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Case Comment

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CASE COMMENT

Biotechnology and Recently Amended Section 337: Federal Circuit Grants No Protection, *Amgen, Inc. v. United States International Trade Commission*, 902 F.2d 1532 (Fed. Cir. 1990)

ABSTRACT

Section 337 of the recently amended Tariff Act of 1930 permits United States patent owners to bar from importation goods that infringe upon their patents. In Amgen, Inc. v. United States International Trade Commission, *the Federal Circuit refused to grant relief to the patent owner because it had no claim on either the final product imported or the process to create the product. The alleged infringer, however, had to use the patented product to create the final product, which, if done in the United States, would infringe the patent.*

This Comment argues for an extension of section 337 to cover this type of behavior, especially in regard to high technology products. For years this industry has been the victim of multi-million dollar piracy and United States corporations require this protection to remain or become competitive. Fledgling biotechnology corporations, who depend heavily upon patent protection, especially need increased protection to develop and market their products.

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A. *Facts of Amgen*

In theory, United States domestic laws should demand no more of those engaging in business in the United States than they demand of importers. Despite the rhetoric of free trade and open markets, tariff laws and import controls may lead one to believe that the United States trade laws favor United States citizens. In the case of high-technology intellectual property, however, the converse may be true, as demonstrated by the case of *Amgen, Inc. v. United States International Trade Commission.*[1]

On January 4, 1988, Amgen, Inc. (Amgen) filed a complaint with the United States International Trade Commission (ITC)[2] against Chugai Pharmaceutical Co. of Japan and Chugai Pharma U.S.A., Inc. (collectively, Chugai) for an alleged violation of former section 337[3] of the

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1. 902 F.2d 1532 (Fed. Cir. 1990).

2. The United States International Trade Commission (ITC) is a six person board appointed by the President to investigate customs' infractions. 19 U.S.C. §§ 1330, 1332 (1988). Appeals from the ITC proceed directly to the United States Court of Appeals for the Federal Circuit, a federal appeals court established in 1982 that sits in Washington, D.C. and hears several types of special appeals, including patent, trademark, and tax appeals. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, § 127, 96 Stat. 25, 37-38 (1982).

3. Tariff Act of 1930, ch. 497, § 337, 46 Stat. 703 (1930) (codified as amended at 19 U.S.C. § 1337 (1988)). The Omnibus Trade and Competitiveness Act of 1988 (1988 Trade Act) amended 19 U.S.C. § 1337 and repealed 19 U.S.C. § 1337a. *See infra* note 10. Prior to these 1988 amendments, section 1337(a), pursuant to which Amgen originally claimed relief, provided:

> *Importation of products produced under process covered by claims of unexpired patent*
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> The importation 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, shall have the same status for the purposes of section 1337 of this title as the importation of any product or article covered by the claims of any unexpired valid United States letters patent.

Tariff Act of 1930.[4] Amgen claimed that Chugai imported a product that infringed Amgen's patent, United States Patent Number 4,703,008 (the '008 patent), which covered the DNA[5] sequences, vectors, and host cells used to make recombinant erythropoietin (rEPO).[6] No patent claim in the '008 patent, however, actually covered the process employed to synthesize rEPO.[7]

B. *The ITC's Decision*

The ITC commenced an investigation into Amgen's allegations on February 2, 1988, referring the matter to an administrative law judge (ALJ).[8] Before the ALJ reached a conclusion, however, Congress, in August 1988, substantially amended section 337[9] and repealed the sec-

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Amgen, 902 F.2d at 1534 n.2.

4. *Amgen*, 902 F.2d at 1534.

5. DNA is an abbreviation for deoxyribonucleic acid, a chemical compound that stores the genetic information and is found in virtually all living things.

6. *Id.* at 1533-34. Erythropoietin is a hormone naturally present in animals that controls red blood cell synthesis. Because erythropoietin stimulates red blood cell production, physicians use it to treat patients with anemia. Through biotechnology Amgen could mass-produce rEPO, thereby making it commercially feasible to use rEPO in the treatment of anemia. *Id.* For details concerning the patent claims of the '008 patent and the biotechnology used to produce rEPO, see Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1741-58 (D. Mass. 1989).

On a related issue, the United States Supreme Court has granted *certiorari* to determine whether genetically engineered life forms must be disclosed fully in patent applications. *See* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir.), *cert. granted*, 42 Pat. Trademark & Copyright J. (BNA) 240 (July 11, 1991).

