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The Process Patent Quagmire

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NOTE

THE PROCESS PATENT QUAGMIRE

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INTRODUCTION

In *Amgen, Inc. v. U.S. International Trade Commission*,¹ the Court of Appeals for the Federal Circuit held that the International Trade Commission (ITC) may not exclude products manufactured abroad by a process involving starting material patented in the United States. However, if any corporation used the patented starting material to manufacture those same products on American soil it would constitute patent infringement.²

¹ 902 F.2d 1532, 14 U.S.P.Q.2d 1734 (Fed. Cir. 1990). This article will not discuss Amgen's patent infringement suit against Genetics Institute, Inc. and its commercial partner, Chugai Pharmaceutical Co. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 13 U.S.P.Q.2d 1737 (Fed. Cir. 1991).

² The manufacturing of a product within the United States by means of an unpatented process using a patented product is infringement of an article claim. *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 861, 221 U.S.P.Q. 937, 939 (Fed Cir. 1984), *cert. denied*, 469 U.S. 856 (1984); 35 U.S.C. § 271(a). Thus, a domestic enterprise could not manufacture rEPO in the United States using Amgen's patented vectors and

The decision effectively highlights the problems caused by *In re Durden*,³ which held, in brief, that a well known process, even if it uses novel starting material and produces a novel product, is not patentable.⁴ This note argues that a legislative solution to the *Durden* problem is required. To a significant extent, what is at stake in this *Durden* quagmire is America's ability to remain a leader in the biotechnology,⁵ pharmaceutical and chemical industries.

Amgen involved an action filed with the International Trade Commission against Chugia Pharmaceutical Co. of Japan and its U.S. subsidiary, Chugia Pharma U.S.A., Inc., for violation of former section 337 of the Tariff Act of 1930.⁶ *Amgen* sought to prevent Chugia Pharma U.S.A., Inc. from importing into the United States recombinant erythropoietin⁷ (rEPO) made by a process⁸

host cells. Yet, according to *Amgen*, it is not unlawful to import products made abroad by an unpatented process which includes the use of a patented product. *Amgen*, 902 F.2d at 1540, 14 U.S.P.Q.2d at 1741. Conversely, the importation of a product "made by a process patented in the United States" is an act of patent infringement. 35 U.S.C. § 271(g) (Supp. 1991). The International Trade Commission (ITC) has the power to exclude products made abroad by a process patented in the United States. Omnibus Trade and Competitiveness Act of 1988, 19 U.S.C. § 1337 (a)(1)(B)(ii) (Supp. 1991).

³ 763 F.2d 1406, 226 U.S.P.Q. 359 (Fed. Cir. 1985).

⁴ *Id.* at 1408-09, 226 U.S.P.Q. at 362.

⁵ Biotechnology refers to "the collection of industrial processes that involve the use of biological systems. For some industries, these processes involve the use of generally engineered microorganisms." R. KING & STANFIELD, A DICTIONARY OF GENETICS 44 (3d ed. 1985).

⁶ Act of June 17, 1930, ch. 497, Title III, Part II, § 337, 46 Stat. 703 (current version at 19 U.S.C. § 1337 (1983 & Supp. 1991)). Section 337 of the Tariff Act of 1930 was amended in 1935 by 19 U.S.C. § 1337a. The current version of 1337a is 19 U.S.C. § 1337 (a)(1)(B) (1983 & Supp. 1991).

⁷ Erythropoietin is a chemical secreted by the kidney that stimulates the release of reticulocytes from bone marrow. STEDMAN'S MEDICAL DICTIONARY 487 (24th ed. 1982). Recombinant erythropoietin is produced in a laboratory as opposed to naturally occurring erythropoietin. *Amgen*, 902 F.2d at 1533. Reticulocytes are young red blood cells. STEDMAN'S MEDICAL DICTIONARY 1225 (24th ed. 1982). Proerythroblasts are red blood cells with a nucleus, the immediate precursor of normal mature red blood cells. *Id.* at 1145. Erythrocytes are mature red blood cells. *Id.* at 485. Although the growth of a red blood cell in reality is a continuous process, there are various labels given to each stage of red blood cell development. For the purposes of this article it is sufficient to mention the above three stages.

⁸ A process is a method for achieving a particular result. See *Cochrane v. Deener*, 94 U.S. 780 (1877): "A process is a mode of treatment of certain materials to produce a given result. It is an act or series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing." *Id.* at 788; *Tilghman v. Proctor*, 102 U.S. 707 (1881):

covered under United States letters patent⁹ No. 4,703,008.¹⁰

A machine is a thing. A process is an act, or a mode of acting. The one is visible to the eye, . . . [t]he other is a conception of the mind, seen only by its effects when being executed or performed. Either may be the means of producing a useful result.

Id. at 728.

In *Re Amtorg Trading Corporation*, 75 F.2d 826 (C.C.P.A. 1935), *cert. denied*, 296 U.S. 576 (1935), provides a concise definition of both a product patent and a process patent:

The product patent is upon an invented or discovered article; the process patent is upon a method of making an article. It not infrequently happens that in the same letters patent [an] invention is recognized in both the article and the method of making it, but it is the well settled rule of law that a product patent protects only the product, and that a process patent protects only the process.

Id. at 832.

⁹ The term "Letters Patent" refers to the instrument that establishes evidence of patent rights. PETER D. ROSENBERG, *PATENT LAW FUNDAMENTALS* § 1.01. (2d ed. 1991). The term derives from the Latin *litterae patentes*, which refers to a written instrument which bears the seal of its author on the face of the instrument so that it could be read without breaking the seal. *Id.*

A patent grants an inventor the right to exclude others from making, using or selling a particular invention for seventeen years in exchange for public disclosure of information regarding how to make and use the invention. 35 U.S.C. § 154 (1984); *Griffin v. Keystone Mushroom Farms, Inc.*, 453 F. Supp. 1283, 1285 (D.C.Pa. 1978). *See also* ERNEST B. LIPSCOMB III, *WALKER ON PATENTS* 43 (3d ed. 1984). Upon expiration of a patent the invention becomes public property. *See, e.g., Brulotte v. Thys Co.*, 379 U.S. 29 (1964), *rehearing denied*, 379 U.S. 985 (1964); *Sears Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1974).

¹⁰ United States Patent No. 4,703,008 was issued on October 27, 1987. The '008 patent was issued out of U.S. Patent Application No. 675,298, which was filed on November 30, 1984. United States International Trade Commission, Initial Determination 114-15 (1989)(Investigation No. 337-TA-281). Amgen asserted that claims 2,4, 5-7, 23-25 and 27-29 of its '008 patent as set forth below were violated:

2. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.

. . . .

4. A procaryotic or eucaryotic host cell transformed or transfected with DNA sequence according to claim 1, 2, or 3 in a manner allowing the host cell to express erythropoietin.

5. A biologically functional circular plasmid or viral DNA vector including a DNA sequence according to claim 1, 2, or 3.

6. A procaryotic or eucaryotic host cell stably transformed or transfected with DNA vector according to claim 5.

7. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron intake.

. . . .

23. A procaryotic or eucaryotic host cell transformed or transfected with DNA

This case is of exceptional importance for several reasons.¹¹ First, this case deals with a genetic engineering¹² breakthrough.

sequence according to claim 7, 8, or 11 in a manner allowing the host cell to express said polypeptide.

25. A transformed or transfected mammalian host cell according to claim 24.

27. A transformed or transfected CHO cell according to claim 25.

28. A biologically functional circular plasmid or viral DNA vector including a DNA sequence according to claim 7.

29. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 28.

Brief for Amgen Inc. at 4-5, *Amgen Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532 (1990) (No. 89-1523).

¹¹ The Court of Appeals for the Federal Circuit explicitly acknowledged the significance of the decision: "Amgen has emphasized that the problem it has presented is 'one of great importance and presents an issue of first impression for this or any other Court.' It says we are faced with 'a precedent-setting question of exceptional importance.'" *Amgen v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1540, 14 U.S.P.Q.2d 1734, 1740 (Fed. Cir. 1990).

¹² The '008 patent at issue in *Amgen* was the harvest of Dr. Lin's research in genetic engineering. This branch of biotechnology involves the deliberate manipulation of genetic material by modifying, deleting or adding the pieces of DNA called genes. RICHARD V. KOWLES, *GENETICS, SOCIETY, AND DECISIONS* 422 (1985).

