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Cover Page Footnote
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Amgen Inc. v. United States International Trade Commission: The Living Cell—Product or Process?

The patenting of life forms and the interrelated conundrum, whether a living thing is a product or a process, have been the subject of struggle in the courts and Congress for over a century. Amgen Inc. v. United States International Trade Commission illustrates the problems inherent in attempting to apply outmoded legal and political formulas to continually evolving scientific technologies.

One of the earliest patent cases on "products of nature" is Ex parte Latimer, 1889 Dec. Comm'r Pat. 123. In Latimer the applicant attempted to claim a patent on the cellular tissues of a pine tree. The Commissioner ruled that tree fibers are not patentable: "Otherwise it would be possible for an element or a principle to be secured by patent, and the patentee would obtain the right, to the exclusion of all other men, of securing by his new process . . . [that which] nature has produced and which nature has intended to be equally for the use of all men." Id. at 125-26. See also, General Elec. v. De Forest, 28 F.2d 641 (3d Cir. 1928) (attempting to claim pure tungsten); American Fruit Growers, Inc. v. Brodex Co., 283 U.S. 1 (1931) (an orange covered by a protective coating of borax); Ex parte Grayson, 51 U.S.P.Q. 413 (Pat. Off. Bd. App. 1941) (shrimp, deheaded and deveined). See generally 1 D. CHISUM, PATENTS § 1.02[7], at 1-32 to 1-51 (1991) (discussing products of nature).

Amgen, Inc. v. United States International Trade Commission, 902 F.2d 1532 (Fed. Cir. 1990). While this case was being heard by the administrative law judge (ALJ) and the International Trade Commission (ITC), Amgen filed a separate suit against Genetics Institute, Inc. (GI) and Chugai Pharmaceutical Co., Ltd. (a Japanese firm, licensed by GI to produce its products in Japan) for domestic violations of its patent claims, alleging that the defendants had "infringed the [Amgen] patent by the production of recombinant EPO . . . and by the use of transformed mammalian host cells containing transforming vectors having recombinant DNA coding for the production of recombinant human EPO . . . and for domestic violations of its patent claims, alleging that the defendants had "infringed the [Amgen] patent by the production of recombinant EPO . . . and by the use of transformed mammalian host cells containing transforming vectors having recombinant DNA coding for the production of recombinant human EPO at its facilities in the District of Massachusetts." Amgen, Inc. v. Chugai Pharmaceutical Co., 18 U.S.P.Q.2d (BNA) 1737, 1739 (D. Mass. 1989). This action against GI and Chugai, as stated by the district court, "is about the highly competitive race between two leading biotechnology companies, among others, to clone the gene for the human hormone erythropoietin ("EPO")." Id. at 1738. The district court found that the Amgen patent was valid and had been infringed. Id. at 1739. At the time of Amgen's action before the ITC, "the race" was over within the United States; Amgen had been awarded the domestic patent on recombinant erythropoietin (rEPO). However, Genetics Institute (GI) and Chugai had effectively nullified Amgen's victory by simply moving the patented products overseas.

This case is based on questions arising out of recombinant DNA technology. Living cells carry genetic information in specific deoxyribonucleic acid (DNA) molecules. DNA controls and determines all of the things that a cell does and produces. When cells replicate, the new cells contain a copy of the parent cell's DNA. Current technology allows scientists to introduce DNA into a host cell and have this cell express the new DNA as if it were part of the cell's original DNA. This process is called DNA transfection. DNA molecules are long linear polymers built from four different nucleotide building blocks, arranged in two complementary chains. During production of a protein (such as EPO) a
Amgen is able to obtain patents on the DNA sequences, vectors, and host cells used to produce recombinant erythropoietin (rEPO), specific sequence on the DNA helix is "copied" by ribonucleic acid (RNA) molecules. The RNA is then "read" by codons (series of ribonucleic acid triplets). As each codon is read, the corresponding amino acid is attached to a chain. This translation process is repeated until the specific RNA chain has been replicated and the protein has been assembled. DNA can be "cut" by laboratory processes at specific nucleotide sequences. By identifying which sequence is responsible for instructing the cell on how to make a specific protein, the technician can "cut out" the sequence and splice it on to a plasmid (a small DNA ring capable of autonomous replication). Plasmids have the useful quality of being able to pass from one cell to another, even between cells from different species. As the plasmid replicates, the newly spliced DNA is also replicated (cloned). Recombinant DNA technology includes this process of splicing DNA material from one cell into another cell for the purpose of controlling the production of a specific protein, either for experimentation or for commercially viable pharmaceutical production. For an in depth explanation of this process, see J. Watson, N. Hopkins, J. Roberts, J. Steitz & A. Weiner, Molecular Biology of the Gene 65-94, 208-09, 211 (4th ed. 1987); J. Watson & J. Tooze, The DNA Story: A Documentary History of Gene Cloning xvi-xxiv (1981). For a detailed description of the specific recombinant technology utilized by Amgen, see Certain Recombinant Erythropoietin, Inv. No. 337-TA-281, USITC Pub. 2186, at 94-109 (May 1989) (initial determination).

4 Amgen Inc. ("Amgen") is a domestic corporation organized under the laws of the State of Delaware and has its principal place of business in Thousand Oaks, California. Certain Recombinant Erythropoietin, USITC Pub. 2186, at 72. Amgen is involved in the research and development of pharmaceutical products based on recombinant DNA technology. Id. Recombinant human erythropoietin, under the trade name Epogen, was the first of these products which Amgen marketed in the United States. On February 21, 1991, the Food and Drug Administration approved Neupogen, Amgen's second drug developed through recombinant techniques. Neupogen, Amgen's name for granulocyte colony-stimulating factor (G-CSF), stimulates the blood stem cells that produce white blood cells.

5 Amgen is the owner of U.S. Pat. No. 4,703,008 (the '008 patent). Id. at 74. Amgen filed the application for a patent on December 13, 1983, in the United States Patent and Trademark Office (PTO). Id. A patent entitled "DNA Sequences Encoding Erythropoietin" was issued on October 27, 1987. Id.

6 Among the specific items included in the '008 patent are: DNA sequences encoding for human erythropoietin; plasmids or vectors including the EPO DNA sequence; and host cells transfected with a DNA sequence. Id. at 21. Transfection refers to the introduction of foreign DNA into host cells, which then express it as if it were part of the cell's own genetic apparatus. A vector or plasmid is the carrier which brings the foreign DNA into the host cell and allows this DNA to replicate as the host cell replicates. A host cell is the cell in which a gene, not normally present, has been inserted for the purpose of expressing the protein coded in the inserted gene. See generally supra note 3.

7 Erythropoietin (from the Greek erythro meaning 'red' and poiesin meaning 'to make') is a glycoprotein produced in the kidney, and to a small extent in the liver, which acts like a hormone, traveling from the kidney through the bloodstream to the sites where blood cells are made (bone marrow and spleen), to stimulate blood stem cells to differentiate and thus give rise to the formation of red blood cells. Under normal conditions the amount of red blood cells (erythrocytes) circulating in adults remains relatively constant, even though these cells are continually dying and being replaced. Scientists who observed this phenomenon hypothesized that a negative feedback mechanism controlled the production of red blood cells. In the early 1950s, the existence of this factor was directly identified and named erythropoietin. In the body, erythropoietin is produced in response to the level of erythrocytes in circulation. The level of erythropoietin rises and falls with the level of red blood cells. Scientists speculate that this is a response to concentration of oxygen (red blood cells carry oxygen from the lungs to the body's cells). Graber & Krantz, Erythropoietin and the Control of Red Cell Production, 29 Ann. Rev. Med. 51, 51, 54-55 (1978); E. Golub, Immunology: A Synthesis 157-78 (1987). Erythropoietin injections are used as a treatment for patients suffering from anemia (low levels of red blood cells) caused by rheuma-
but failed to establish the claims directly relating to the "process" involved. In spite of Amgen's patent, a Japanese firm was able simply to remove the patented cells from the United States to Japan, replicate the process using the host cells in Japan, and then import the finished product, recombinant erythropoietin, back into the United States.