7. *Amgen*, 902 F.2d at 1533-34. A process patent protects the method for producing the product, not the end product. In other words, competitors are free to make the end product by another method. The Patent and Trademark Office refused to grant a process patent for the production of rEPO because the examiner considered the process to be obvious in light of the prior art within the scope of section 103 of the Patent Act, 35 U.S.C. § 103, *In re* Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) 1906, 1910; the examiner also considered the process obvious based on the holding of *In re* Durden, 763 F.2d 1406 (Fed. Cir. 1985) (holding that no patent could issue on a process that used a patentable starting product and yielded a patentable final product). *Amgen*, 902 F.2d at 1534 n.1. An amendment is now before Congress that would reverse the holding of *In re Durden*. *See* 40 Pat. Trademark & Copyright J. (BNA) 211, 212 (June 28, 1990) (description of the Biotechnology Protection Act of 1990). *See also* S. Res. 654, 102d Cong., 1st Sess., 137 CONG. REC. S3284 (daily ed. Mar. 13, 1991) (statement of Sen. DeConcini) (introducing the Biotechnology Patent Protection Act of 1991, intended to revise and refine the proposed Biotechnology Patent Protection Act of 1990).

8. *Amgen*, 902 F.2d at 1534.

9. Prior to the 1988 amendments, Congress had renumbered section 337 to section 1337. The literature uses these section numbers as synonyms, and that tradition will not

tion under which Amgen sought relief by passing the Omnibus Trade and Competitiveness Act of 1988 (1988 Trade Act),[10] which applied to all pending cases.[11] Amgen amended its complaint to allege that Chugai's behavior fell under section 1337(a)(1)(B)(ii) of the 1988 Trade Act, which bars from importation articles that "are made, produced, processed, or mined under, or by other means of, a process covered by the claims of a valid and enforceable United States patent."[12] Amgen argued first that, to produce rEPO, Chugai had to use Amgen's patented material covered by the claims of the valid '008 patent, and, therefore, Chugai's behavior of importation was unfair.[13] Second, Amgen alleged that the host cell[14] claims of the '008 patent were "unique hybrid claims," which covered not only the host cells themselves, but also the specific intracellular processes carried out by those cells.[15] On January 10, 1989, the ALJ held that although the ITC had subject matter jurisdiction over the case, Chugai's process for rEPO production did not infringe upon the '008 patent claims, and therefore, no violation of section 1337 had occurred.[16]

The ITC reviewed the decision of the ALJ, holding that a process claim was a prerequisite for subject matter jurisdiction under section

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be broken herein.

10. Pub. L. No. 100-418, 1988 U.S.C.C.A.N. (102 Stat.) 1107 (codified as amended at 19 U.S.C. § 2901).

11. *Interim Rules Governing Investigations and Enforcement Procedures Pertaining to Unfair Practices in Import Trade*, 53 Fed. Reg. 33,043, 33,044 (1988).

12. *Amgen*, 902 F.2d at 1534. The full text of section 1337(a)(1)(B)(ii) states:

> (a) *Unlawful activities; covered industries; definitions*
>
> (1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section: . . .
>
> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that. . . .
>
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

Id.

13. *Amgen*, 902 F.2d at 1534.

14. A host cell is a bacterium that has been infected by foreign DNA and is thereafter capable of producing the protein or proteins encoded by the foreign DNA. *See id.* at 1533. This genetic engineering technique has empowered scientists to produce large quantities of proteins for which they know or have isolated the particular gene that encodes that protein. *Id.*

15. *Id.* at 1534.

16. *Id.* at 1534-35.

1337(a)(1)(B)(ii).[17] Because Amgen held no process claim in the '008 patent for the production of rEPO, the ITC dismissed the case for lack of subject matter jurisdiction.[18] On appeal to the United States Court of Appeals for the Federal Circuit: **vacated and remanded. Held:** Subject matter jurisdiction existed over the case, but nevertheless, Congress did not intend for section 1337 to bar from importation goods made outside the United States that used an article patented in the United States if no process patent claim existed.[19]

II. LEGAL BACKGROUND

A. *The Patent Laws*

Currently, the patent laws of the United States[20] grant to the patentee the exclusive right to make, use, or sell the patented article within the United States.[21] A patentee's right to exclude others explicitly encompasses the right to prevent others from using the patented article,[22] which includes the right to exclude others from unauthorized use of the article as part of a manufacturing process.[23] For example, in *Aro Manufacturing Co. v. Convertible Top Replacement Co.*,[24] the United States Supreme Court held that because the defendant used the plaintiff's invention without authorization by replacing patented materials, a claim of infringement existed.

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17. *Certain Recombinant Erythropoietin*, 10 U.S.P.Q.2d (BNA) at 1909.

18. *Id.* at 1911.

19. *Amgen*, 902 F.2d at 1540. Amgen, however, has received some relief in this case. The Federal Circuit upheld Amgen's patent infringement claims against Chugai on appeal from the United States District Court of Massachusetts. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991).

20. Congress passed the patent laws pursuant to its grant of authority in the United States Constitution: "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. CONST. art. I, § 8, cl. 8.

21. 35 U.S.C. § 271(a) (1988).

22. "Under the common law the inventor had no right to exclude others from making and using his invention." Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 525-26 (1972).

23. *See* Hanson v. Alpine Valley Ski Area, Inc., 611 F.2d 156, 161, *aff'd*, 718 F.2d 1075 (Fed. Cir. 1983) (unauthorized use of patented machine constitutes infringement).