Each cell in the human body contains a nucleus, which contains 46 chromosomes that are grouped into 23 pairs. CECIL, *TEXTBOOK OF MEDICINE* 122-23 (James B. Wyngaarden & Lloyd H. Smith, Jr. eds, 17 ed. 1985). Chromosomes are made up of genes. *Id.* A group of bases along the strand of a DNA molecule that contain hereditary information is called a gene. GERARD J. TORTORA & NICHOLAS P. ANAGNOSTAKOS, *PRINCIPLES OF ANATOMY AND PHYSIOLOGY* 65 (5th ed. 1987). A molecule of DNA consists of two strands with crossbars. The strands twist around each other to form a double helix, which resembles a twisted ladder. *Id.* at 40-41. The crossbars are called nucleotides (bases), of which there are four nitrogen bases: adenine, thymine, cytosine, and guanine. KARL DRLICA, *UNDERSTANDING DNA AND GENE CLONING: A GUIDE FOR THE CURIOUS* 31 (1984). The strands consist of two parts: sugar molecules (deoxyribose) and phosphate molecules.

Broadly stated, the process of genetic engineering consists of four main steps: (1) the isolation and synthesis of the DNA segment or gene to be transferred; (2) the cloning of the DNA segment; (3) the transfer of the DNA segment to the host cell or organism; and (4) the stabilization of the DNA segment in its new surroundings. KOWLES, *supra* at 422.

Once the DNA sequence, in this case the gene for EPO, is isolated and synthesized *in vitro* (in an artificial environment such as a laboratory test tube), the cloning process may begin. Cloning refers to the production of millions of identical copies of a specified gene or other fragment of DNA. Before this replication process can occur, recombination techniques must be used to insert the gene sequence into a vector. A vector or shuttle vector is a term that refers to the vehicle to which the chosen DNA fragment or gene is joined or inserted so that the vector may carry the DNA fragment into the host cell. URSULA GOODENOUGH, *GENETICS* 13-14, 502 (3d ed. 1987). Vectors are usually plasmids and viruses. KOWLES, *supra*, at 422-23. The DNA fragment's destination is the host cell's nucleus, where it will be incorporated into the host cell's chromosomes. GOODENOUGH, *supra*, 13-14, 502. Subsequently, the host cell may construct the desired new trait by using the foreign DNA. *Id.* The cloned organism will have the characteristics of the cell

Dr. Fu-Kuen Lin of Amgen Inc.¹³ was the first individual to clone the erythropoietin gene and to express it by creating a unique, "living host cell" to produce, for the first time, useful quantities of erythropoietin.¹⁴ Amgen Inc. assigned Dr. Lin the project of cloning the EPO gene and to insert it into host cells which would produce large amounts of erythropoietin for the purpose of treating people with anemia.¹⁵ There are staggering technological changes occurring in the biotechnology field.¹⁶ Ad-

that was the source of the foreign DNA. *Id.* at 262; B. K. ZIMMERMAN, *BIOLOGICAL FUTURE, CONFRONTING THE GENETIC ERA* 43 (1984).

¹³ Amgen employs some 700 persons in Thousand Oaks, Ca. and Boulder Co. and has an annual payroll of \$30 million. 101st Cong. 2d Sess. 136 Cong. Rec. E. 852 (1990). The company was the first to receive a U.S. patent relating to Granulocyte Colony Stimulating Factor (G-CSF). *Id.* The product promises to aid the immune systems of cancer patients undergoing chemotherapy. *Id.*

¹⁴ Erythropoietin is a hormone secreted by the kidneys which stimulates the production of red blood cells in bone marrow. *STEDMAN'S MEDICAL DICTIONARY* 430, 444 (24th ed. 1982); *CECIL, TEXTBOOK OF MEDICINE* 501, 868-69 (James B. Wyngaarden & Lloyd H. Smith, Jr. eds., 17th ed. 1985).

¹⁵ *Id.* Recombinant erythropoietin has proved useful in treating patients suffering from anemia. A person who has too few red blood cells is said to suffer from anemia. Red blood cells carry oxygen to the tissues of the body. The lack of a sufficient number of red blood cells results in reduced oxygen level in the blood. There is a wide variety of causes of anemia. LOUISE J. GORDY & ROSCOE N. GRAY, 3 *ATTORNEY TEXTBOOK OF MEDICINE* § 60.00 (3d ed. 1990). Clinical studies have indicated that rEPO is especially effective in treating the anemia that results from chronic renal failure (kidney failure). Eschbach, Kelly, Haley, Abels & Adamson, *Treatment of the Anemia of Progressive Renal Failure With Recombinant Human Erythropoietin*, *THE NEW ENGLAND JOURNAL OF MEDICINE*, July 20, 1989, at 158. Evans, Rader, Manninen & The Cooperative Multicenter EPO Clinical Trail Group, *The Quality of Life of Hemodialysis Recipients Treated With Recombinant Human Erythropoietin*, *JAMA*, Feb. 9, 1990, at 825.

A kidney disease could stem from infection, inflammation or high blood pressure. *An 'insulin' for Anemia Sufferers*, *U.S. NEWS & WORLD REPORT*, June 12, 1989, at 13. Diseased kidneys fail to clear waste from the bloodstream and fail to adequately produce erythropoietin. LOUISE J. GORDY & ROSCOE N. GRAY, 3 *ATTORNEY TEXTBOOK OF MEDICINE* § 60.74 (3d ed. 1990). Thus the production of red blood cells is impaired. The result is anemia. Anemia resulting from chronic renal failure usually is treated by either dialysis or androgen, a male hormone. *Id.* Recombinant EPO does not eliminate the need for dialysis, but does, however, eliminate the need for blood transfusions, which tend to expose recipients to various diseases. *An 'insulin' for Anemia Sufferers, supra*, at 13. Dialysis involves the process of removing waste from the blood by passing blood through a device, serving essentially as a kidney, and then circulating the blood back into the person. *CECIL, TEXTBOOK OF MEDICINE* 559-60 (James B. Wyngaarden & Lloyd H. Smith, Jr. eds., 17th ed. 1985). A transfusion involves transferring the blood from one person to another. *STEDMAN'S MEDICAL DICTIONARY* 1474 (24th ed. 1982).

¹⁶ See generally John Pekkanen, *Genetics: Medicine's Amazing Leap*, *READER'S DIGEST*, September 1991, at 23-32. "The genetics revolution will change medicine more in the next 20 years than it has changed in the past 2000." (quoting Dr. Leroy Hood, one

vances in the field of biotechnology have found applications in treating diseases such as AIDS, diabetes, influenza, and muscular dystrophy, just to name a few.¹⁷ In addition to the medical benefits, the technology could be applied to alleviate food shortages, to clean up hazardous oil spills in the ocean and to extract scarce minerals from the soil.¹⁸

Second, this is the first case to call for the interpretation of 19 U.S.C. section 1337(a)¹⁹ of the Omnibus Trade and Competi-

of the country's leading geneticists). *Id.*

The United States Office of Human Genome Research has set its sights on mapping the position of each of the 50,000 to 100,000 genes contained in the body's 46 chromosomes. In brief, the Human Genome Initiative is a project to locate and identify all the genes that make up a human being. The human genome can be found in every cell of every human. The task will involve sequencing three billion base pairs of nucleotides. See Office of Technology Assessment, U.S. Congress, Mapping Our Genes; Genome Projects: How Big, How Fast? (1988). See generally JOEL DAVIS, MAPPING THE CODE: THE HUMAN GENOME PROJECT AND THE CHOICES OF MODERN SCIENCE (1990). What is truly amazing is that scientists do not know the function of 95% of those three billion nucleotides, so scientists often refer to them as "junk." Bernard D. Davis and Colleagues, *The Human Genome and Other Initiatives*, SCIENCE, July 27, 1990, at 342. Scientists of the Department of Energy and the National Institutes of Health must grapple not only with purely scientific issues but with a wide array of practical but complex issues such as: What is the most economical method for sequencing? What kind of computer systems must be devised for effectively storing and accessing the data? How much money should be spent on this project and thereby reduce the amount left for research in other areas in biotechnology? *Id.* The magnitude of the undertaking and its significance in the history of mankind has been compared to nothing less than the Manhattan Project. Paul Kroll, *The Gene Healers, Curing Inherited Diseases*, PLAIN TRUTH, Sept. 1990, at 4.

¹⁷ John Pekkanen, *Genetics: Medicine's Amazing Leap*, READER'S DIGEST, September 1991, at 23-32; Theodore Friedmann, *Progress Toward Human Gene Therapy*, SCIENCE, June 16, 1989, at 1275. See generally *Human Gene Therapy—A Background Paper* Washington, D.C. U.S. Cong., Office of Technology Assessment, OTA-BP-BA-32 (Dec. 1984).