Amgen brought suit claiming violations of the Tariff Act of 1930. The International Trade Commission (ITC) and the Federal

to arthritis, chronic infection, and some cancers. Graber, supra, at 59. Injections of erythropoietin are also a significant therapeutic agent in the treatment of anemia caused by kidney disease (since erythropoietin is produced in the kidneys, patients lacking kidneys or with kidney disease do not produce sufficient erythropoietin). Id. at 60. Thus, erythropoietin has the potential of becoming a widely used clinical treatment. However, as it is naturally produced in amounts too small to harvest efficiently, it must be "manufactured" by recombinant DNA techniques in order for sufficient supplies to be available for widespread pharmaceutical use.

Recombinant erythropoietin (rEPO) refers to erythropoietin manufactured through the use of cells altered by human intervention. DNA, containing specific gene sequences, is isolated and removed from human cells and then "recombined" with the DNA of host cells (in this case extracted from hamsters) by a laboratory process (DNA transfection). The host cell then produces erythropoietin. For a detailed description of the recombinant technology involved in Amgen's discovery, see Certain Recombinant Erythropoietin, USITC Pub. 2186, at 94-109; Chugai, 13 U.S.P.Q.2d (BNA) at 1742-45.

Recombinant erythropoietin differs from "natural" erythropoietin in its carbohydrate composition. More significantly, the host cell differs from the naturally occurring cell in the quantity of EPO produced. Testimony at the ALJ hearing indicated that a recombinant host cell produces erythropoietin at a rate at least a million times greater than the human kidney cell. Certain Recombinant Erythropoietin, USITC Pub. 2186, at 123. Thus the recombinant technology allows clinical use of the hormone which would not otherwise be possible.

Claims which covered the process of growing cells in a culture medium and then isolating and extracting the EPO produced by these cells were rejected by the Patent and Trademark Office (PTO) examiner on the basis of 35 U.S.C. § 102 (which requires the invention to be novel, i.e., not known, used, patented, or described in print by others) because they recited nothing more or less than what happens each and every time a cell grows and expresses a protein. Certain Recombinant Erythropoietin, USITC Pub. 2186, at 130. In response Amgen amended its application, dropping the rejected process claims. In re Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) 1906, 1910 (Int'l Trade Comm'n 1989). The use of a patented product constitutes patent infringement if done in the United States. 35 U.S.C. § 271 (1988). However, the grant of exclusive patent rights is limited to the United States. See infra note 18 and accompanying text.


The Tariff Act of 1930 created a tariff commission to investigate unfair acts by foreign importers that injured domestic industries. Section 337 of the Tariff Act of 1930 provides for relief against unfair methods of competition and unfair acts in the importation of articles into the United States. Pub. L. No. 71-361, 46 Stat. 590, 703 (1930). However, as the courts subsequently interpreted section 337, it proved to be insufficiently broad to completely protect United States industries. In re Amtorg Trading Corp., 75 F.2d 826 (C.C.P.A.), cert. denied, 296 U.S. 576 (1935). Amtorg held that the importation of a product made abroad by a patented process did not constitute an unfair trade practice. In
Circuit both found no violation of the Tariff Act, as in their opinions only the product was patented, not the process. The Federal Circuit stated that the issue was a narrow one—whether or not the Trade Act was intended to prohibit importation of non-patented articles made abroad by a process which in itself was not patented, but which utilized patented products, or if protection is limited to importation of products made by expressly patented processes. However, the effect of its ruling is much more extensive. By following outmoded formulas, the patent office and the court left Amgen, and similar biotechnology companies, with adequate patent protection within the United States, but completely defenseless against compe-

response to this decision, Congress expanded patent protection by enacting 19 U.S.C. § 1337a which stated that the importation, sale, or use of a product produced outside the United States using a process covered by the claims of a United States process did constitute an unfair act for the purposes of section 337. For a review of the history of section 337, see Clark, The Future of Patent-Based Investigations Under Section 337 After The Omnibus Trade And Competitiveness Act Of 1988, 38 Am. U.L. Rev. 1149, 1153-59 (1989).

Amgen's complaint was pending when Congress passed, on August 23, 1988, the 1988 Trade Act, which amended sections 1337 and 1337a of the former act. The Trade Act stated that the amended section would apply to all pending Commission investigations. Therefore, Amgen's complaint became one under section 1337(a)(1)(B)(ii), which reads:

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


Amgen, 902 F.2d at 1538. Patent law distinguishes between product and process patents. Product patents are upon invented or discovered articles; process patents cover the method of making an article. Amgen originally submitted both product and process claims, but the final patent lacked specific process claims, because the patent office rejected the original process claims and Amgen did not reapply for the rejected items. Amgen's valid patents were on the "products" used in the process, such as DNA, vectors, and host cells.

The final product, erythropoietin, was not patented because it falls into the unpatentable category of products of nature. A product of nature cannot be patented because it is not "new" under the definition of patentable subject matter: "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101 (1988). Even though Amgen's techniques facilitate an unnaturally rapid production of erythropoietin, EPO is produced naturally in the body. Thus the "product" that Chugai imported, EPO, was not and cannot be directly protected by a U.S. patent. However, Chugai did use patented products in order to produce the EPO. Chugai could not have "used" these products within the United States, without violating patent laws, but is free to use U.S. patented products overseas. This situation does not occur in the majority of patent cases because the typical invention involves processes which are patentable and thus can be protected by 19 U.S.C. § 1337 (1988).
tion mounted from a foreign base. This Note examines the decision of the Federal Circuit, the development of patent law concerning “products of nature,” and the ramifications of a biotechnology company’s inability to protect its research investment from overseas production and subsequent importation into the United States.

Statement of the Case

Amgen Inc., brought a complaint with the International Trade Commission (ITC) alleging that importers had violated former section 337 of the Tariff Act of 1930 by importing recombinant erythropoietin (rEPO) made by a process covered by a patent. Respondents admitted that they used the host cells which are within the claims of Amgen’s patent (the ’008 patent) in the manufacture of recombinant DNA abroad, but asserted that the use of a patented product abroad does not constitute patent infringement under 35 U.S.C § 271 because the grant of exclusive patent rights on a product is limited to the territory of the United States. In the


16 Amgen argued that, although it did not have a “process” claim labeled as such, “the claims that did issue are ‘hybrid’ in that they cover both a product (the host cells) and the intracellular processes that are inherent in the product (which synthesize EPO).” Id. at 23. The ALJ, ITC, and Federal Circuit all dismissed the possibility of a “hybrid” claim, stating that according to patent law the claim must explicitly cover a process: “In addition to the prosecution history, the testimony of the inventor, Dr. Lin, rebuts Amgen’s argument that the claims of the ’008 patent cover the host cell’s intracellular processes for making EPO. Dr. Lin was unable to indicate where the claims or specifications of his own patent indicated that he was claiming the intracellular processes.” Id. at 25. See also In re Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) at 1910; Amgen, 902 F.2d at 1537.

17 Certain Recombinant Erythropoietin, USITC Pub. 2186, at 1. See also id. at 60 (the ALJ’s detailed explanation of this admission).