24. 377 U.S. 476, 484 (1964).

B. *The Tariff Act of 1922*

In general, however, substantive patent rights extend only to the territorial borders of the United States.[25] In limited instances, Congress has extended patent protection internationally, through import laws, by granting to the patentee the additional right to exclude from importation articles that infringe certain intellectual property rights.[26]

The Tariff Act of 1922[27] provided the first statutory basis for United States corporations to enjoin importers from engaging in unfair competition.[28] The Tariff Act of 1930 specifically protected the owner of a valid United States patent from the importation of infringing goods.[29] *In re Amtorg Trading Corp.*[30] provided the impetus for Congress to expand the unfair competition branch of the trade laws to protect patentees instead of the substantive patent laws, which provide a remedy only for domestic infringement.[31] The *Amtorg* court held[32] that importation into the United States of unpatented goods, made by a process for which a valid United States patent existed, did not constitute unfair competition.[33] Thus, the *Amtorg* decision implicitly granted a license to competing corporations to have goods, which could not be made legally in the United States because of a competitor's process patent, made outside the United States, and then to import those goods into the United States. Congress responded by protecting process patents explicitly.[34]

In 1979, Congress amended the Tariff Act again, and this broader statutory protection dramatically increased the number of cases filed with

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25. *See* 35 U.S.C. § 271(a) (1988).

26. *See* 19 U.S.C. § 1337 (1988).

27. Pub. L. No. 67-318, tit. III, § 303, 42 Stat. 935.

28. For discussion of the development of the Tariff Act, see Ronald A. Brand, *Private Parties and GATT Dispute Resolution: Implications of the Panel Report on Section 337 of the US Tariff Act of 1930*, 24 J. WORLD TRADE, June 1990, at 5.

29. Tariff Act of 1930, ch. 497, § 337, 46 Stat. 703 (1930) (original version at 19 U.S.C. § 337 (1930)).

30. 75 F.2d 826 (C.C.P.A. 1935).

31. H.R. REP. No. 1781, 76th Cong., 3d Sess. 1 (1940).

32. Only one year earlier, the court had held that importation of products made under a patented process constituted unfair competition. *See In re* Orion Co., 71 F.2d 458 (C.C.P.A. 1934); *see also In re* Northern Pigment Co., 71 F.2d 447 (C.C.P.A. 1934).

33. *Amtorg*, 75 F.2d at 835.

34. *See* H.R. REP. No. 1781, 76th Cong., 3d Sess. 1 (1940); *see also* S.REP. No. 1903, 76th Cong., 3d Sess. 1 (1940). The holding of *In re* Von Clemm demonstrates that Congress successfully reversed the *Amtorg* holding. *In re* Von Clemm, 229 F.2d 441 (C.C.P.A. 1955).

the ITC in the 1980s.[35] This increase may have resulted in part from United States corporations lobbying for an increase in protection afforded them by the Tariff Act of 1930.[36] The revisions facilitated relief for a plaintiff by broadening section 337's scope of protection and by increasing the speed with which a plaintiff could obtain relief.[37] Despite these revisions, the ITC appears reluctant to grant relief to parties without an egregious case.[38]

Prior to the 1988 Trade Act, for a court to exclude the goods of an importer, the plaintiff must have shown:

(1) that the importer engaged in an unfair act, and
(2) that the act had a detrimental effect on the plaintiff.[39]

Moreover, the President had sixty days in which to rescind an ITC order to exclude goods if policy reasons conflicted with the order.[40] The 1988 Trade Act, however, obviated the detrimental effect requirement.

Prior to the 1988 Trade Act, courts stringently interpreted the detrimental effect requirement, thus barring many parties from relief. In *Corning Glass Works v. United States International Trade Commission*,[41] the court held that although the importer's goods infringed upon the plaintiff's patent, the imports caused only a de minimis injury to the plaintiff because the expansion of the market for the product at that time greatly exceeded production. Similarly, in *Textron, Inc. v. United States International Trade Commission*,[42] the court held that although the importer's goods violated the plaintiff's trademark, it would not grant an exclusion order because the plaintiff's goods were not inherently

35. *See* H.R. REP. NO. 1781, 76th Cong., 3d Sess. 1 (1940); *see also* S.REP. NO. 1903, 76th Cong., 3d Sess. 1 (1940).

36. Robert W. Kastenmeier & David Beier, *International Trade and Intellectual Property: Promise, Risks, and Reality*, 22 VAND. J. TRANSNAT'L LAW 285, 289-90, 293-96 (1989).

37. At least one commentator has argued that these are the major causes. *See* Martin B. Schwimmer, Note, *Defining Domestic Industry in the Tariff Act of 1930: Removing the Gremlins From Section 337*, 11 FORDHAM INT'L L.J. 165, 168 (1987).