¹⁸ GERARD J. TORTORA & NICHOLAS P. ANAGNOSTAKOS, PRINCIPLES OF ANATOMY AND PHYSIOLOGY 40 (5th ed. 1987).

¹⁹ The issue in *Amgen* hinges on the interpretation of section 1337 of the 1930 Trade Act as amended under the 1988 Trade Act. Section 1337(a)(1)(B)(ii) of the 1988 Trade Act provides as follows:

(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.

tiveness Act of 1988, which reenacted 19 U.S.C. section 1337a.²⁰ The major area of dispute in this case was whether section 337 as amended by the 1988 Trade Act was intended to expand the rights of product patent holders or was merely a reenactment of section 337 whereby the importation of a product made abroad by a patented process constitutes unfair competition.²¹ The decision may serve as a catalyst to spur Congress to amend 35 U.S.C. section 103 and thereby help protect domestic industry from their indefatigable foreign competitors.²²

Part I of this article summarizes the facts and holding of the *Amgen* decision. Part II analyzes the *Amgen* and *Durden* cases and examines some of the ramifications of the decisions. In part III this note concludes that the legislative approach is necessary to clarify the law for the benefit of the business community and to provide reasonable certainty in this area of process patents. Part IV presents the potential consequences of legislative change.

I. AMGEN, INC. v. U.S. INTERNATIONAL TRADE COMMISSION

On February 10, 1988, the ITC instituted an investigation under former section 1337(a)²³ pursuant to a complaint filed by

19 U.S.C. § 1337 (a) (1983 & Supp. 1991).

²⁰ Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418, Stat. 1107. 19 U.S.C. § 1337(a) (1989).

²¹ *Amgen*, 902 F.2d at 1538, 14 U.S.P.Q.2d at 1739.

²² The distribution of U.S. patents is noted to be a good indicator of which companies are instrumental in setting the pace for modern technology. A study of U.S. patents issued to American and Japanese inventors between 1975 and 1985 revealed that U.S. patents issued to Japanese inventors doubled from nine to eighteen percent. W. Scouton, M. Glover, *Study Shows That Number of U.S. Patents Issued To Japanese Has Grown Over Last Decade*, BUSINESS AMERICA, Sept. 25, 1989, at 13. By way of contrast, the U.S. share decreased from 65% to 56%. *Id.* By 1984, the Japanese held more U.S. patents than British, French and German inventors combined. By 1986, Hitachi had become the number one recipient of U.S. patents. In 1987, the top three U.S. patent recipients were Hitachi, Canon, and Toshiba. *Id.* From 1961 to 1986 General Electric was the number one recipient of U.S. patents. B. Rudolph, *Eyes on the Prize: Japan challenges American's reputation for creativity and innovation*, TIME, March 21, 1988, at 50. As of 1987, it was ranked fourth. *Id.*

²³ The forerunner of section 337 of the 1930 Tariff Act was section 316 of the Tariff Act of 1922 (the Fordney-McCumber Tariff Act). Tariff Act of 1922, ch. 356, § 316, 42 Stat. 858, 943-44. In the Tariff Act of 1930, popularly known as the Smoot-Hawley Tariff Act, Congress amended section 316, and designated the amended provision as section 337. Tariff Act of 1930, ch. 497, title III, Part II, § 337, 46 Stat. 590, 703-04 (codified as

Amgen on January 4, 1988.²⁴ The complaint alleged that the defendants, Chugia Pharmaceutical Co., Ltd. and Chugia Pharma U.S.A., Inc., had violated former section 1337(a) by unlawfully importing into the United States recombinant erythropoietin (rEPO) manufactured by a process covered by Amgen's '008 patent. On August 23, 1988, Congress passed the 1988 Trade Act which substantially amended former section 1337(a).²⁵ The

amended at 19 U.S.C. § 1337) (1983 & Supp. 1991).

ITC investigations under section 337 have steadily increased from 1974 to 1987 and the trend is expected to continue. Melise R. Blakeslee, R.V. Lupo & George M. Schwab, *The Int'l Trade Comm'n Section 337 Action: An Improved Weapon For U.S. Industries In Intellectual Property Battleground*, in *PATENT LITIGATION* 217 (Practising Law Institute 1989). Section 337 protects intellectual property rights from infringement by imports, by providing a remedy for unfair practices in import trade. 19 U.S.C. § 1337(a) (1983 & Supp. 1991). It empowers the ITC to investigate allegations that an accused patent infringer is importing into the United States a product that violates the intellectual property rights of the patent owner and thereby is engaging in unfair competition. In the majority of section 337 cases, the unfair act takes the form of patent infringement. Gary M. Hnath & James M. Gould, *Litigating Trade Secret Cases at the International Trade Commission*, 19 AIPLA Q. J. 87, 88 n. 4 (Fall 1991). "Of the 331 cases brought before the ITC since 1974, 274 have involved allegations of patent infringement." *Id.* It is well settled that patent infringement is an unfair method of competition. *E.g.*, Massachusetts Institute of Technology v. AB Fortia, 774 F.2d 1104, 1108 (Fed. Cir. 1985).

Former 19 U.S.C. section 1337(a) was enacted in response to the decision by the Court of Customs and Patent Appeals in *In Re Amtorg Trading Corporation*. 75 F.2d 826 (C.C.P.A. 1935), *cert. denied*, 296 U.S. 476 (1935). The issue in that case was whether the importation of a product manufactured abroad by a process that was patented in the United States constituted an unfair trade practice under section 337. The Court in a prior decision, *In Re Northern Pigment Co.*, 71 F.2d 447 (C.C.P.A. 1934), had held that such importations constitute unfair trade practices. In *Amtorg*, however, the Court reversed itself, and held that the importation of a product manufactured abroad through a patented process did not constitute an unfair practice. *Amtorg*, 75 F.2d at 834.

The Court reasoned that in enacting section 337 Congress had not sought to expand substantive patent rights to the point where the conduct complained of constituted unfair competition. Since the grant of an exclusive patent is limited to the territory of the United States, the Court held that use of the patented process abroad did not constitute infringement. Therefore, the court found that since there was no patent infringement there could be no unfair competition. *Id.* at 834.

²⁴ *Amgen Inc., v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1534, 14 U.S.P.Q.2d 1734, 1736 (Fed. Cir. 1990).

²⁵ In response to the *Amtorg* decision Congress eventually provided legislative relief in the form of 19 U.S.C. section 337 of the Tariff Act of 1930. However, in the 1980s, Congress became dissatisfied with the protection afforded to American intellectual property under former section 337, because the necessary showing to prevail under the criteria of section 337 was too high. Act of August 23, 1988, P.L. 100-418, 1988 U.S.C.C.A.N. (1107 Stat.) 1666-67. Moreover, meaningful relief was not available to process patent owners as they had no right to an infringement action against those who imported into the United States products made by the patented process, *id.* at 2120-22, and had

Trade Act specifically stated that it applied to all pending Com-

no right to monetary damages against such importers. Act of August 23, 1988, P.L. 100-418, 1988 U.S.C.C.A.N. (1107 Stat.) 2120-22; 35 U.S.C. § 287(b). (1981 & Supp. 1991).

Prior to the 1988 changes in the trade law, in order for the ITC to determine that an unfair act had been committed, the owner of the U.S. patent must first have established that the act of a foreign competitor threatened to destroy or substantially injure a domestic industry efficiently and economically functioning. Former 19 U.S.C. § 1337 (d), (e) and (f) (1983). Only if the patent holder made such a showing could the ITC issue a cease and desist order or an exclusion order. *Id.*

The 1988 Omnibus Trade and Competitiveness Act, section 1342 of the 1988 Omnibus Trade and Competitiveness Act made, *inter alia*, four major changes to § 337. One, it eliminated the economic injury requirement where infringement of a United States patent or federally registered trademark, copyright or semiconductor mask work is involved. 19 U.S.C. § 1337 (a)(1)(B) (1983 & Supp. 1991) (amending 35 U.S.C. § 1337a (1983)).

Two, it expanded the definition of the term domestic industry. For purposes of the Trade Act an industry is defined as one that exists in the United States if there is: (1) significant investment in plant or equipment; (2) significant employment of labor or capital; or (3) substantial research and development, or licensing. 19 U.S.C. § 1337 (a)(3) (1983 & Supp. 1991) (amending 35 U.S.C. § 1337a (1983)). The criteria of the section are set forth in terms of the disjunctive "or" rather than the conjunctive "and", which means that a complainant in a patent based § 337 investigation need only satisfy one of the three alternatives.