18 35 U.S.C. § 271(a) states: “Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, [directly] infringes the patent.” The grant of exclusive patent rights is limited to the United States. The Supreme Court addressed the question of whether or not this section also applied to use of a patented machine abroad in Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972). In Deepsouth, Laitram Corporation held a patent on shrimp deveining equipment. Deepsouth Packing Co. manufactured similar deveining equipment and because of Laitram’s patent could not sell this equipment within the United States. To avoid the patent restrictions, Deepsouth exported its machine abroad in parts (the individual parts were not patented). Once abroad, the parts were assembled into the machine. The Court held that under § 271 “it is not an infringement to make or use a patented product outside of the United States.” In order to secure an injunction Laitram had to show “that Deepsouth ‘makes,’ ‘uses,’ or ‘sells’ the patented product within the bounds of this country.” Id. at 527. The Court held that a patent only protects the operable assembly of the invention and not the manufacture of its parts. Id. at 528. Congress reacted to this decision by adding a new subsection to section 271: “Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would
initial determination, the Administrative Law Judge (ALJ) found that the ITC had jurisdiction, but that the rEPO process was not protected under the Trade Act because Amgen’s patent covered only the product and not the process. The ITC agreed that Amgen’s patent did not cover the process. However, the ITC further reasoned that because Amgen did not have a process patent, the complaint was not covered by the scope of the Trade Act and, therefore, the ITC lacked subject matter jurisdiction. The ITC dismissed Amgen’s complaint for lack of subject matter jurisdiction, taking no position on the merits of the case. Amgen appealed to the United States Court of Appeals for the Federal Circuit, which found that: (1) the Commission’s order terminating the investigation for lack of subject matter jurisdiction was appealable; (2) the Commission should have decided the case on its merits; (3) the patent holders’ host cell claims were not unique “hybrid” claims; and (4) the Tariff Act does not apply to a “process” utilizing products covered by a United States patent.

The Federal Circuit first focused on the question of jurisdiction. The ITC had terminated Amgen’s claim on the ground that it lacked subject matter jurisdiction because in its opinion the claimed process infringement was not a violation under section 337 of the Tariff Act of 1930. The court of appeals explained that authority to review an infringement of a patent if such combination occurred within the United States, shall be liable as an infringer.” 35 U.S.C. § 271(f)(1) (1988).

Thus, the importation of a product manufactured abroad through the use of a process which, if done within the United States, infringes a valid patent is an unfair act under the Tariff Act. The export of unassembled parts of a patented product in order to avoid patent laws is also prohibited. However, Amgen patents do not fall into either of these categories. They failed to establish “process” claims and the end product, erythropoietin, is not patentable.

9 Certain Recombinant Erythropoietin, USITC Pub. 2186, at 20-21. The ALJ found that the intent of 19 U.S.C. § 1537 (a)(1)(B)(ii) is to make relief available only when the patent claims cover a process.


21 Id. Commission Chairman Brunsdale and Vice Chairman Cass disagreed with the majority’s decision to dismiss the complaint without a finding on the merits. The dissent construed the enabling statute to grant jurisdiction: “No conceivable basis exists for reading that expansion of our authority [the enactment of Section 337a] as if it were intended to contract the scope of ITC jurisdiction . . . . That, however, is the effect of the majority’s decision today.” Id. at 1914.

22 Amgen, 902 F.2d at 1536, 1538, 1540.

23 The original Amgen patent application included claims which described the process involved in growing the transfected cells in a culture medium and then isolating the EPO from the medium (steps done by a technician, not the cell itself). Amgen dropped those claims after the Patent and Trademark Office (PTO) examiner rejected them as obvious in view of known processes that entail growing other types of host cells to produce other proteins. Amgen then stated in its amendment that none of the rewritten claims covered the process described in its dropped claims. The ITC found that, since the “process” claims had been dropped, the ‘008 patent no longer described a process and was, therefore, not covered by 19 U.S.C. § 1337a which specifically protects patented U.S. processes from unfair importation. It concluded that “subject matter jurisdiction under
decision of the ITC is limited by 19 U.S.C. § 1337(c), which limits appeals to final determinations. Both the ITC and Chugai filed motions to dismiss the suit on the ground that no "final determination" had been entered. The Federal Circuit, however, agreed with Amgen's reply that the Commission's April 10 order is "intrinsically a final determination not to exclude articles from entry," and thus is appealable. The court noted that otherwise a commission could effectively "shield all determinations from judicial review simply by labelling the determination as a dismissal for lack of jurisdiction." This would be contrary to the statutory scheme by preventing judicial review of negative determinations.

The Federal Circuit explained that treating the case on the merits is preferable because subject matter jurisdiction is commonly included in the same statute as that which grants a federal right to the complaining party. The court relied on the Supreme Court decision in Bell v. Hood which held that "failure to state a proper cause of action calls for a judgment on the merits and not for a dismissal for want of jurisdiction." The court found this precedent applicable to

subsection 337(a)(1)(B)(ii) may be invoked only when process patent claims exist." In re Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) at 1911.

24 Section 1337(c) of the Trade Act states: "Any person adversely affected by a final determination of the Commission under subsection (d), (e), (f), or (g) of [section 1337] may appeal such determination . . . to the United States Court of Appeals for the Federal Circuit . . . ." 19 U.S.C. § 1337(c) (1988).

25 Amgen, 902 F.2d at 1535.

26 Id.

27 Id. In support of this holding, the court cited Block v. United States Int'l Trade Comm'n, 777 F.2d 1568 (Fed. Cir. 1985). In Block, the Commission had itself terminated an investigation after the patent forming the basis for the alleged section 1337 violation was substantially changed and no findings had been entered. The court found that nothing in the termination order prejudiced the parties in a future proceeding. Block, 777 F.2d at 1571-72. In Amgen's case, the Federal Circuit distinguished Block, stating that the Commission did make "one very important finding: that the claims of the '008 patent do not, in fact, cover a process." Amgen, 902 F.2d at 1535. The court found that this finding clearly reached the merits of Amgen's case and thus gave the court jurisdiction under section 1337. Additionally, the court found that any future actions brought by Amgen would be dismissed for the same reason. Id. at 1536.

28 Bell v. Hood, 327 U.S. 678, 682 (1946). In Bell, petitioners brought suit in federal district court to recover damages from FBI agents who had allegedly falsely imprisoned the plaintiffs, illegally searched the plaintiff's premises, and illegally seized property belonging to the plaintiffs. The complaint alleged federal jurisdiction under the Fourth and Fifth Amendments. After hearing motions to dismiss and for summary judgment, the district judge dismissed, on his own motion, for want of federal jurisdiction because the action did not arise under the Constitution. Id. at 680. The Supreme Court granted certiorari because of the importance of the jurisdictional issue involved and held that failure to state a proper cause of action calls for a judgment on the merits. "Whether the complaint states a cause of action on which relief could be granted is a question of law and just as issues of fact it must be decided after and not before the court has assumed jurisdiction over the controversy." Id. at 682. The Federal Circuit also distinguished the two exceptions to the above rule stated by Bell. The first exception is applicable where the alleged claim is immaterial, brought solely to obtain jurisdiction. This was not the case in Amgen. The second Bell exception involves claims which are "wholly insubstantial and frivolous," also not applicable to Amgen. Amgen, 902 F.2d at 1537. See also Jackson Transit
the instant case because Amgen's complaint had stated on its face "that Chugai was importing rEPO and that the rEPO was made by a process covered by the '008 patent." The fact that Amgen could not later obtain relief under this claim was not material, and, therefore, the court held that Amgen's case should not have been dismissed based on jurisdiction. Finding that the decision was intrinsically determined on the merits, the court further held that it had jurisdiction to review the Commission's order.

The Federal Circuit next addressed Amgen's assertion that its product claims differ from standard product claims, because they cover not only the named products, but also processes going on within the products—i.e., not only the host cells, but also the process of EPO production going on within the host cells. Analogizing the microorganisms in *Diamond v. Chakrabarty*, the court stated that host cells are a "composition of matter," and although cells are living "machines" in that they perform intracellular processes, this does not make them any different from any other mechanical machine. Following this reasoning, the court concluded: "A host cell claim does not 'cover' intracellular processes any more or less than a claim to a machine 'covers' the process performed by that machine." Finding that Amgen's claims are thus "legally indistinguishable" from any other product claim, the court asserted that the issue in this case was whether or not section 1337 was intended to prohibit importation of an article made abroad by a process utilizing


29 *Amgen*, 902 F.2d at 1536.