38. For an example of an egregious case in which the Federal Circuit granted relief under the 1988 Trade Act, see Hyundai Electronics v. United States Int'l Trade Comm'n, 899 F.2d 1204 (Fed. Cir. 1990) (upholding the exclusion order barring from importation certain erasable programmable read only memories (EPROMs) because the EPROMs infringed a valid United States patent).

39. New England Butt Co. v. Int'l Trade Comm'n, 756 F.2d 874, 876 (Fed. Cir. 1985). *See* 19 U.S.C. § 1337(a)(1)(A)(ii) (1988).

40. 19 U.S.C. § 1337(j) (1984).

41. 799 F.2d 1559 (Fed. Cir. 1986).

42. 753 F.2d 1019 (Fed. Cir. 1985).

distinctive.

These cases focus on the market effect of an importer's action, not on the plaintiff's substantive rights.[43] This dichotomy underlies the tension between the monopoly granted to a patentee by the patent laws and the public's interest in a free market.[44] Congress, however, has relaxed the Tariff Act's requirements by deleting the need for an industry to be "efficiently and economically operated" and by expanding the definition of "industry" in the 1988 Trade Act.[45]

Congress clearly has the power to close the United States borders to foreign goods.[46] Moreover, the legislative history of the Tariff Act of 1930 underscores the congressional intent to protect domestic industries from unfair acts of importers.[47] Congress passed the 1988 Trade Act to extend this protection.[48] By holding importers, sellers, and users potentially liable as infringers, Congress achieved this protection, which both increases the jurisdiction of courts and provides incentives for importers to leverage manufacturers to avail themselves of United States jurisdiction for possible infringement suits.[49] Further evidence of congressional intent to expand protection of patentees can be found in the Process Patent Protection Act of 1988,[50] which amended the Patent Act.[51] Congress made its intent to increase protection for United States patentees clear in the stated policy behind the Trade Act of 1988: "(1) to reduce substantially U.S. trade and current account deficits; [and] (2) to seek by 1992 more consistent equilibrium in such accounts."[52] Two of the enumerated

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43. The converse argument is that a patentee's monopoly is a matter of legislative grace and may be altered by Congress as it sees fit.

44. The public interest may be to obtain the goods as cheaply as possible in open trade. This interest, however, often conflicts with the patent law's policy to grant a monopoly to the inventor, which in turn encourages inventions.

45. 19 U.S.C § 1337(a) (1988). The industry, however, must exist or be in the process of being established. *Id.* § 1337(a)(2).

46. *See* Buttfield v. Stranahan, 192 U.S. 470 (1904) (importation is not a vested right). Moreover, courts have rejected constitutional challenges to the authority of Congress to regulate importation. *See, e.g.*, Sealed Air Corp. v. United States Int'l Trade Comm'n, 645 F.2d 976 (C.C.P.A. 1981) (holding that domestic industries may be protected from unfair competition by Congress under its plenary power grant in Article I, Section 8, Clause 3 of the United States Constitution).

47. *See supra* note 27 and accompanying text.

48. H.R. REP. No. 576, 100th Cong., 2d Sess. 515-16 (1988), *reprinted in* 1988 U.S.C.C.A.N. 1548-49.

49. *See supra* note 45 and accompanying text.

50. 1988 Trade Act, *supra* note 10, *reprinted in* 1988 U.S.C.C.A.N. at 2118-2126 (amending 35 U.S.C. §§ 154, 271, 287 (1988)).

51. 35 U.S.C. § 271(g) (1988).

52. H.R. REP. No. 576, 100th Cong., 2d Sess. 515 (1988), *reprinted in* 1988

purposes of the act were "to strengthen U.S. trade laws" and "to improve management of U.S. trade strategy."[53] Furthermore, Congress stated that "the existing protection under section 337 of the Tariff Act of 1930 against unfair trade practices is cumbersome and costly and has not provided United States owners of intellectual property rights with adequate protection against foreign companies violating such rights."[54] Congressional intent to expand the substantive rights of a patentee could not have been more explicit, especially in regard to the high-technology area of intellectual property.

C. *The GATT*

Related to the amendment of the Tariff Act of 1930, a proposal has been made recently[55] to expand the General Agreement on Tariffs and Trade (GATT)[56] to include specific regulations for intellectual property.[57] The pressure in the United States for this inclusion again comes from corporate owners of patents, and owners of other forms of intellectual property, in need of stronger protection.[58] Notwithstanding the GATT's failure to cover intellectual property, many foreign states maintain that section 337 violates the GATT's provisions mandating "identical procedures and standards."[59] Indeed, section 337 has been declared inconsistent with the GATT provision on non-discrimination,[60] yet the

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U.S.C.C.A.N. 1548.

53. *Id.* at 1549.

54. 134 CONG. REC. 5579 (daily ed. July 13, 1988).

55. 134 CONG. REC. S10711, S10714 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg). *See* Mark Modak-Truran, Comment, *Section 337 and Gatt in the* Akzo *Controversy: A Pre- and Post-Omnibus Trade and Competitiveness Act Analysis*, 9 NW. J. INT'L L. & BUS. 382, 389 (1988).