Three, it eliminated the requirement that the domestic industry be "efficiently and economically operated." 19 U.S.C. § 1337 (a)(1)(B) (1983 & Supp. 1991) (amending 35 U.S.C. § 1337a (1983)). Four, the 1988 amendments provide for awards of damages against process patent infringers. 35 U.S.C. § 287 (b) (1981 & Supp. 1991). However, section 337 of both the Tariff Act of 1930 and the Trade Act of 1988 permit the ITC to refrain from issuing a cease and desist order if it believes doing so would be in the public interest.

The 1988 Trade Act also added a new subsection to 35 U.S.C. section 271, which provides that the importation into or sale or use within the United States of a product made by a patented process constitutes infringement. 35 U.S.C. § 271(g) (1981 & Supp. 1991).

In the 1988 Trade Act, the United States acknowledged the serious shortcomings in its trade policy and the inadequate growth in the productivity and competitiveness of United States firms in comparison to their overseas competition. Act of August 23, 1988, P.L. 100-418, § 1001 (a)(3)(G), (H), 1988 USCCAN (1120 Stat.). The Trade Act then spelled out essential United States objectives. One paramount objective is to guarantee the continued vitality of the technological and industrial base of the United States. *Id.* at § 1001(a)(4)(A).

The purpose of the amendments to section 337 was to strengthen the protection given to the intellectual property rights of United States firms. Act of August 23, 1988, P.C. 100-418, § 1341(b), 1988 U.S.C.C.A.N. (1212 Stat.). For a fuller discussion of the changes under the 1988 Trade Act with respect to unfair competition, see Terry L. Clark, *A Review of Recent Decisions of the United States Court of Appeals For the Federal Circuit: The Future of Patent Based Investigations Under 337 After Omnibus Trade and Competitiveness Act of 1988*, 38 AM. U. L. REV. 1149 (1989).

mission investigations.²⁶ Therefore, the case at bar became governed by the new Trade Act.²⁷

Following institution of the action, the Administrative Law Judge (A.L.J.) conducted a thorough investigation.²⁸ The primary issue disputed between the parties was whether Amgen's '008 patent covered the process by which Chugia produced rEPO overseas, within the meaning of section 1337(a)(1)(B)(ii), even though Amgen conceded its patent contained no traditional process claims.²⁹ The A.L.J. concluded that there was no violation of section 337 in the importation of rEPO.

The A.L.J. determined that the '008 patent did not cover the process by which the defendant produced rEPO. Instead, the A.L.J. determined that the '008 patent covered only a product (genetically engineered host cells, vectors, and DNA sequences used to make rEPO) and did not directly, or by implication, protect a process (growing a transfected host cell and isolating the protein).³⁰ Hence the claimed process infringement was not suffi-

²⁶ Section 1342 (d) provides that, subject to an exception not material here, "the amendments made by [§ 1337] shall take effect on the date of the enactment of this Act." 19 U.S.C. 1342 (d) (1983 & Supp. 1991).

²⁷ *Amgen*, 902 F.2d at 1534, 14 U.S.P.Q.2d at 1736.

²⁸ Administrative Law Judge Sidney Harris issued an extremely comprehensive 188-page opinion.

²⁹ A traditional process claim is one that recites a step-by-step procedure. *Phillips Petroleum Co. v. Sid Richardson Carbon & Gasoline Co.*, 416 F.2d 10 (1969) ("A process patent is one concerning the mode of treatment of certain materials to produce a certain result."). *Thomson Machinery Co. v. Larose*, 197 F.Supp. 636 (E.D.La. 1961), *aff'd*, 320 F.2d 218 (5th Cir. 1963) ("A process, or method, patent is one which outlines a procedure for producing a physical result independent of the producing mechanism" and "a separate patent may be obtained on producing mechanism provided it rises to the standard of invention.").

³⁰ The A.L.J. began his analysis by determining the scope of § 1337(a). He interpreted the language of § 1337(a) to mean that the statute is triggered when an imported product utilizes a patented process to manufacture the product. U.S. Int'l Trade Comm'n, Initial Determination 15 (Investigation No. 337-TA-281) (Jan. 1989). He was not persuaded by plaintiff's contention that section 1337(a) prohibits importation of a product made by a process "covered by" the claims of a patented product. *Id.* at 13.

The A.L.J. then determined that plaintiff's contention that the claims that it did receive from the patent examiner covered both a product (the host cells) and the intracellular processes that are inherent in the product (synthesis of rEPO) was without merit. First, under 35 U.S.C. §§ 102 and 103, the claims examiner denied Amgen claims to the process for the production of rEPO that comprised the growth of the transfected host cells and the isolation of the rEPO produced by the host cells. *Id.* at 23, 24. Second, after its process patents applications were rejected Amgen amended its application to describe claims that were directed solely to products, i.e., DNA sequences, DNA vectors,

cient grounds for finding a violation under section 337.

On April 10, 1989, after a full review of the Initial Determination, the Commission entered its final opinion denying Amgen any relief.³¹ The Commission adopted and relied upon major portions of the Initial Determination, including the critical finding that Amgen's patent did not cover a process for the manufacture of rEPO.³² The Commission, however, dismissed Amgen's complaint on the grounds of lack of subject matter jurisdiction, rather than ruling on the merits of the case.³³ The Commission reasoned that the plaintiff did not establish a pro-

and transformed and transfected host cells, not to any processes. *Id.* at 24. Third, Dr. Lin, the inventor of rEPO, testified that he did not consider the intracellular processes of the host cell to be part of his invention. *Id.* at 25.

³¹ Pursuant to the Commission's order, Amgen's complaint was dismissed and the investigation was terminated. In the MATTER OF CERTAIN RECOMBINANT ERYTHROPOIETIN, U.S. Int'l Trade Comm'n (Investigation No. 337-TA-281) (1989).

³² In its opinion, the Commission stated:

The [A.L.J.] determined that the '008 claims do not cover any processes. The [A.L.J.'s] determination is based on: (1) the cancellation of certain process claims during prosecution of the '008 patent at the PTO, (2) the inventor's testimony that he did not invent the intracellular processes, and (3) the inventor's failure to point out where the claims or the specification indicated that the inventor was claiming the intracellular processes (citations omitted). We adopt the [A.L.J.'s] finding that the '008 patent does not claim a process. However, we base our determination on principles of claim interpretation. (The Commission added in a footnote that the inventor's testimony is normally not considered a basis for claim interpretation.).

In the Matter of CERTAIN RECOMBINANT ERYTHROPOIETIN, U.S. Int'l Trade Comm'n 8 (Investigation No. 337-TA-281) (1989).

³³ Four of the six Commissioners concluded that since subsection 337(a)(B)(ii) only applies when process patent claims exist, and Amgen failed to present a patent claim that covered a process, the Commission did not have subject matter jurisdiction. *Id.* at 12 (Investigation No. 337-TA-281) (1989). To the extent the majority concluded that Amgen was not entitled to relief, the two concurring Commissioners agreed. *Id.* at 13. The concurring Commissioners would not have dismissed the case on the grounds of lack of subject matter jurisdiction. *Id.* In their view the investigation should have been disposed of on the merits. *Id.* The concurring Commissioners reasoned that since Amgen alleged a patent that covered a process in its complaint, the Commission not only had jurisdiction but was statutorily obligated to instigate an investigation. *Id.* at 16. The Commission turned to the express language of 19 U.S.C. § 1337(b)(1). That section provides:

The Commission shall investigate any alleged violation of this section on complaint under oath or upon its initiative. Upon commencing any such investigation, the Commission shall publish notice thereof in the Federal Register. The Commission shall conclude any such investigation, and make its determination under this section, at the earliest practicable time

19 U.S.C. § 1337 (b)(1) (emphasis added by Commissioners).

cess patent claim and that such a claim is a "condition precedent" for invoking jurisdiction under 19 U.S.C. section 337(a)(1)(B)(ii). On June 9, 1989, Amgen filed a timely appeal in the United States Court of Appeals for the Federal Circuit.³⁴ The court based its authority to review the Commissioner's decision on 1337(c).³⁵

The court found that the ITC decision here fell into one of the two categories of final determinations set out in *Block v. U.S. Int'l Trade Comm'n.*³⁶ Under 19 U.S.C. section 1337(c), as interpreted in *Block*, an intrinsic final determination requires a "final determination decision on the merits, excluding or refusing to exclude articles from 'entry'."³⁷ The other category of determinations are those deemed the equivalent of a final determination.³⁸ The court accepted Amgen's argument that the Commission's order was the equivalent of a final determination

³⁴ Brief for Amgen Inc. at 4, *Amgen Inc. v. Intern. Trade Commission*, 902 F.2d 1532 (1990)(No. 89-1523).