30 *Id.* In a footnote, the court distinguished cases presented by the Commission in support of its rejection for lack of jurisdiction. In *Federal Trade Comm'n v. Raladam Co.*, 283 U.S. 643 (1931), the complaint had been brought sua sponte by the commission and could thus be distinguished from cases brought by private parties. *Albert v. Kevex Corp.*, 729 F.2d 757 (Fed. Cir. 1984) was distinguished on the basis that the jurisdictional finding did not mesh with the finding on the merits.

31 *Amgen*, 902 F.2d at 1537.

32 *Id.* at 1537-38. Amgen asserted that the claims at issue were hybrid in that they covered not only the host cells but also "intracellular processes, inseparable from the cell, that are utilized by the cell to manufacture EPO." Certain Recombinant Erythropoietin, USITC Pub. 2186, at 13. See also infra notes 89-101 and accompanying text.

33 447 U.S. 303, 309 (1980) (holding that living organisms are not per se unpatentable); See infra notes 62-64 and accompanying text.

34 *Amgen*, 902 F.2d at 1537.

35 *Id.*

36 *Id.* at 1538. The court explained that the statutory interpretation issue in the Amgen case involved the precise meaning of the word "cover" in section 1337(a)(1)(B)(ii): "a process covered by the claims of a . . . patent." Amgen asserted that its patent claims naming the host cell also "covered" the process going on within the host cell. The Federal Circuit disagreed, holding that the correct interpretation of "covered" should be the plain meaning of the term among the patent lawyers to whom the statutes are directed. The court concluded, therefore, that the correct interpretation is: "a patent 'covering' a process is a patent containing at least one claim defining a process." *Id.*
a product claimed in a U.S. patent, namely the host cell.\textsuperscript{37}

Examining the relevant statutes, the Federal Circuit noted that the key language in section 1337, "process covered by the claims," was not altered by the 1988 Trade Act, and, therefore, the legislative history of the former section was pertinent.\textsuperscript{38} House and Senate reports accompanying the original bill indicate that 1337a was directed toward correcting a problem which arose after a federal circuit decision\textsuperscript{39} had held that importation of products made abroad using a United States process patent did not constitute an unfair method of competition.\textsuperscript{40} The \textit{Amgen} court asserted that there was no indication in the legislative history\textsuperscript{41} that section 1337 was intended "to prohibit the importation of goods made by a process which merely used abroad a product, apparatus, or material patented in this country."\textsuperscript{42} Amgen cited legislative history of the 1988 Trade Act to as-

\textsuperscript{37} Id.
\textsuperscript{38} Id. Pertinent extracts from this legislative history were compiled by the ALJ and published with the determination in Certain Recombinant Erythropoietin, USITC Pub. 2186, at appendix A. This summary of the legislative history indicates Representative Peterson of Florida introduced a bill in 1973 whose stated purpose was "[t]o amend the Tariff Act of 1930 to protect against unfair methods of competition and unfair acts in the importation and sale of certain articles and defining certain terms used in connection therewith." \textit{Id.} at appendix A-1. This first attempt died in committee. After another failed attempt, Rep. Peterson introduced an amended bill in 1940. The Senate Committee, reporting on this bill stated: "Since the \textit{Amtorg} decision owners of American process patent [sic] are helpless to prevent the infringement abroad of their patent rights. This bill will give to them the same rights which the owners of product patents have." \textit{Id.} at appendix A-6 (quoting S. Rep. No. 1903, 76th Cong., 3d Sess. 4 (1940)). The final bill agreed to by both the House and Senate (H.R. 8285) was approved by the President on July 2, 1940.

\textsuperscript{39} In \textit{re} \textit{Amtorg} Trading Corp., 75 F.2d 826 (C.C.P.A.), cert. denied, 296 U.S. 576 (1935), questioned whether the importation of a product made abroad by a patented process constituted an unfair trade practice. The court reversed a prior decision, \textit{In re Northern Pigment Co.,} 71 F.2d 447 (C.C.P.A. 1934), and held that such importations do not constitute an unfair trade practice. The \textit{Amtorg} court held that relief under section 337 if the Tariff Act of 1930 (19 U.S.C. § 1337) related "solely" to the use abroad of a patented process and was not meant to "broaden the field of substantive patent rights, and create rights in process patents extending far beyond any point to which the courts have heretofore gone in construing the patent statutes." \textit{Amtorg}, 75 F.2d at 834. Because the patent grant is limited to the United States, the \textit{Amtorg} court held that use of a patented process abroad and its subsequent importation does not constitute infringement. \textit{Id.} at 831. In response to this decision, Congress enacted H.R. 8285. \textit{See supra} note 38. The bill was codified as part of the Tariff Act of 1930, § 337, as amended, 19 U.S.C. § 1337. "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." 19 U.S.C. § 1337a (1940).

\textsuperscript{40} \textit{Amgen}, 902 F.2d at 1538, 1539.

\textsuperscript{41} The court cited the following House Report: "This bill is designed to correct the present problem which was created when the Court of Customs and Patent Appeals in the case \textit{In re Amtorg Trading Corporation} reversed its former decision 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." \textit{Id.} (quoting H.R. Rep. No. 1781, 76th Cong., 3d Sess. 1 (1940)).

\textsuperscript{42} \textit{Amgen}, 902 F.2d at 1539.
sert that Congress did indeed intend to prohibit such practices, but the court disagreed with Amgen's interpretation, asserting that a substantive change in its scope could not have been intended because one of the bill's sponsors twice stated that the amended section 1337 is merely a reenactment of the former section.

The Federal Circuit then stated that it was its "impression" that Chugai's utilization of the host cells in Japan to produce rEPO is something that had not been considered by the Congress and therefore not discussed or dealt with in the Trade Act. Amgen's allegation that the problem is one of first impression and that the court was faced with "a precedent-setting question of exceptional importance," further convinced the court that Congress had not given it a thought. The court concluded that if there is a need to alter the understanding of the "process covered by the claims" language, "which has persisted unchanged for nearly half a century," it is a task not for the courts, but for Congress, "which can explore its impact and side effects."

The Federal Circuit concluded that the complaint must be dismissed because none of the claims of Amgen's patent covered the process performed overseas. The Commission's April 10, 1989, order, however, was vacated and remanded for entry of a final determination dismissing the complaint on the merits because the dismissal should not have been for lack of jurisdiction.

**Background**

Amgen's assigned patents on the host cell, DNA sequences, and vectors stem from a line of cases which established that some categories of "products of nature" are eligible for patent protection. A

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43 In support of its argument Amgen quoted the following statement made by Senator Lautenberg:

Section 337(a)(1) (a reenactment of section 337a) will provide the assistance necessary for emerging U.S. industries, such as the biotechnology industry, to compete in a marketplace without interference due to unfair acts of foreign competitors. The continued broad jurisdiction of the International Trade Commission will help U.S. industry address the unfair activity of foreign competitors who, for example, import products manufactured using patented genetic engineering technology. Merely moving manufacture offshore does not absolve the wrongdoer from the requirement to compete fairly. This Trade Act protection prohibits the foreign enterprise from taking jobs from American workers by doing offshore that which they could not lawfully do in the United States.