56. *General Agreement on Tariffs and Trade*, 61 Stat. A3, 55 U.N.T.S. 187 [hereinafter GATT].

57. Kastenmeier & Beier, *supra* note 36, at 285-86.

58. *Id.* at 293-94. The Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Stockholm on July 14, 1967, protects patents to a lesser degree. *Id.* at 294. Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305.

59. "The European Community, Japan, Canada, and South Korea all joined in a GATT complaint against section 337." Kastenmeier & Beier, *supra* note 34, at 298. *See also EC Endorses Panel's Ruling That § 337 Violates GATT Non-Discrimination Rules*, 37 Pat. Trademark & Copyright J. (BNA) 302 (Feb. 2, 1989).

60. *See* Kenneth W. Abbott, *Decision: GATT Dispute Settlement Panel: United States-Section 337 of the Tariff Act of 1930*, 84 AM. J. INT'L L. 274, 274 (1990). The Panel held that section 337 conflicted with the nondiscrimination clause of GATT in article III-4. *Id.* One commentator has argued that the reason section 337 has withstood

Federal Circuit has rejected challenges to section 337 on this ground.[61]

At least one court has noted that Congress passed the 1988 Trade Act to conform the United States trade laws to the GATT requirements. The Federal Circuit in *PPG Industries v. United States*[62] stated that one of the motives behind the 1979 Trade Act's amendments to the Tariff Act of 1930 was "the [c]ongressional purpose of conforming our law with GATT."[63]

The amendments to the Tariff Act of 1922 and the legislative history of section 337 reveal a clear and deliberate plan to protect all forms of intellectual property, particularly the high-technology forms, which includes the biotechnology industry. Although some conflicting evidence exists concerning the potential problems between section 337 and the GATT, little doubt exists that United States high-technology corporations need more protection than they currently receive.

III. THE FEDERAL CIRCUIT'S DECISION

The Federal Circuit described the issues on appeal in the instant case as follows:

> (1) whether the ITC's decision that it did not have subject matter jurisdiction because Amgen's patent contained no process claim was appealable as a final determination;
>
> (2) whether subject matter jurisdiction existed where Amgen's patent contained no process claims in a section 1337(a)(1)(B)(ii) complaint;
>
> (3) whether patent claims covering host cells are unique in a process patent context; and
>
> (4) whether the importation of goods made by a process that used patented material violated section 1337(a)(1)(B)(ii) of the Tariff Act.[64]

First, the court held that the ITC's dismissal for lack of subject matter jurisdiction was essentially a dismissal on the merits.[65] The court

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the scrutiny of the GATT member states is that the industry requirement has been so difficult to meet. Michael Stein, *Comments on Section 337 Amendments*, in 1 LAWS OF INTERNATIONAL TRADE, para. 211.22 (William A. Hancock ed., 1991). After the 1988 Trade Act, however, the industry requirement can be met more easily. *See supra* notes 34-38 and accompanying text.

61. Akzo N.V. v. United States Int'l Trade Comm'n, 808 F.2d 1471 (Fed. Cir. 1986). *See also* Modak-Truran, *supra* note 55, at 383-84, 398-404 (description and critique of *Akzo*).

62. 928 F.2d 1568 (Fed. Cir. 1991).

63. *Id.* at 1575. *See generally* Trade Agreements Act of 1979, Pub. L. No. 96-39, 1979 U.S.C.C.A.N. (93 Stat.) 144.

64. *Amgen*, 902 F.2d at 1532.

65. *Id.* at 1535.

adopted Amgen's argument that the ITC's decision was intrinsically a decision to deny its motion to exclude Chugai's material from entry and, therefore, could be considered a final determination.[66] The court stated that section 1337(c) allowed appeal from a final determination.[67] The court relied upon *Block v. United States International Trade Commission*,[68] which interpreted section 1337(c) to require "a final [administrative decision] . . . on the merits, excluding or refusing to exclude articles from entry."[69] The *Block* court also recognized that a decision that is intrinsically a determination on the merits is subject to appeal.[70] The Federal Circuit held that because the ITC found that Amgen's patent did not cover any process claims for rEPO, the decision went to the merits of the case and could be appealed.[71]

The court also reversed the ITC's holding that subject matter jurisdiction did not exist.[72] The court relied on the United States Supreme Court decision in *Bell v. Hood*,[73] which held that when a plaintiff makes factual allegations sufficient to warrant relief in a federal court, the case should be decided on its merits.[74] Because Amgen's complaint contained factual allegations warranting relief under the Tariff Act, the court held that the case should have been decided on its merits.[75]

The court then addressed whether Amgen's host cell claims were unique. Amgen argued that section 1337(a)(1)(B)(ii) was not limited to patents with "traditional process claims."[76] The court stated that this reasoning raised the question of whether Amgen's claims contained any "non-traditional process claims."[77] Amgen argued that because the '008 patent covered claims for the host cells of rEPO, these claims also should cover the specific intracellular processes carried out by these cells leading to production of rEPO.[78] The court cited *Diamond v. Chakrabarty*,[79] in which the United States Supreme Court held that a patent could issue on