³⁵ *Amgen Inc. v. U.S. Intern. Trade Comm'n.*, 902 F.2d 1532, 1535, 14 U.S.P.Q.2d 1734, 1737 (Fed. Cir. 1990).

³⁶ 777 F.2d 1568, 228 U.S.P.Q. 37 (Fed. Cir. 1985). The *Block* case involved an appeal of the United States International Trade Commission decision to terminate its self-initiated investigation and to vacate the initial determination of the A.L.J. *Id.* at 1569, 228 U.S.P.Q. at 37. The article under investigation was a flow injection apparatus. *Id.* The United States Department of Agriculture (USDAS) owned United States Patent No. 4,013,413. *Id.* The patented article was a device which analyzed the composition of various liquids. *Id.* at 1570, 228 U.S.P.Q. at 37. Bifok AB, the manufacturer, and five other corporations involved in the development and importation of the apparatus were named as respondents. *Id.* at 1570 n.3, 228 U.S.P.Q. at 37 n.3. The Secretary of Agriculture appealed the ITC's decision to terminate its investigation. *Id.* at 1569, 228 U.S.P.Q. at 37.

The Court of Appeals for the Federal Circuit held that the ITC decision to terminate was not a final determination and therefore was not appealable. *Id.* at 1572, 228 U.S.P.Q. at 38-39. The court reasoned that the ITC did not reach a final determination within the meaning of 19 U.S.C. § 1337(c) because to terminate the investigation was not a decision to exclude nor a decision to refuse to exclude the articles from entry. *Id.* at 1571, 228 U.S.P.Q. at 39. The court came to the conclusion that the ITC decision was neither intrinsically a final determination nor its equivalent because the Secretary of Agriculture was free to request a second investigation under 19 U.S.C. § 1337(b)(1) and because the ITC decision was not a final judgment for the purposes of claim or issue preclusion. *Id.* at 1571-72, 228 U.S.P.Q. at 39.

³⁷ *Amgen*, 902 F.2d at 1535, 14 U.S.P.Q.2d at 1737 (quoting *Block*, 777 F.2d at 1571, 228 U.S.P.Q. at 38).

³⁸ See *Block*, 777 F.2d at 1571 n.5, 228 U.S.P.Q. at 38 n.5. See also *Import Motors Limited v. United States Int'l Trade Comm'n.*, 530 F.2d 940, 944-46, 188 U.S.P.Q. 491, 494-95 (C.C.P.A. 1976).

because, unlike in *Block*, the Commission made a finding as to whether 19 U.S.C. section 1337 was violated.³⁹ In addition, the dismissal of Amgen's complaint on jurisdictional grounds works only to prejudice Amgen in any future proceeding.⁴⁰ Finally, the court found that in cases where a statute sets forth the bases for federal jurisdiction and prevailing on the merits within the same statutory language, a court should generally dismiss the complaint on the merits.⁴¹

The *Amgen* court went on to discuss the substantive issue in the case: whether Chugia violated section 1337 by importing a product made abroad by a process which involved the use of a product patented in the United States.⁴² The court first had to decide whether Amgen's host cell product claims should be accorded the same treatment under section 1337 as any other claims to a patented product.⁴³ The court found that there was no difference between Amgen's host cell claims and any other product claim. The court reasoned that a host cell is much like a machine.⁴⁴ When one patents a machine, one only has a patent to the machine itself and not to the processes that take place inside the machine.⁴⁵ Hence, Amgen had a patent that covered the host cell itself and not the processes that take place inside that host cell.⁴⁶

The court then reached the question "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."⁴⁷ After determin-

³⁹ *Amgen*, 902 F.2d at 1535-37, 14 U.S.P.Q.2d at 1737-39. When explaining the *Block* case, the court in *Amgen* stated, "[i]n concluding that the Order was not an intrinsically final determination, this court found the lack of any findings by the Commission to be critical; nothing in the termination Order prejudiced the Commission or any private party in a future proceeding." *Id.* at 1535, 14 U.S.P.Q.2d at 1737 (citations omitted).

⁴⁰ If Amgen attempted to bring a new action on the claims of the '008 patent, the finding of the Commission that there was no patent infringement would presumably bar Amgen from relitigating the issue under the doctrine of collateral estoppel. *Id.* at 1535-36, 14 U.S.P.Q.2d at 1737.

⁴¹ *Id.* at 1535, 1537, 14 U.S.P.Q.2d at 1737, 1738-39.

⁴² *Id.* at 1538, 14 U.S.P.Q.2d at 1739.

⁴³ *Id.* at 1537, 14 U.S.P.Q.2d at 1739.

⁴⁴ *Id.* at 1537-38, 14 U.S.P.Q.2d at 1739.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.* at 1538, 14 U.S.P.Q.2d at 1739.

ing the plain meaning of the word "cover" and reviewing the legislative history of former section 1337a, the court determined that it was intended to prohibit the importation of articles made using patented *processes*, and not to prohibit importation of articles made by a process using patented *products*.⁴⁸ The court then concluded that the 1988 Trade Act merely re-enacted former section 1337a and was not intended to change the scope of the section.⁴⁹

II. THE IMPACT UPON THE AMERICAN BIOTECHNOLOGY INDUSTRY

A. Troublesome Problems Raised by Amgen

The *Amgen* decision brings to light three problems in the present patent laws. First, the law is unfair to Amgen. The effect of the court's decision is that since Amgen did not have a process patent, Chugia could freely use Amgen's patented articles to manufacture products that could later be imported into the United States. The inequity of the decision is highlighted by the fact that the exact same conduct Chugia is engaging in abroad would be prohibited if it were done in the United States.⁵⁰ The court's decision renders Amgen's patent virtually meaningless with respect to foreign corporations.

The absence of any real protection is made clear when one examines both the articles Amgen patented and the acts a foreign corporation is prohibited from engaging in. Chugia used (and is presumably still using) Amgen's patented DNA sequence, vectors and host cells to manufacture rEPO abroad.⁵¹ There is no known way to manufacture rEPO except by using Amgen's patented articles.⁵² The research Dr. Lin performed for Amgen was undertaken for the purpose of discovering how to replicate the gene for erythropoietin in order to produce large amounts of rEPO.⁵³ Chugia can manufacture rEPO abroad via a process utilizing Amgen's patented articles and then import the

⁴⁸ *Id.* at 1538-39, 14 U.S.P.Q.2d at 1739-41.

⁴⁹ *Id.* at 1539-40, 14 U.S.P.Q.2d at 1740-41.

⁵⁰ U.S. Int'l Trade Comm'n, Initial Determination 2 (Investigation No. 337-TA-281) (Jan. 1989).

⁵¹ *Id.* at 174-75.

⁵² *Id.*

⁵³ *Id.* at 134-36.

rEPO into the United States. It merely cannot perform the production in the United States.⁵⁴ Any foreign corporation, based on this decision, can utilize Amgen's patented articles in the process of manufacturing rEPO abroad and then export the rEPO to the United States.

The problem is that in a global economy, this gap in the patent law undermines the very purpose of the American patent system. The patent system is a mechanism for providing inventors incentive to create new products and perhaps whole new industries. The patent grants the inventor the exclusive right to profit from his or her labor. Hence, the patent functions like a reward.⁵⁵

If Chugia, in collaboration with the Genetics Institute, produces and markets the rEPO as it intended to, it may result in millions of dollars in lost profits for Amgen.⁵⁶ In a field such as biotechnology millions may be spent on research and development before any profitable products may be discovered.⁵⁷ When a corporation finally does develop some product which appears

⁵⁴ *Id.* at 2.