44 Amgen, 902 F.2d at 1539.

45 Id. at 1540.

46 Id.

47 Id.

48 Id.

49 Id.

50 For a detailed review of the history of patenting "products of nature," see 1 D. Chisum, PATENTS § 1.02[7], at 1-32 to 1-51 (1991). For specific information on the history
United States patent gives the owner the exclusive right to make, use, or sell the patented invention in the United States for seventeen years. In order to obtain a patent, the applicant must prove that what he has invented is new. The invention must also be nonobvious, not already available or readily discoverable by using previously known techniques. These patent doctrines were first applied to man-made products of nature in *Funk Brothers Seed Co. v. Kalo Inoculant Co.* *Funk* addressed a patent application for an inoculant of mixed bacteria used to infect leguminous plants, increasing the plants' ability to fix nitrogen from the air. The Court stated that patents cannot cover the function of the bacteria: "[T]hose qualities are not patentable.... [P]atents cannot issue for the discovery of the phenomena of nature." However, a patent could cover "the application of the law of nature to a new and useful end." Ten years later, the Fourth Circuit expanded on the product of nature doctrine in *Merck v. Olin Mathieson Chemical.* In that case, Merck & Co. applied for a patent on modified Vitamin B-12, which can be found naturally in the rumen of cattle, but in minute quantities. The Fourth Circuit found that the applicant had identified a previously unidentified and unknown substance and thus the step from the natural product was one "from complete uselessness to great and perfected utility." The principle formulated in the *Merck* decision was applied in Amgen's suit for patent infringement. The court rejected the argument that Amgen's claim covered a natural DNA sequence, but accepted it when construed as limited to the "purified DNA sequences, see Eisenberg, *Patenting the Human Genome,* 39 Emory L.J. 721 (1990). For a thorough bibliography of books and articles dealing with the subject of genetic patents, see *Bibliography: Genetics and the Law,* 39 Emory L.J. 875, 896-901 (1990).

55 *Id.* at 128-29.
56 *Id.* at 130.

57 The Court explained that the qualities of the bacteria are "like the heat of the sun, electricity, or the qualities of metals... part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes." *Id.* In the case of the mixed bacteria in *Funk Bros.*, the Court stated that adding two strains together to make a more powerful inoculant was "hardly more than an advance in the packaging of the innoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected." *Id.* at 131. The Court admitted that the combination represented a commercial advantage in that the farmer no longer needed to buy different packages for different crops, but this was not an adequate development to meet the patent requirements: "[A] product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery." *Id.* at 131-32.

59 *Id.* at 163

and isolated" DNA sequence.\textsuperscript{61}

The landmark 1980 Supreme Court decision \textit{Diamond v. Chakrabarty} held that a living genetically-engineered microorganism is patentable subject matter under section 101.\textsuperscript{62} The Court emphasized that Chakrabarty's claim was not to a natural phenomenon, "but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'"\textsuperscript{63} The Court concluded that the patentee's bacterium was "markedly different" from any in nature: "His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101."\textsuperscript{64}

The \textit{Chakrabarty} decision paved the way for Amgen's successful host cell claims because under \textit{Chakrabarty} the relevant inquiry is whether the claimed invention is the result of human intervention. Dr. Lin,\textsuperscript{65} the Amgen scientist responsible for cloning the EPO gene, spent more than two years in research trials attempting to isolate and transfect the correct DNA sequence.\textsuperscript{66} Although the carbohydrate

\textsuperscript{61} Amgen had argued that the invention it claimed was the DNA sequence encoding human EPO. The court explained that, since that would be a nonpatentable natural phenomenon, the claim was for "the 'purified and isolated' DNA sequence encoding erythropoietin." \textit{Id.}

\textsuperscript{62} \textit{Diamond v. Chakrabarty}, 447 U.S. 303, 305 (1980). Chakrabarty, a microbiologist employed by General Electric, modified an existing bacterial strain by introducing new DNA into the cell, giving the resulting organism the ability to break down crude oil. This property, possessed by no naturally-occurring bacteria, had significant value for containing oil spills. The patent examiner allowed Chakrabarty's claims except for those on actual bacteria, as under prior law living products of nature were not patentable. The Patent Office Board affirmed, but the Court of Customs and Patent Appeals reversed. The Supreme Court upheld the patent, finding that while "laws of nature, physical phenomena, and abstract ideas" are not patentable, Chakrabarty's claim was not to a "hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter," and thus the microorganism qualified as patentable subject matter. \textit{Id.} at 309. For a list of journal articles and notes analyzing the \textit{Chakrabarty} decision, see 1 D. Chisum, \textit{Patents} § 1.02[7], at 1-40 to 1-42 & n.24 (1991).

\textsuperscript{63} \textit{Chakrabarty}, 447 U.S. 303 at 309-10 (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)). The \textit{Chakrabarty} Court explained that earlier cases, which had denied patents to products of nature, such as \textit{Ex parte} Latimer, 1889 Dec. Comm'r Pat. 123 (holding that plants are natural products not subject to patent protection), were superseded by the Plant Patent Act, 35 U.S.C. §§ 161-64. In enacting this legislation Congress stated that the work of plant breeders "in aid of nature" was a patentable invention. S. Rep. No. 315, 71st Cong., 2d Sess. 6-8 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., 7-9 (1930). The Court stated that Congress had "thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made invention. Here, respondent's micro-organism is the result of human ingenuity and research." \textit{Chakrabarty}, 447 U.S. at 313.

\textsuperscript{64} \textit{Chakrabarty}, 447 U.S. at 310.

\textsuperscript{65} Dr. Lin, who holds a Ph.D. in Biochemistry from the University of Illinois, joined Amgen in 1981 after doing research work on cancer at Purdue University, the University of Nebraska, Louisiana State University, and the University of South Carolina. Dr. Lin's first assignment at Amgen was to solve the problem of cloning the gene encoding for erythropoietin. Certain Recombinant Erythropoietin, Inv. No. 357-TA-281, USITC Pub. 2186, at 133-34.

\textsuperscript{66} \textit{Id.} at 142. Transfection refers to the process of introducing isolated DNA sequences, which carry the particular genetic message the scientist desires to replicate, into a
structure of naturally occurring erythropoietin and recombinant erythropoietin is not significantly different, the processes that take place within the recombinant host cell are both qualitatively and quantitatively different from processes occurring in the natural cell. In the body, erythropoietin is only produced when oxygen levels in the bloodstream fall below the triggering level. The transfected host cell differs in that it spontaneously produces erythropoietin—no oxygen level signal is needed. Additionally, the amount of erythropoietin that can be isolated from human urine is insufficient for therapeutic treatment, whereas, host cells express erythropoietin in “enormous amounts.” Testimony at the ALJ hearing indicated that not only did the host cell contain a new DNA sequence, but “the cell is taken over and dominated by the presence of the introduced gene. The presence of the introduced gene, and its need to express its genetic information, influences the rest of the cell’s characteristics, such that the cell is a different one than it was before.” Thus Amgen’s scientists produced a recombinant material that does not occur in nature, but is the result of human intervention, making it patentable subject matter under the Chakrabarty decision.

The Chakrabarty holding introduced the general concept that manipulation of living things can be patentable; however, it does not protect all discoveries based on recombinant technology from challenge. For example, recombinant DNA discoveries can be challenged as obvious applications of already known techniques.

host cell which will then produce the desired protein. For an explanation of this process, see supra note 3.

67 Id. at 144. Testimony from both sides indicated that there was no clinically significant difference between the structure or effect of urinary erythropoietin versus recombinant erythropoietin. Id. at 144-45.

68 Id. at 125.

69 Id. at 112. Scientists who testified at the initial determination hearing theorized that the natural and recombinant host cells differed in that the recombinant gene possesses a “very open chromatin structure,” making it accessible to the transcriptional machinery, regulatory factors, and polymerases which produce messenger RNA for EPO. Id. at 126.