66. *Id.*
67. *Id.*
68. Block v. ITC, 777 F.2d 1568 (Fed. Cir. 1985).
69. *Amgen*, 902 F.2d at 1535 (quoting *Block*, 777 F.2d at 1571) (emphasis in original).
70. *Block*, 777 F.2d at 1571.
71. *Amgen*, 902 F.2d at 1535-36.
72. *Id.* at 1536-37.
73. 327 U.S. 678 (1986).
74. *Bell*, 327 U.S. at 682.
75. *Amgen*, 902 F.2d at 1537.
76. *Id.*
77. *Id.*
78. *Id.* at 1537-38.
79. 447 U.S. 303 (1980).

living creatures, micro-organisms in this case. Thus, the Supreme Court's holding that micro-organisms are a "composition of matter" or "manufacture"[80] allows a patent to issue on them under the Patent Act.[81] Amgen argued that the rEPO host cells constituted a living machine performing unique processes leading to the production of rEPO.[82] Further, because the '008 patent covered the host cells, the patent covered the unique process carried out by these cells as a "non-traditional process claim."[83]

The court rejected the argument that compared a host cell to a machine, holding that although a patent covers the machine, it does not necessarily cover the process carried out by the patented machine.[84] Moreover, the Patent and Trademark Office's denial of claims for the process of producing rEPO may have weighed heavily against Amgen's construction of the patent claims.[85]

Because the '008 patent contained no process claims, the court worded the final issue before it as "whether section 1337(a)(1)(B)(ii) was intended to prohibit the importation of articles made abroad by a process in which a *product* claimed in a U.S. patent is used, namely the new host cell."[86] Amgen argued that the court should construe the language "a process covered by the claims of a . . . patent" in section 1337(a)(1)(B)(ii) broadly to include Chugai's behavior, which would have constituted infringement had it been done in the United States.[87] The court, however, held that the "plain meaning of the word 'covered' " in a process patent context, "in normal parlance among patent lawyers," is a claim that defines a process.[88]

The court studied the legislative history of the language that had been introduced into the statute in response to the Court of Customs and Patent Appeals' decision *In re Amtorg Trading Corporation*.[89] The *Amtorg* court held that because nothing in the legislative history of section 1337 authorized the extension of the substantive patent law outside the borders of the United States, the importation into the United States of a product made abroad by a process that was covered by a United States

80. *Id.* at 307, 309-10.
81. *See* 35 U.S.C. §§ 101-103 (1988) (the requirements of patentability).
82. *Amgen*, 902 F.2d at 1537-38.
83. *Id.*
84. *Id.*
85. *Id.* at 1534, 1538 n.1.
86. *Id.* at 1538 (emphasis in original).
87. *Id.*
88. *Id.*
89. *See supra* notes 30-33 and accompanying text.

patent did not constitute unfair competition.[90] The instant court found that the legislative history of section 1337(a) applied only to process patents.[91] The applicable House Report states:

> This bill is designed to correct the present problem which was created when the Court of Customs and Patent Appeals in the case of *In re Amtorg Trading Corporation* reversed its former decisions and held that the importation of products made abroad in accordance with a United States process patent without consent of patentee was not regarded as an unfair method of competition.[92]

The court found no indication in either the House or the Senate Reports that Congress intended to prohibit the importation of articles that used a patented product during manufacture of another article.[93] The court concluded that Chugai's actions were beyond the contemplation of Congress when it enacted the 1988 Trade Act.[94] Somewhat paradoxically, the court noted in its final footnote that the decision of the ITC led to the introduction of House Report 3957 into Congress, which called for amendment to section 1337(a)(1)(B).[95] After the court published its decision, the Industrial Biotechnology Association, which helped draft the proposed amendment,[96] stated that "[t]he second section [of the amendment] responds to the decision in [*Amgen*] . . . by creating new avenues of relief under [19 U.S.C. § 1337(a) and 35 U.S.C. § 271] against foreign use of patented genes, vectors, host cells, and hybridomas."[97]

In March 1991, several senators introduced the Biotechnology Patent Protection Act of 1991 to "correct[] the inadequacies in our patent laws

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90. *Id.*

91. *Amgen*, 902 F.2d at 1538-39. For the full text of section 1337a before the 1988 Trade Act amended it, see *supra* note 3.

92. *See supra* note 34 and accompanying text.

93. *Amgen*, 902 F.2d at 1539.

94. *Id.* at 1540.

95. *Id.* at 1540 n.14. Part of the proposed amendment states:

> (h) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by using a biotechnological material . . . which is 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 patent.