⁵⁵ See, e.g., *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974), noting that patent laws offer a right of exclusion to inventors as an incentive to undertake risks and costs associated with research and development. In addition to encouraging invention, the patent system functions to encourage investment and to encourage disclosure. Gerald Sobel, *Antitrust & Technology*, in *PATENT LITIGATION* 194 (Practising Law Institute 1982). Some commentators, however, have identified more complex economic functions of the patent system. The most frequently cited work in this area is Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

⁵⁶ Two significant facts indicate that the *Amgen Inc. v. Int'l Trade Comm'n*, 902 F.2d 1532, 14 U.S.P.Q.2d 1734 (Fed. Cir. 1990) decision may have a material adverse effect on the financial position of the company. First, Amgen Inc. engaged in a fierce legal battle fought from the ITC to the Court of Appeals for the Federal Circuit to protect its invention. The corporation would not have undertaken such an expensive legal endeavor, if the rEPO patent was not critical to the company's financial interest. Second, subsequent to the *Amgen Inc. v. Int'l Trade Comm'n*, 902 F.2d 1532, 14 U.S.P.Q.2d 1734 (Fed. Cir. 1990) decision the corporation engaged in lobbying efforts to change the current law, such that it will be more favorable to American companies in need of process patent protection.

⁵⁷ Amgen's product Epogen (recombinant erythropoietin) represented the result of more than five years of research. *AMGEN INC.*, 1991 ANNUAL REPORT 12 (1991). Amgen's product neupogen was the result of over six years of research. *Id.* at 5. The average cost to develop a pharmaceutical product is approximately \$230 million. Bruce N. Kuhlik & Richard F. Kingham, *The Adverse Effects of Standardless Punitive Damage Awards on Pharmaceutical Development and Availability*, 45 *FOOD DRUG COSM. L.J.* 693, 695 (1990).

to be promising its efforts seem wasted when others are given the opportunity to capitalize on its discovery.

The court does not explicitly acknowledge that its decision may not be fair to Amgen.⁵⁸ But it does tacitly acknowledge that Amgen may well be left in an untenuous position. Yet, the court concludes the deficiency in the trade laws cannot serve as a basis for the court to abdicate its judicial function of statutory interpretation and resort to legislation by judicial decree.⁵⁹ Thus, the court suggests that it is Congress' responsibility to address this problem in the trade and patent laws.⁶⁰

Some may contend that it is not unfair to require the U.S. patentee to secure a patent in various foreign countries to protect its invention from exploitation by foreigners. However, it is difficult to comprehend why a U.S. patentee should be compelled to secure a patent overseas to prevent the exploitation of its invention on U.S. soil.

Second, apart from the fact that the *Amgen* decision is not fair to the Amgen corporation itself, the consequences of the decision on American industry as a whole are equally unattractive. The *Amgen* decision provides an incentive to foreign corporations to pirate American discoveries any time a new invention is made in any field, whether it be biotechnology or some other area where a patentable starting material is used in a known process to make an unpatentable end product.⁶¹ The foreign corporation need only decide whether the American discovery appears sufficiently profitable to warrant investment. Once the technology as to how to produce the product is obtained from America, the foreign corporation can either enter a joint venture with an American corporation, set up a subsidiary in America or merely locate an American distributor. After the manufacturing abroad is completed, the American corporation or the subsidiary

⁵⁸ *Amgen*, 902 F.2d at 1540, 14 U.S.P.Q.2d at 1741.

⁵⁹ The decision is a logical application of § 337. But the reason § 337 is inapplicable stems from the interpretation of *In re Durden*, 763 F.2d 1406, 226 U.S.P.Q. 359 (Fed. Cir. 1985). This point is explored further *infra*.

⁶⁰ *Amgen*, 902 F.2d at 1540, 14 U.S.P.Q.2d at 1741.

⁶¹ Although the media often focuses on the trade friction between the United States and Japan, the United States experiences trade friction with its other trading partners as well, such as Germany, the United Kingdom, and France. See Edson W. Spencer, *Japan: Stimulus or Scapegoat?* 62 FOREIGN AFFAIRS 123 (1983-84).

can then import and market the product in the United States.

The third objection is the unfairness to society. Due to the absence of patent protection, foreign competition is permitted to exploit an American invention. Thus, to the extent foreign competition sells the final product, an American firm loses sales. Thus, the American firm has less capital available for research and development. In turn, less jobs are created for American citizens. Moreover, some American scientists may choose to forgo a certain area of enterprise because of their awareness of the absence of patent protection, and technological developments will evolve at a slower rate. Over time, society's standard of living may suffer. The fate of Amgen Inc., by itself, may have no significant impact on society. Yet, the risk that there will be future cases similar to Amgen raises the specter that the cumulative effect on American society may be significant.⁶²

B. *The Durden Quagmire*

The underlying problem with the *Amgen* decision, which is not discussed in the Court of Appeals opinion, hinges on *In re Durden*.⁶³ In *Durden*, the court held that a conventional process is not patentable, even though both the starting material and the end product may be novel.⁶⁴ The court reasoned that the process would have been obvious to persons of ordinary skill in the art within the meaning of 35 U.S.C. section 103.⁶⁵

When the biotechnology industry steps into the *Durden* quagmire the surface yields and the industry is then drawn down into it. This is so because there are only a few biotechnological processes that industry uses, all of which are well known.⁶⁶ Moreover, where the final product is not patentable be-

⁶² Experts estimate that total domestic and export sales lost from counterfeiting (trademark copying) and piracy (patent and copyright infringement) in 1984 were as high as 20 billion. 133 CONG. REC. E984 (daily ed. Mar. 17, 1987) (statement of Rep. Hou).

⁶³ 763 F.2d 1406, 226 U.S.P.Q. 359 (Fed. Cir. 1985). The issue on appeal in that case involved the patentability of a process of making a novel insecticide.

⁶⁴ *Id.* at 1408-09, 226 U.S.P.Q. at 362.

⁶⁵ *Id.* at 1408, 226 U.S.P.Q. at 362.

⁶⁶ Kevin Kelly, Comment, *The Elimination of Process: Will The Biotechnology Patent Protection Act Revive Process Patents*, 24 J. MARSHALL L. REV. 263, 279-80 (1990).

cause it is a product found in nature,⁶⁷ as in *Amgen*, the patentee is left to patent only the starting material. Yet as discussed, with this limited patent protection, the patentee has no remedy against the foreign competitor.

The *Durden* decision reversed Board of Appeals decisions *Ex parte MacAdams*⁶⁸ and *Ex parte Klioze*.⁶⁹ *Ex parte MacAdams* held that it is not proper to determine the patentability of a process solely on the lack of novelty of the physical manipulative steps.⁷⁰ According to that court, the method employing the novel starting material, when viewed as a whole, must be considered nonobvious, because the starting material was unknown to the art before the applicant invented it.⁷¹ Before that time, no one skilled in the art would have thought to use it in the conventional process.

The Patent and Trademark Office (PTO) has interpreted the *In re Durden* decision as a rejection of the *MacAdams* approach and applied it to deny Amgen process patents on the ground of obviousness. While the *Durden* court did not clearly define what is obvious, the PTO examiner used *Durden* to find that it would have been obvious to a person having ordinary skill in the scientific field of genetic engineering to employ the procedure Amgen used to clone erythropoietin. As indicated earlier, in a simplified version, the isolated erythropoietin gene is inserted into a vector, in this case a plasmid, to recombine the DNA sequence of EPO with the DNA present in the host cell. In brief, the process claims sought by Amgen were for the application of an old process to new materials.⁷²

The application of the *In re Durden* case led the PTO to deny Amgen's patent of the process to manufacture rEPO. The denial of the process patent left Amgen with no claims defining a process. The Tariff Act of 1930, section 337, as amended, 19

⁶⁷ Products of nature are not patentable subject matter under 35 U.S.C. §§ 101 and 102. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

⁶⁸ 206 U.S.P.Q. 445 (1978).

⁶⁹ 220 U.S.P.Q. 91 (1983). The *Durden* court reversed these two decisions in a footnote. *In re Durden*, 763 F.2d 1406, 1409, n.2, 226 U.S.P.Q. 359, 359-60, n.2 (Fed. Cir. 1985).

⁷⁰ *Ex Parte MacAdams*, 206 U.S.P.Q. at 447.

⁷¹ *Id.* at 447-48.

⁷² U.S. Int'l Trade Comm'n, Initial Determination 130-31 (Investigation No. 337-TA-281)(1989).

U.S.C. section 1337(a), only applies to process patents.⁷³ Although Chugai used patented products in the process of manufacturing rEPO, section 1337(a) has no application, and therefore Chugai did not violate section 1337(a).