70 Id. at 113.

71 Id. at 112.

72 Id. at 114.

73 35 U.S.C. § 103 states:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103 (1988). The scope of section 103 was outlined by the Supreme Court in Graham v. John Deere Co., 383 U.S. 1 (1966), in which a patent for plow shock absorbers was found invalid because the subject matter was obvious to a person having ordinary skill in the art. The Supreme Court granted certiorari to review the test of obviousness that
Hybritech, Inc. v. Monoclonal Antibodies, Inc., the Supreme Court applied this obviousness standard to a patent claiming invention of a laboratory technique which fused spleen cells with cancer cells in order to create a large supply of antibodies that would seek out and mark specific antigens in patient fluids, facilitating more accurate disease diagnosis. The district court held Hybritech's claims for this process to be obvious because of the existence of prior laboratory techniques which demonstrated ways to prepare similar assays. The Federal Circuit reversed, noting that the prior art could at most be characterized as "invitations to try monoclonal antibodies" but did not "suggest how that end might be accomplished." The ALJ in Amgen followed the Hybritech reasoning, finding that Amgen's claim was not invalid for obviousness, as nowhere in the prior art is there a description of the EPO gene's structure; information that was available was incorrect; and the nonobviousness was apparent in light of the failure of other highly qualified scientists to succeed in isolating the gene encoded for erythropoietin.

Chakrabarty and more recent case law thus legitimized Amgen's claims on host cells and DNA sequences, but the product patents proved to be useless protection against foreign production of er-

Congress added to the patent law in the 1952 Patent Act. Id. at 2. The Graham Court reviewed the history of patent law in the United States and concluded that the ultimate question of patent validity is one of law but section 103 involves a factual inquiry:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved .... Such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc. might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. Id. at 17-18.

75 Id. at 84.
76 Id. at 90-91. Specifically, the court found that of the eight articles cited as disclosing prior art, four were actually published after the date of Hybritech's conception of the idea and the earlier four "discuss production of monoclonal antibodies . . . but none discloses sandwich assays." Id. at 91.
77 In order to create rEPO, scientists needed to isolate the natural EPO gene. This was done by screening genomic DNA libraries (a genomic library contains the repository of genetic information held in the DNA of a cell). The genomic library screened by Dr. Lin contained 1,500,000 phage plaques. To screen one and a half million phages for the correct DNA sequences, Dr. Lin used 30 filters with approximately 50,000 plaques per filter. After more than two years of effort, Dr. Lin succeeded in isolating and cloning the EPO gene by narrowing the field from 1.5 million to 40. No researchers before Lin were reported to have used his exact screening technique. Certain Recombinant Erythropoietin, USITC Pub. 2186, at 140-42. The ALJ stated: "The '008 patent teaches the structure of the gene encoding for human erythropoietin. Nowhere in the prior art is there a description of this gene's structure." Id. at 54.
78 The ALJ's determination includes a detailed description of the eminent scientists who had attempted to clone the EPO gene before Dr. Lin and the amount of effort and funds other companies had put into the search (Biogen alone had committed approximately six million dollars). Certain Recombinant Erythropoietin, USITC Pub. 2186, at 153-60.
ythropoietin using Amgen's host cell, because Amgen had been unable to patent its process. The patent office's rejection of these critical process claims is based on its interpretation of the holding in *In re Durden.* In that case, patent applicants had filed a claim for the process of making an insecticide. The appellants had summarized their claim as one for:

A chemical process which (a) employs a novel and unobvious starting material or (b) is for the production of a novel and unobvious product compound or (c) which employs a novel and unobvious starting material and also is for the production of a novel and unobvious product compound, is patentable, regardless of the extent of other similarities to prior art processes.

The court of appeals discussed contradictory holdings in previous cases and then stated that it would "put an end for now to this potentially endless debate." The *Durden* court defined process as "doing something to or with something according to a schema" and concluded that using an old process with a predictable outcome, but making use of a new material, does not make the process itself any less obvious.

The Patent and Trademark Office interprets *Durden* to mean that patents cannot be granted on known manipulations or methods, even though novel starting materials are used, and novel end products result. In its examination of Amgen's patent application, the PTO rejected the process claims on the basis of the *Durden* holding, finding that the extracellular processes were known laboratory practices and that the intracellular processes were "nothing more or less than what happens each and every time a cell grows and...

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80 *Id.* at 1406, 226 U.S.P.Q. (BNA) at 360.
81 The holding in *Ex parte MacAdams*, 206 U.S.P.Q. (BNA) 445 (P.T.O. Bd. App., 1978), is directly opposite to *In re Durden*. *MacAdams*, which dealt with claims involving molding plastics, held that the specific nature of the material employed in the process bears upon patentability of the process and if its use is not obvious from the art or creates unexpected results, the method as a whole must be considered unobvious. *Id.* at 448. The *Durden* court expressly overruled *MacAdams* and instead followed *In re Albertson*, 332 F.2d 379, 141 U.S.P.Q. (BNA) 730 (C.C.P.A. 1964). In *Albertson* process claims dealing with a formula for preparing chemical compounds were rejected as obvious in view of references showing the same chemical reduction process applied to other materials: "We do not agree with appellant's proposition that the 'use of an unobvious starting material renders a process unobvious.' Were this true, every step, for example dissolving or heating, when performed on a new compound would result in a patentable process." *Id.* at 382, 141 U.S.P.Q. (BNA) at 733. The dissenting judge referred to two of his previous dissents in obviousness cases, lamenting the "shackles with which traditional claim forms had enslaved" the patent law's provisions and terming the *Albertson* decision "the third movement in the requiem for the 'new use of a known process' provision of 35 U.S.C. § 100(b)." *Id.* at 382, 141 U.S.P.Q. (BNA) at 733.
82 *Albertson*, 332 F.2d at 382, 141 U.S.P.Q. (BNA) at 733.
83 *In re Durden*, 763 F.2d at 1410, 226 U.S.P.Q. (BNA) at 362.
84 Certain Recombinant Erythropoietin, USITC Pub. 2186, at 28. See 5 D. CHISUM, PATENTS § 5.04[8] n.47.1 (1991) (using *Amgen* to illustrate "the potential difficulties that the apparent holding of *Durden* can create for obtaining effective patent protection in an area of technology such as recombinant DNA technology").
expresses a protein." As asserted by the ALJ: "the only reason that § 1337a is not applicable to the respondent's importations of EPO is the policy of the Patent and Trademark Office, because of its interpretation of In re Durden." It was this interpretation by the PTO that caused Amgen to drop its explicit process claims. If these claims had instead been allowed, the question of whether or not Chugai was violating § 1337's prohibition against importing a product made abroad by a patented process could never have arisen.

Significance

1. Barriers to Recombinant Technology

The combination of the PTO's rejection of Amgen's process claims under Durden with the Federal Circuit holding that section 1337 only protects express process claims leaves recombinant DNA technology with no effective protection against unfair overseas competition. The crucial process involved in recombinant DNA technology, production of the required protein, takes place within the cell, but the International Trade Commission held that "[t]he '008 claims cannot, as a matter of law, cover these intracellular processes" because patent law has been interpreted by the Supreme Court to "preclude the grant of a patent on articles or processes of nature." The Federal Circuit went further than the ITC, stating that there was no difference between Amgen's host cell product claims and any other product claim. The court asserted that because Chakrabarty's bacteria were analogous to host cells, host cells too were just a "composition of matter." The court did move in the direction of admitting that a cell might be thought of as a "living 'machine' in the sense that it performs certain intracellular processes in the course of producing rEPO," but backed off from admitting that the process was patentable by comparing a host cell to "any mechanical machine which performs certain 'intramachinery' processes in the course of producing..."
whatever the machine is designed to produce.”

The court concluded that a host cell claim cannot cover intracellular processes “any more or less than a claim to a machine “covers” the process performed by that machine.” This logic ignores the fact that processes performed by machines are patentable under U.S. statutes and would unquestionably be patented by the company involved, whereas, under the Federal Circuit’s interpretation of Chakrabarty, intracellular processes cannot be patented.