39 Pat. Trademark & Copyright J. (BNA) 279 (Feb. 8, 1990).

96. *See* H.R. 3957, 101st Cong., 2d Sess., 136 CONG. REC. E207, E213-14 (daily ed. Feb. 7, 1990) (statements of Rep. Moorhead and Rep. Boucher); S. Res. 2326, 101st Cong., 2d Sess., 136 CONG. REC. S3107 (daily ed. Mar. 22, 1990) (statement of Sen. DeConcini).

97. *Role of Patents in Biotechnology is the Focus of Two Conferences*, 40 Pat. Trademark & Copyright J. (BNA) 211, 212 (June 28, 1990).

that limit the patentability in the biotechnology field."[98] This legislation would amend section 103 of the Patent Act by overruling *In re Durden*, decided by the Federal Circuit in 1985.[99] While this legislation would have no direct effect on section 337, it would provide much needed protection for the United States biotechnology industry. Moreover, a possibility exists that patents received under this new section 103 would be able to qualify for section 337 protection because importers would act unfairly by importing a product made by a patented process.

IV. THE NEED FOR REFORM

In a case of first impression, the Federal Circuit interprets section 1337 of the 1988 Trade Act. The court interpreted the legislative history of a subsection of section 1337[100] to apply only to process patents infringed by the importation of goods that could be sold within the United States without direct infringement. This reasoning follows from a restricted view of the court system in the enforcement of the nation's tariff laws, particularly in regard to high-technology products. Several factors weigh against such a limited view.

First, Congress passed the 1988 Tariff Act with explicit hopes of strengthening both the tariff laws and the protection of high-technology industries.[101] The Senate stated that one of its purposes in passing the Tariff Act was to strengthen the current trade laws.[102] Moreover, in the intellectual property field, Congress specifically addressed the issues of developing and strengthening the international rules and of gaining and enforcing adequate protective measures.[103] These purposes seem to argue for a broader interpretation of section 1337,[104] and one commentator has

98. S. Res. 654, 102d Cong., 1st Sess., 137 CONG. REC. S3285 (daily ed. Mar. 13, 1991) (statement of Sen. DeConcini). The report discusses the difficulties of patent protection in the biotechnology field and underscores the unique dependency of the field on this protection. *Id.*

99. *Id. See also In re* Durden, 763 F.2d 1406 (Fed. Cir. 1985) (holding that no patent could issue on a process that used a patentable starting product and yielded a patentable final product).

100. 19 U.S.C. § 1337(a)(1)(B)(ii) (1988).

101. *See supra* note 48 and accompanying text.

102. H.R. REP. NO. 576, 100th Cong., 2d Sess. 516 (1988), *reprinted in* 1988 U.S.C.C.A.N. at 1549. *But see id.* at 1550 (one of the purposes of the amendments was to obtain a more open market).

103. *Id.* at 1556.

104. One commentator has argued that the expansive growth of the importance of intellectual property warrants more protection of these rights. Kenneth W. Dam, *The Growing Importance of International Protection of Intellectual Property*, 21 INT'L LAW. 627, 628 (1987).

classified the court's holding as nothing less than an endorsement of a legislative "loophole."[105]

Admittedly, Congress did pass the 1988 Trade Act with the intent to conform the United States trade laws with the GATT. With section 337 already suspect, at least from the perspective of several GATT member-states,[106] Congress may have been in an awkward position to strengthen the import requirements. Nevertheless, in the high-technology industries, United States corporations need more protection than they currently receive. Whether this need creates a conflict with the GATT should be discussed in a different forum—namely during GATT negotiations.[107]

Second, an expansive reading of the word "covered" in section 1337 would bring the unfair competition laws of the Tariff Act more into conformity with current patent laws. A patentee has the right to exclude others from making, using, or selling the patented item, for which it owns a valid, current United States patent, within the United States.[108] One policy reason for granting a patent is to reward the inventor.[109] This policy is achieved through a grant to the patentee of a monopoly to make, use, or sell the patented article in the United States for a period of seventeen years.[110] If importers can ship articles into the United States that were made by using a patented article, then the importers can undermine the patentee's monopoly. While a "patentee exchanges full and complete disclosure of how to make and use the new invention for the protected right to exclude others from making, using or selling the claimed invention,"[111] importers frustrate this policy by skirting the pat-

105. "The court observed that Congress did not appear to consider the loophole in section 337(a)(1)(B)(ii), exploited by Chugai in this case, during its 1988 revisions to the statute." Michael L. Keller and Kenneth J. Nunnenkamp, *Patent Law Developments in the United States Court of Appeals for the Federal Circuit During 1990*, 40 AM. U. L. REV. 1157, 1180 (1991).

106. *See supra* notes 60-61 and accompanying text.

107. Congress nevertheless should be concerned with the conformity of United States laws to GATT mandates. If, however, corporations require the protection, Congress should pass the enabling legislation, and then later, if necessary, GATT negotiators could bargain concerning the problematic provisions. Moreover, according to a presentation by Robert G. Krupka, President Bush has stated that section 337 will not be altered until issues pertaining to other GATT problems have been resolved. 42 Pat. Trademark & Copyright J. (BNA) 133 (May 30, 1991).