The reasoning in *Durden* is contrary to that of the decision in *In re Mancy*,⁷⁴ which is not mentioned in the *Durden* case. *Mancy* dealt with the patentability of the process of producing the antibiotic danunorubicin.⁷⁵ The starting material, the microorganism *streptomyces bifurcus*, strain DS 23, 219, was novel. The final product, the antibiotic, was not novel. The process of producing the antibiotic by aerobically cultivating the microorganism was well known to the prior art.⁷⁶

The court reasoned that in determining obviousness under 103, the inquiry is "whether in view of the prior art the invention as a whole would have been obvious at the time it was made."⁷⁷ The process of producing the antibiotic, when viewed as a whole, included the use of a novel microorganism, and one having no knowledge of that starting material would not find it obvious to produce the final product using the new starting material.⁷⁸ Thus, the claimed process was patentable.⁷⁹

Although the *Durden* court stated that it agreed with the proposition that an invention should be viewed as a whole when determining obviousness, its actions indicated its understanding of that approach was different from that of the *Mancy* court. The underlying premise in *Durden* relies on either one of two bases. One, given the identity of the final product, using the new starting material for the process would be obvious,⁸⁰ or two, given the similarity between the new starting material and those that are well known in the art, one skilled in the art would apply the new starting material to the old process. The fallacy in the first premise is that the final product did not exist before the

⁷³ *Amgen Inc. v. U.S. Intern. Trade Com'n*, 902 F.2d 1532, 1539-40, 14 U.S.P.Q.2d 1734, 1740-41 (Fed. Cir. 1990).

⁷⁴ 499 F.2d 1289, 182 U.S.P.Q. 303 (1974).

⁷⁵ *Id.* at 1290, 182 U.S.P.Q. at 304.

⁷⁶ *Id.*

⁷⁷ *Id.* at 1292, 182 U.S.P.Q. at 305.

⁷⁸ *Id.* at 1292-94, 182 U.S.P.Q. at 305-06.

⁷⁹ *Id.* at 1294, 182 U.S.P.Q. at 306.

⁸⁰ THE BNA SPECIAL REPORT SERIES ON BIOTECHNOLOGY, BIOTECHNOLOGY PATENTS: A BUSINESS MANAGER'S LEGAL GUIDE 32 (1989).

new set of ingredients were combined to produce the final product. Thus, regardless of whether the final product itself is novel and patentable, its identity was unknown to the prior art. Similarly, the fallacy in the second, alternative, premise is that one skilled in the art could not choose to use the new starting material in lieu of what was used in the past, because "one cannot choose from the unknown."⁸¹

Commentators have decried the *Durden* decision because of the gaping hole it left in the armor of those who would seek patent protection.⁸² They have suggested that there should be some legislation, i.e., either by amendment of the patent laws or by special legislation granting some new form of protection to the biotechnology companies. Alternatively, they have suggested that the Court of Appeals for the Federal Circuit clarify the requirements for patentability under section 103 with respect to biotechnological processes.

III. THE LEGISLATIVE SOLUTION

A. Pending Legislation

Regardless of what may be said of the relative unfairness of the *Amgen* decision, the court took the wisest approach. The validity of the *Durden* decision was not an issue before the court. Moreover, if the court found that the ITC had jurisdiction to prohibit importation of Chugai's products, it would have been forced to conclude that Congress sought to make a major innovation in United States trade laws by reenacting section 1337(a).⁸³

⁸¹ In re Mancy, 499 F.2d 1289, 1293, 182 U.S.P.Q. 303, 306 (1974).

⁸² BIOTECHNOLOGY PATENT PROTECTION ACT OF 1991, S. REP. No. 102-260, 102d Cong., 2d Sess. (1991); Rochelle K. Seide & Aimee H. Weiss, *The Biotechnology Patent Protection Act of 1991: The Battle Lines Have Been Drawn*, J. PROPRIETARY RIGHTS 6 (Mar. 1992); Harold C. Wegner, *Biotechnology Process Patents: Judicial or Legislative Remedy*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 24 (1991); Harold C. Wegner, *Much Ado About Durden*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 785 (1989); David Beier & Robert H. Benson, *Biotechnology Patent Protection Act*, 68 U. DENVER L. REV. 173 (1991); Louis S. Sorell & Susan K. Lehnhardt, *Current State of Law Regarding Biotechnology Process Patents* (1991) (unpublished, on file with author); Kevin Kelly, *Comment, The Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents*, 24 J. MARSHALL L. REV. 263 (1990). For a comprehensive discussion of the *Durden* case and other major patent issues in biotechnology, see BNA GUIDE, *supra* note 80.

⁸³ Congress is presumed to be aware of a judicial interpretation of a statute and to

The primary reason for the court's reluctance to read section 1337(a) broadly is the court's implicit asseveration that the international arena is not the canvass for the court to paint with a broad brush.⁸⁴ A court simply lacks the expertise and tools to frame an opinion that could take into account the far-reaching implications of a holding that extends patent protection significantly beyond the areas that Congress had envisioned.⁸⁵ The democratic process accords the legislature the province of balancing competing interests with regard to high policy matters.

Against this background, the plain meaning approach adopted by the court carried out the legislature's intent.⁸⁶ While it may at first blush appear unfair to allow Chugai or any other foreign industry to reap the rewards of Dr. Lin's invention without Amgen's authorization, fairness, like beauty, is in the eyes of the beholder.

The United States' definition of fairness may not square fully with that of its trading partners.⁸⁷ The question of fairness essentially boils down to basic assumptions about what is valua-

adopt that interpretation when it re-enacts a statute without change. See *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 414 n. 8 (1975); *NLRB v. Gullett Gin Co. v. United States*, 252 U.S. 140, 147 (1920). The answer to whether section 1337(a) was intended to prohibit the importation of goods made by a process which used a product patented in the United States was not clear, because this was a case of first impression. *Amgen*, 902 F.2d at 1540, 14 U.S.P.Q.2d at 1541. There was no long-established and familiar interpretation of the Tariff Act of 1930, as amended § 1337a, as recodified § 1337(a)(1)(B)(ii), upon which the court could rely.

⁸⁴ See *Weinberger v. Rossi*, 456 U.S. 25, 32 (1982); *Diamond v. Chakrabarty*, 447 U.S. 303, 319 (1980) (Brennan, J., dissenting). If the court held in favor of Amgen, the decision would face a backlash of arguments both at home and abroad. Apart from arguments as to its consistency with prior case law, opposition to such a holding would argue that the decision might severely undermine the credibility of the United States in ongoing multilateral trade negotiations, and thus pose a serious threat to the potential success of the negotiations. *PAT. TRADEMARK & COPYRIGHT J.* (BNA) 3 (September 26, 1990). See *infra* notes 177-217 and accompanying text for a discussion of the arguments opposing the bill, which would provide for the kind of patent protection Amgen Inc. urged the court to find in the language of 1337(a).

⁸⁵ The judiciary "must proceed cautiously when . . . asked to extend patents rights into areas wholly unforeseen by Congress." *Parker v. Flook*, 437 U.S. 584, 596 (1978).

⁸⁶ *Amgen Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1538 (Fed. Cir. 1990).

⁸⁷ For a full discussion of United States laws concerned with unfair trade, see generally, Diane P. Wood, "Unfair" Trade Injury: A Competitive Based Approach, 41 *STAN L. REV.* 1153 (1989). For a general critique of the United States conception of free trade, see John M. Culberston, *A Realist View of International Trade and National Trade Policy*, 18 *N.Y.U. J. INT'L L. & POL.* 1119 (1986).

ble in life: assumptions about what is good, true, desirable and useful.⁸⁸ The architects of virtually any statute must perforce make a policy decision as to what is fair.⁸⁹

The confusion surrounding the *Durden* case makes legislation imperative. "The PTO has . . . applied *Durden* regularly to claims to processes of making and processes of using, on the

⁸⁸ The United States and Japan do not labor under the same assumptions. RICHARD T. PASCALE & ANTHONY G. ATHOS, *THE ART OF JAPANESE MANAGEMENT* 128, 135-160 (1981). With regard to the economy, the United States operates under principles based on the writings of Adam Smith, where the invisible hand of the free market satisfies consumer needs and the economy functions most efficiently with minimal government intervention. C. PRESTOWITZ, JR., *TRADING PLACES, HOW WE ARE GIVING OUR FUTURE TO JAPAN AND HOW TO RECLAIM IT* 115, 254 (1989). Companies should function like lone cowboys. *Id.* at 103-04. If they cannot make their way to success and happen to falter, let them die. *Id.*

Yet, the Japanese do not operate according to the rules and assumptions of Western values. Government, management and labor form a cohesive unit. The three work in concert to reach a national goal—domination of a particular industry. *Id.* at 129-30, 193. The Japanese operate, at least in part, under principles based on the writings of Joseph Schumpeter, an Austria economist. *Id.* at 254. Government intervention to spur economic development is viewed as not only desirable but in fact necessary to achieve national objectives. *Id.* at 233, 253, 256. Government intervention involves an array of activity to reduce the risk of loss to industry. *Id.* at 135. These activities involve more than just subsidies and tax incentives. The government provides financial support for research and development, encourages private lenders to make low interest loans, impedes the efforts of foreigners to enforce patent infringement claims and encourages the growth of cartels. *Id.* at 222, 229, 259-60, 264, 273.