The Federal Circuit’s reasoning ignores much of the scientific testimony presented at the initial determination. As Dr. Lin testified, “[t]he cell is basically a bag of cellular processes.” Dr. Sadler testified that he did not understand Amgen’s claims to describe a process, but later described the environment within a cell to be “a dynamic one with many molecules moving from place to place . . . When the recombinant host cell expresses erythropoietin there are processes going on within the cell.” Dr. Goldwasser testified that a “vast number” of intracellular processes are performed by host cells making erythropoietin. Additionally, he stated: “These processes are integrated into the cell. These processes cannot be separated from the host cell if the cell is to make a useful quantity of erythropoietin.” Dr. Wall stated that in order to work properly intracellular processes must occur within the cell: “The processes which are separable from the cell are incapable of producing EPO in useful amounts.” Thus the host cell’s value is limited to the process that it performs. If the process cannot be protected from overseas competition, nothing of value is protected.

The International Trade Commission insisted on a further hurdle—a detailed description of the exact steps involved in the process. This is simply impossible at the present stage of scientific

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93 Id. at 1537-38.
94 Id. at 1538.
96 Certain Recombinant Erythropoietin, Inv. No. 337-TA-281, USITC Pub. 2186, at 109. See, Comment, Toward the Right of Commerciality, 34 UCLA L. Rev. 207, 209 (1986) which asserts that human cells are indispensable to the creation and production of biologics. The article points out that “biotechnology allows only the manipulation, not the creation, of life . . . . The manifold and subtle intricacies of the cell, which in the aggregate allow the cell to ‘live,’ remain undefined and beyond the power of the biotechnologist.” Id. at 209 n.6. Human cells are thus necessary to act as “miniature factories.” Id. at 209.
97 Certain Recombinant Erythropoietin, USITC Pub. 2186, at 121.
98 Id. at 122.
99 Id.
100 Id. at 123.
101 “The claimed host cell has no practical utility other than to make recombinant erythropoietin.” Id. at 175.
102 In re Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) 1906, 1911 (Int’l Trade Comm’n 1989) (quoting 35 U.S.C. § 112). The disclosure requirement serves the functions of ensuring that after the 17 year patent has expired the public will have full use of the invention and permits the PTO to determine that the applicant has developed an
knowledge. Dr. Goldwasser testified that "[s]cientists do not understand very much of the processing of the mRNA to a translatable message.' He described other intracellular mechanisms as moderately well known and some as not well understood at all. Specifically, the ongoing processes in the host cell "are not fully understood, have not been identified, and cannot be fully described.'

The requirement of a description which enables other practitioners to practice the claimed invention has been modified in other areas in which the hurdle would be insurmountable. In *Ex parte Goeddel* the Patent Board held that a deposit of starting materials from which one of ordinary skill in the art could produce the claimed product would constitute sufficient disclosure where detailed description was not possible. On January 1, 1990, the Patent and Trademark Office amended its rules of practice to include procedures to govern the deposit of biological materials for patent practices. The new rules prescribe deposit procedures that will satisfy the description requirements of 35 U.S.C. § 112. Therefore, a patent application covering intracellular processes, such as occur in the production of rEPO, is no longer incompatible with 35 U.S.C. § 112, even if the processes are not yet understood or describable. Basing rejection of Amgen's process claims on *Durden* can also be questioned. The patent examiner interpreted the *Durden* holding


*Id.*

*Wiseman, Biotechnology Patent Practice—A Primer*, 16 Am. Intell. Prop. L.A. Q.J. 394, 400-02 (1989). *Wiseman* suggests allowing deposits of the microorganism as a substitute for a full description. He acknowledges that the requirement of disclosure is "particularly troublesome in the area of biotechnology where the knowledge of cause and effect relationships is in its infancy when compared to the more traditional chemical sciences." *Id.* at 401-02. *See also* Eisenberg, supra note 102, at 207-11 (suggesting that a deposit of the microorganism should suffice); Lentz, *Adequacy of Disclosures of Biotechnology Inventions*, 16 Am. Intell. Prop. L.A. Q.J. 314 (1989) (reviewing the United States practice of deposits and comparing it with European practices).

*Id.*


*Id.*

The final rule was first published on August 22, 1989 (four months after the ITC's ruling on Amgen's claims). 54 Fed. Reg. 34,880 (1989). The specific regulations are contained in 37 C.F.R. § 1.801-1.809 (1990). Section 1.801 defines biological material as "material that is capable of self-replication either directly or indirectly ... including ... eukaryotic cells, cell lines, hybridomas, plasmids ... [v]iruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material." 37 C.F.R. § 1.801 (1990). Section 1.802 allows deposit of such material: "Where an invention is, or relies on, a biological material, the disclosure may include reference to a deposit of such biological material." 37 C.F.R. § 1.802 (1990). Sections 1.803 to 1.809 deal with the issues of acceptable depositories, tining, replacement, term, viability, furnishing of samples, and examination procedures. 37 C.F.R. §§ 1.803-1.809 (1990). Also applicable to Amgen's patent are new regulations codified at §§ 1.821-1.823 which deal with the proper manner to submit disclosures dealing with nucleotides and/or amino acid sequences. 37 C.F.R. §§ 1.821-1.825 (1990).
as rejecting application of "an old process to new materials." Implicitly, this indicates that the patent examiner regarded the intracellular process as "old." However, scientific testimony shows that the process which takes place in the host cell is not the same as the process in a natural cell. The generalized process of DNA replication applies to all cells, but the particular process going on inside host cells differs from that in natural cells which make erythropoietin. The difference is manifested both by the quantitative difference in cell output (a host cell produces a thousand times more erythropoietin) and by the production of erythropoietin in a host cell without any signal (whereas there must be a trigger for the process to take place in the natural cell). Therefore, while the details of the intracellular processes are not yet known, the results of the cell's activity provide clear evidence that the processes going on in the host cell are measurably different from those occurring in the natural cell. Therefore, the Amgen application did not merely apply "an old process to new materials," and the Durden rule was inapplicable to the case. Similarly, the mandate that natural phenomena are "free to all men and reserved exclusively to none," does not apply, as the host cell activity would not occur without human intervention.

2. Effect on Congressional Mandate

The International Trade Commission and subsequently the Federal Circuit focused their decisions on whether or not Amgen possessed a valid process patent under the current policies of the patent office. There are two problems with this approach. First, such a focus gives the patent office indirect control over essentially international trade questions. Second, limiting the scope of the Tariff Act to

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108 Certain Recombinant Erythropoietin, USITC Pub. 2186, at 23.

109 Testimony before the ALJ indicated that the host cell functions differently from natural cells because it is "totally separate from its original tissue source." Id. at 112. Regulatory signals are different because it no longer interacts with other cells. The scientists emphasized that, even though Amgen used hamster cells, the basic difference was not the source of the cells, but the fact that the host cells had been transfected. Id. at 114.

110 Dr. Lin testified that although the "generalized transcription, translation, glycosylation, and secretion processes apply to all cells . . . in the recombinant host cells, the actual processes going on inside the cells are different from those in natural cells which make EPO." Id. at 145.

111 Id. at 113.

112 Id. at 112-13.


114 Chakrabarty clearly distinguishes purely natural phenomena from phenomena occurring only after man's intervention:

His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity . . . . [T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.

patent violations unduly restricts the original intent of Congress to protect domestic industries from unfair trade practices.

As the Administrative Law Judge pointed out, the International Trade Commission limited its investigation to the question of whether or not Amgen had a patented process that could be protected.115 The ALJ asserted that such a narrow interpretation of the scope of protection afforded by the Tariff Act could potentially upset the balance of power between two governmental agencies and, thereby, distort Congressional intent.116 He explained that the application of Durden to Amgen’s patent claims should be viewed merely as current patent office policy, not black letter law: “Such policy has been different in the past, and could change again tomorrow.”117 More importantly, Congress did not delegate responsibility for international trade to the patent office. Allowing patent office decisions to limit the scope of the Tariff Act ignores the underlying purpose of section 337, “to protect United States industry from unfair practices involved in imported goods manufactured abroad.”