108. 35 U.S.C. § 154 (1988).

109. A patent monopoly "was a reward, an inducement, to bring forth new knowledge." Graham v. John Deere Co., 383 U.S. 1, 9 (1966).

110. 35 U.S.C. § 154 (1988).

111. Walter J. Williams, *Transnational Legal Aspects of Biotechnology*, 19 LAW & TECH. J., 2nd Quarter 1986, at 3, 10-11.

ent laws through engaging in infringing behavior overseas and then importing the goods into the United States.

Another policy reason underlying the grant of a limited monopoly to an inventor is to encourage investment in research and development of new products.[112] Assuming Corporation A must invest ten percent of its profits into research for new products, Corporation B, which imports products made by the use of a patented article overseas, does not have to invest the ten percent into research and development. Corporation B then can bring its product to the market considerably cheaper than Corporation A. Although this behavior may benefit the consumer initially, the long term effects include deterring corporations from engaging in any research for new products, a result that will hurt the consumer and society.

A corporation's ability to behave outside of the United States in a manner that, if perpetrated within the United States, would infringe a patent, and then to ship the goods into the United States, causes the same disincentive to corporations and individuals doing business in the United States. This frustrates the goal of benefitting society by the encouragement of investments into better products. A recently declassified ITC report estimated that intellectual property piracy by foreign corporations costs United States firms between forty-three and sixty-one billion dollars annually.[113] Although the amount of money that has been lost as a result of behavior like Chugai's is unknown, the loss undoubtedly has a "chilling effect on the economic incentives for companies to engage in the expensive research and development of new technology."[114]

Third, the extension of protection in the intellectual property field argued for here does have some clearly defined limits. The United States patent laws are time-tested in adapting to new technology. Because these laws have been in operation for over two centuries and have functioned well, fears of mismanagement may be allayed. For precisely this reason, the trade laws of the United States need to parallel the patent laws. Importers should be barred from importing goods, which, if made in the United States, would infringe a valid patent.

Also, the President has the right to rescind any order to exclude im-

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112. *Id.* at 10.

113. *U.S., Trading Partners Must Step Up Efforts to Protect Goods From Piracy, ITC Head Says*, 5 Int'l Trade Rep. (BNA) 509 (Apr. 6, 1988). *See also* Edwin A. Finn Jr., *That's the $60 Billion Question*, Forbes, Nov. 17, 1986 at 40 (discussing the financial loss of United States corporations due to intellectual property piracy).

114. Modak-Truran, *supra* note 55, at 382.

ports if the exclusion is against "policy."[115] This presidential power acts as an additional safeguard against abuse by the courts. For instance, if a court's concern is whether an exclusion order would have international repercussions, the presidential procedure should remove this concern. The President's duty is to determine whether an exclusion order is against policy; this determination is not the concern of a court. One commentator predicted continued deference to the executive branch because of the intricacies of foreign trade and the quest for open trade.[116] Moreover, courts cannot review the President's decision to rescind an order to exclude goods from importation.[117]

Although these factors support expansion of a patentee's substantive rights, they fail to explain the instant decision. The court interpreted section 1337 narrowly. Admittedly, if Congress intended to protect more than a process patentee, the statutory language and the legislative history do not state this intention explicitly. Support, however, exists in the stated goals of the revisions, a logical extension of the trade laws, and the proposed amendments to section 1337 for Amgen's argument that Congress intended section 1337 to protect more than a process patent.

V. CONCLUSION

This case demonstrates the need for further clarification of the Tariff Act of 1930. The 1988 Trade Act amendments may have clarified certain provisions, brought the import laws into conformity with GATT mandates, and granted broader protection to certain industries. High-technology industries, and specifically the biotechnology industry, however, have not received the protection needed to combat intellectual property piracy.

The proposed amendment to section 103 of the Patent Act, however, may provide part of the protection needed for the biotechnology industry. This legislation would permit United States corporations to prevent the importation of certain articles by using section 337 if they obtain a process patent that has a patented starting product and finished product. This protection, however, may not be enough for a corporation in

115. 19 U.S.C. § 1337(j) (1988).

116. Jane A. Restani, *Judicial Review in International Trade: Its Role in the Balance Between Delegation by Congress and Limitation of Executive Discretion*, 37 AM. U. L. REV. 1075, 1086 (1988).

117. Duracell, Inc. v. United States Int'l Trade Comm'n, 899 F.2d 1204 (Fed. Cir. 1985). *See also* Young Engineers, Inc. v. United States Int'l Trade Comm'n, 721 F.2d 1305, 1311-13 (Fed. Cir. 1983) (court cannot modify original order after the President has rescinded it).

Amgen's situation.

United States trade laws should be extended to cover the kind of behavior engaged in by Chugai. To protect enormous investments in intellectual property made by United States corporations, the trade laws must protect patentees to the same extent as the patent laws.

John C. Herman