Apr. 11, 1991) (submitted by Rep. Levine). Such finding by the GATT council does not necessarily sound the death knell for § 337. A number of findings by the council have been left unimplemented, pending the outcome of the Uruguay Round. *GATT: Failure to Adopt Panel Reports an Agenda of Council Session, But Little Action Taken*, 8 INT'L TRADE REP. 662, 662 (1991). Both the EC and Japan, parties which raised the complaint against the Tariff Act in the GATT council, have also failed to implement findings. Peter Montagnon, *Fears Grow for GATT Disputes System*, FINANCIAL TIMES, April 25, 1991, at 13.

Although § 337 does give the ITC jurisdiction over foreign and not domestic companies, this observation ignores an important issue. Foreign companies whose only contact with the United States is the misappropriation of ideas from American patents are not subject to the jurisdiction of United States courts. "[T]he lack of [U.S. District Court] jurisdiction over foreign manufacturers results in inadequate protection for many U.S. patentees . . . . [We need to] make enforcement useful and available, fair to everyone." *The Sixth Annual Judicial Conference of the United States Court of Appeals for the Federal Circuit*, 122 F.R.D. 281, 315 (1989) (statement by Don Banner, former U.S. Commissioner of Patents and Trademarks). Thus, even if a domestic corporation obtained an injunction against a foreign corporation, it could not enforce the remedy in a foreign country, but it could enforce the injunction against another domestic corporation.

Injunctive relief is available to a party only upon a showing of a threat of irreparable injury for which it has no adequate legal remedy. 11 CHARLES A. WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2942 (1973) [hereinafter WRIGHT & MILLER]. Failure to abide by the injunction may

States has, in the past, set its trade policy by considering issues broader than the literal terms of GATT.[151] The United States has often engaged in trade agreements with other individual countries, such as Israel and Canada, and a consortium of countries, such as other NATO member countries.[152] Occasionally, the United States has even acted unilaterally to restrain trade when reform was needed.[153] Thus, acting in a way not specifically sanctioned by GATT in order to protect domestic corporations from unfair foreign trade practices has ample precedent.[154]

Patent protection is critical to the United States' trade competitiveness. Congress should act even if GATT is violated. The standards in several international intellectual property conventions do not provide for adequate intellectual property protection. What protections do exist are ineffectively enforced.[155]

The intellectual property conventions are not universal. Indeed, some countries do not have patent, copyright, or trademark laws at all.[156] Even in countries with intellectual prop-

---

result in a finding of contempt of court. *Id.* § 2960. Obviously a party over which the court has no personal jurisdiction cannot be found in contempt.

Section 337 addresses this inconsistency by giving the United States Customs officials the power to prevent items from ever entering the United States market. Just as an injunction grants enforcement powers to a sheriff, the Tariff Act authorizes Customs officials to prevent infringing domestic goods from unfairly entering the United States market.

The EC also complained that § 337 places foreign companies at a disadvantage because they are required to defend themselves twice, once before the ITC to prevent the issuance of an exclusionary order, and again in federal district court on the grounds of infringement. Kastenmeier & Beier, *supra* note 146, at 298. This argument ignores that a domestic company desiring a preliminary and permanent injunction would also have to litigate twice. FED. R. CIV. P. 65. Domestic companies are able to obtain temporary preliminary relief; however, they must still, if necessary, fully litigate the infringement suit on its merits to obtain any permanent relief. 11 WRIGHT & MILLER, *supra*, § 2950.

151. *See* Bello & Holmer, *supra* note 48, at 307.

152. *Id.*

153. *See, e.g.*, Proclamation No. 5631, 52 FED. REG. 13,412 (1987).

154. Clyde Prestowitz, the principal advisor on Japanese affairs to the U.S. Secretary of Commerce from 1983 to 1986, maintains that the faith placed in GATT for ensuring the world's economic prosperity is misguided, and that there are serious weaknesses in the current multilateral trading system. *See* Clyde V. Prestowitz et al., *The Last Gasp of GATTism*, HARV. BUS. REV., Mar.-Apr. 1991, at 130; Clyde V. Prestowitz, *Life After GATT: More Trade Is Better Than Free Trade*, TECH. REV., Apr. 1991, at 22.

155. *See, e.g.*, Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645; International Convention for the Protection of New Varieties of Plants, Oct. 23, 1978, 33 U.S.T. 2703.

156. Bello & Holmer, *supra* note 48, at 312.

erty laws, enforcement is often poor.[157] Injunctive relief, useful in minimizing monetary losses, is often not available.[158] Thus, the ITC exclusionary order authorized by the Tariff Act remains the most powerful mechanism by which American corporations can enforce their intellectual property rights.

The proposed amendment to the Tariff Act should not have an adverse effect on the GATT negotiations.[159] Foreign companies have taken advantage of the current law to acquire a competitive advantage over American industries. These foreign companies will oppose the proposed amendment, which is precisely why the amendment should be adopted. The Tariff Act amendment would level the playing field by forcing foreign industries to abide by patent protection restrictions already applied to domestic industries. Congress could thus close the gap in United States patent protection laws with a solution consistent with the original purpose of the Tariff Act.[160] The Tariff Act amendment would be in accord with GATT's purpose of ensuring that both domestic and foreign corporations receive equal treatment.[161]

CONCLUSION

The Federal Circuit in *Amgen, Inc. v. United States International Trade Commission* interpreted the Tariff Act of 1930, as amended by the Omnibus Trade and Competitiveness Act of 1988, to prohibit the importation of patented end-products or non-patented products made using a patented process, but not the importation of non-patented products made using a patented intermediate product. This interpretation of the Tariff Act leaves the emerging biotechnology industry largely unprotected because most of its commercial end-products and processes cannot be patented.

---

157. *Id.*

158. *Id.* at 313.

159. *See supra* notes 144-47 and accompanying text (discussing the GATT negotiations).

160. *See supra* notes 46-48 and accompanying text (discussing the purpose of the Tariff Act).

161. While we do not believe that American biotech companies should get special protection against foreign competition, we do believe that our companies should be allowed to compete on a level playing field. Foreign companies should not be able to evade U.S. patent laws for products sold in the United States simply by moving production offshore. And our companies should receive the same process patent protection that their competitors receive in Japan and Europe.

136 CONG. REC. E207 (daily ed. Feb. 7, 1990) (statement of Rep. Moorhead).

Congress has responded with proposals to amend the Tariff Act, modify patentability requirements, or change the patent infringement statute. Intermediate product patents should receive the same protection from unfair foreign trade practices as end-product and process patents. Congress intended in both the Tariff Act and the amended Omnibus Act to amplify the domestic patent protection laws. This Comment argues that Congress should close this gap in the patent protection laws by amending the Tariff Act to include process-by-product patent claims, thereby allowing the United States to issue exclusionary orders against foreign end-products that are created with intermediate products patented in the United States.