The Commission and not the PTO is responsible under section 337, for the protection of American industry from unfair acts and practices in the importation of goods . . . . [T]he underlying purpose of section 337, which is to protect United States industry from unfair practices involved in imported goods manufactured abroad is ignored. Permitting the decision concerning whether there is an unfair act or practice involved in respondents’ importations of EPO to be decided on the PTO’s view of In re Durden, is to leave these international trade questions in the hands of the PTO.118

Fifty-five years earlier, the courts came to a similar decision to narrowly construe Congressional intent to protect American industry from unfair trade practices.119 In In re Amtorg, the court held that the importation of foreign products made abroad by a patented process did not constitute unfair trade practices.120 In response to this decision, Congress amended the Tariff Act of 1930 to specifically state that products made abroad by means of a process patented in the United States could not be imported for use, sale, or exchange.121 The Senate report on this amendment stated: “Since the Amtorg decision owners of American process patent [sic] are helpless to prevent the infringement abroad of their patent rights.”122 Anticipating the Congressional reaction to the majority opinion, the dissenting
judge in Amtorg had explained that the intent of the Tariff Act must have been to protect process as well as product patents: "The reason it is unfair for one to import a patented article protected by an American patent is because it puts the holder of the American patent at an unfair disadvantage and destroys the industry Congress was seeking to preserve, and the same reasons exactly apply to the importer of the product of an American process patent." This reasoning can easily be applied to Amgen's case. By not allowing Amgen either to patent the vital process involved in its technology or to be protected from imports on the grounds of unfair competition, Amgen has been put at an unfair disadvantage. The dissent in Amtorg rebutted the proposition that if Congress had intended a specific type of importation to constitute an unfair trade act, it would have specifically provided for the situation, by quoting a Senate report on interstate commerce:

The committee gave careful consideration to the question as to whether it would attempt to define the many and variable unfair practices which prevail in commerce and to forbid their continuance or whether it would, by a general declaration condemning unfair practices, leave it to the commission to determine what practices were unfair. It concluded that the latter course would be the better, for the reason, as stated by one of the representatives of the Illinois Manufacturers' Association, that there were too many unfair practices to define, and after writing 20 of them into the law it would be quite possible to invent others.

Advances in biotechnology have left holders of recombinant DNA patents just as helpless as the process patent holders that Congress sought to protect by enacting section 1337. The Amgen decision can thus be criticized for allowing patent office policy to replace the International Trade Commission as the arbiter of what does or does not constitute unfair acts of trade.

The Tariff Act is not on its face limited to patent violations. Section 1337(a)(1)(A) applies to "[u]nfair methods of competition and unfair acts in the importation of articles . . . or in the sale of such . . . by the owner, importer, or consignees, the threat or effect of which is — (i) to destroy or substantially injure an industry in the United States." It is only sections (B)(i) and (B)(ii) that explicitly mention patent infringement. The ALJ suggested that the Commission might "wish to reinstitute this investigation on a different basis, and determine whether there are unfair trade practices involved in respondent's importation of EPO, which may fall short of or not involve

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123 In re Amtorg Trading Corp., 75 F.2d at 840 (emphasis in original).
124 Id.
125 19 U.S.C. § 1337(a)(1)(A). Amgen did satisfy the criterion of a domestic industry, by demonstrating that a plant 24,000 square feet in size was constructed at a cost of approximately $20 million for rEPO research and manufacture. Certain Recombinant Erythropoietin, Inv. No. 337-TA-281, USITC Pub. 2186, at 63, 69.
By limiting the scope of the Tariff Act to patent violations, the ITC limits its own authority and in the process makes the Tariff Act less comprehensive than Congress originally intended.

The Federal Circuit concluded its decision with the comment that, if there is a need to alter the understanding of section 1337, it is a task for Congress and not the courts. A differing, but equally authoritative, statement on statutory interpretation was offered in an earlier patent case. In Chakrabarty the Supreme Court asserted that "Congress, not the courts, must define the limits of patentability," but added (citing Marbury v. Madison) that it is "equally true that once Congress has spoken it is 'the province and the duty of the judicial department to say what the law is.'" It is within the province of the courts to interpret section 1337 as applying not only to patent infringement per se, but also to other unfair methods of competition or unfair acts in the importation of articles.

**Conclusion**

Biotechnology research offers a promising path to the diagnosis and potential cure of many previously untreatable genetic defects and diseases. However, as government is no longer willing or capable to provide the vast sums necessary to underwrite this research, future developments depend on the ability and willingness of private companies to make the massive investments necessary for biotechnological product research. It has been estimated that $1.5 to $2

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129 According to commentators, the express purpose of the 1988 changes in the Tariff Act was to increase the incentive for United States companies to invest in research and development by enabling United States industries "to protect better their intellectual property rights from unfair trade acts or unfair methods of competition by foreign importers." Clark, The Future of Patent-Based Investigations Under Section 337 After the Omnibus Trade and Competitiveness Act of 1988, 38 AM. U. L. REV. 1149, 1151-52 (1989).
billion was invested by private industry in biotechnology research and development in the year 1987 alone.\textsuperscript{131} The Supreme Court's decision in \textit{Diamond v. Chakrabarty} was a major impetus for the commercial development of biotechnology.\textsuperscript{132} Now, however, the \textit{Amgen} decision, coming at a time when the dynamism of scientific research abroad is already threatening to overtake some American industries, could deal a death blow to domestic biotechnology. If, after spending $20 million on product development, a company finds that its patent is worthless because it does not protect the most vital component of its research from foreign competition—that there is, in effect, no protection against foreign removal of the product for production abroad and subsequent importation—the company will find it economically infeasible to continue its efforts. Private funds for biotechnological research will disappear. Congress did not intend for this to happen. Legislative history indicates that Congress amended the Tariff Act because it found existing protection under section 337 to be inadequate. The law was amended to make it a more effective remedy for the protection of United States intellectual property rights.

In order to promote domestic biotechnology, the courts can either broaden the acceptable definition of “process” to include altered intracellular processes, or interpret 1337 to encompass any unfair trade act involving U.S. patents.\textsuperscript{133} Members of Congress have affirmed their intent to protect biotechnology.\textsuperscript{134} It is now up to the International Trade Commission and the courts to interpret the laws in a manner consistent with Congressional intent, thereby facilitating the future growth of biotechnology in the United States. Congres-


\textsuperscript{132} Comment, \textit{Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue}, 34 UCLA L. Rev. 207, 211 n.18 (1986).

\textsuperscript{133} In \textit{Chakrabarty} the Supreme Court stated:

> The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting the Progress of Science and the useful Arts with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms. \textit{Chakrabarty}, 447 U.S. at 315.

\textsuperscript{134} Senator Lautenberg, one of the sponsors of the amendment to the Trade Act, made the following statement during Senate hearings on section 1337(a)(1)(B)(ii): “The emerging biotechnology industry has pioneered a revolutionary genetic engineering technology that produces recombinantly derived materials used to make previously unavailable products. . . . Section 337(a)(1) (a reenactment of section 337a) will provide the assistance necessary for emerging U.S. industries, such as the biotechnology industry, to compete in a marketplace without interference due to unfair acts of foreign competitors.” \textit{134 Cong. Rec.} S10,711, 10,713 (1988). Senator Lautenberg was also one of the co-sponsors of a bill introduced in the Senate to amend Title 35 in order to “provide protection from the ever increasing foreign infringement of American biotechnology ingenuity.” \textit{136 Cong. Rec.} S3107 (1990). \textit{See supra} note 122 and accompanying text.
vocational statutes can be made applicable to changing technology if the courts are willing to interpret statutes in the light of current scientific capabilities and advances.

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