Perhaps the quintessential example of how the United States and Japan differ on what is fair and unfair is the Japanese encroachment strategy of the United States semiconductor industry. *Id.* at 120-178. By selling the chips below cost, the Japanese dumping during 1985-86 drove five American D-RAM manufacturers out of business and enabled Japan to capture 90% of the world D-RAM market. See George Gilder, *How the computer companies lost their memories*, *FORBES*, June 13, 1988, at 79-84; George Gilder et al, *Who caused the D-RAM crisis?*, *FORBES*, July 25, 1988, at 70-71. D-RAMs (Dynamic Random Access Memory) are memory chips found in all computers. George Gilder, *How the computer companies lost their memories*, *FORBES*, June 13, 1988, at 79. For a discussion of the subject, see David Hirsch, *International Trade-Arrangement Between the Government of Japan and the Government of the United States Concerning Trade in Semiconductor Products* 28-29 *HARV. INT'L L.J.* 175 (1987-88). The Japanese did not consider dumping unfair, but rather just an intelligent means by which to capture a desired market share. C. PRESTOWITZ, JR., *supra*, at 137, 147. From Japan's point of view, it plays fair; America simply does not work hard enough. *Id.*

⁸⁹ Hon. Carlos J. Moorhead of California, in his closing remarks in regards to the introduction of The Patent Protection Act, stated "[f]undamental fairness requires as much and so does our obligation to innovative American companies, American workers, and all the many people who will enjoy the benefits of Biotechnology products." 136 *CONG. REC.* E207 (daily ed. Feb. 7, 1990) (statement of Rep. Moorhead).

ground that . . . the claimed process is not novel.”⁹⁰ Thus, however narrow the *Durden* court may have viewed its holding,⁹¹ the PTO does not view it as having limited application. The American government has an interest in furthering the primary objective of the patent system, which is to promote the development of science by offering an incentive to pursue research,⁹² and in ensuring that American companies remain competitive. Legislation would be the most effective way to attain these goals.

Moreover, a legislative change in the laws would promote uniformity in the application of the patent laws. Process patent protection, ultimately based on the subjective eye of the reviewing court, only serves to create disarray among the courts. Since commercial enterprises place a premium on certainty, that disarray is likely to have a disruptive effect on those enterprises. If Congress grants additional process patent protection by statute, there will be more stability and predictability in the administration of the patent laws. A clear law creates settled expectations that allow businesses to structure their conduct with some minimum assurance as to what the potential benefits or drawbacks of that conduct will be.

On February 6, 1990 the Biotechnology Patent Protection Act (the Act) of 1990 was introduced.⁹³ With an eye towards fairness, Congress, by proposing such a bill, sought to create a “level playing field.”⁹⁴ The bills, H.R. 3957 and S. 2326,⁹⁵ were designed to correct the problem created by the *Durden* decision. The bills would amend 35 U.S.C. section 103, making a process which involves known techniques nonobvious if novel starting material is used.

The two bills each had three sections and were identical apart from their effective dates. Section 1 provided that a process which involves known manipulations or methods to make a

⁹⁰ *In re Dillion*, 919 F.2d 688, 695, 16 U.S.P.Q.2d 1897, 1903 (Fed. Cir. 1990).

⁹¹ The court stated that it is “to decide each case on the basis of its own particular fact situation.” *In re Durden*, 763 F.2d 1406, 1410, 226 U.S.P.Q. 359, 361 (1985).

⁹² *Kewanee Oil Co. v. Bicron*, 416 U.S. 470, 480-481 (1974); *Universal Oil Co. v. Globe Co.*, 322 U.S. 471, 484 (1944).

⁹³ H.R. 3957, 101st Cong., 2d Sess. (1990).

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

⁹⁵ The senate bill S. 2326, an identical version of H.R. 3957, was introduced on March 22, 1990. S. 2326, 101st Cong., 2d Sess. (1990).

product will be considered patentable, if the starting material is novel.⁹⁶ Section 2(a) provided that the jurisdiction of the United States International Trade Commission (ITC) would be expanded to cover imports made from patentable starting materials,⁹⁷ and that the ITC would have the power to exclude such articles.⁹⁸ Section 2(b) provided that patent infringement actions against importation of products covered under the bill may be brought in district court.⁹⁹ The Bill would permit an American firm holding a patent to freely license the biological starting material to foreign industry if it so elected.¹⁰⁰ Section 3 provided that the Act would apply to all patents granted both before and after the effective date of the Act.¹⁰¹

On September 18, 1990 a revised version of the bill was proposed.¹⁰² Although the basic purpose of the bill remained unchanged, the language of the revised version of the legislation,

⁹⁶ 136 CONG. REC. E213-14 (Feb. 7, 1990) (statement of Rep. Boucher). H.R. 3957 and S. 2326 provide, in pertinent part:

SECTION 1. PATENTABILITY OF CERTAIN PROCESSES.

Section 103 of title 35, United States Code, is amended by adding at the end the following new paragraph:

'A process of making a product shall not be considered obvious under this section if an essential material used in the process is novel under section 102 and otherwise nonobvious under section 103.'

⁹⁷ Section 2(a) of H.R. 3957 and S. 2326 would amend § 337(a)(1)(B) of the Tariff Act of 1930 (19 U.S.C. 1337(a)(1)(B)) by adding the following (new language in *italics*):

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

S. 2326, 101st Cong., 2d Sess. § 2(a) (1990); H.R. 3957, 101st Cong. 2d Sess. § 2(a) (1990).

⁹⁸ 136 CONG. REC. E214 (daily ed. Feb. 7, 1990) (statement of Rep. Boucher).

⁹⁹ Under H.R. 3957 and S. 2326 title 35 U.S.C. § 271 would be amended as follows: 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 (as defined under section 154(b)) 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.

S. 2326, 101st Cong., 2d Sess. § 2(b) (1990); H.R. 3957, 101st Cong. 2d Sess. § 2(b) (1990).

¹⁰⁰ 136 CONG. REC. E214 (daily ed. Feb. 7, 1990) (statement of Rep. Boucher).

¹⁰¹ S. 2326, 101st Cong., 2d Sess. § 3 (1990); H.R. 3957, 101st Cong. 2d Sess. § 3 (1990); 136 CONG. REC. E207 (daily ed. Feb. 7, 1990) (statement of Rep. Moorhead).

¹⁰² H.R. 5664, 101st Cong., 2d Sess. (1990).

H.R. 5664, was substantially rewritten.¹⁰³ In addition, H.R. 5664 eliminated certain provisions found in H.R. 3957 and S. 2326. Section 2(a) of the original version of the bill regarding the extension of ITC jurisdiction was dropped, because the legislature agreed that the language was unnecessary.¹⁰⁴ The ITC already has jurisdiction over suits relating to unfair practices in import trade under 19 U.S.C. 1337(a). Section 2(b) of the original version was also deemed unnecessary, because Federal district courts already have original jurisdiction over patent infringement actions under section 1338(a).¹⁰⁵ The bills would apply to patents granted on or after the date of enactment, and to patent applications pending or filed on or after the date of enactment.¹⁰⁶ The much criticized provision regarding retroactive application of the Act was eliminated.

On March 13, 1991 H.R. 1417 and S. 654, entitled the Biotechnology Patent Protection Act of 1991, were introduced.¹⁰⁷ The language of the bills was identical to the language found in H.R. 5664. During mark up, the Senate Subcommittee on Patents, Copyrights and Trademarks redrafted the bill and on July 25, 1991 approved the amended version of S. 654.¹⁰⁸ Under the

¹⁰³ Under H.R. 5664, § 103 of title 35 was to be amended as follows:

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

H.R. 5664, 101st Cong., 2d Sess. (1990).

¹⁰⁴ Telephone Interview with Mr. Vanhorn, Director of Biotechnology and former Assistant Secretary and Commissioner of Patents and Trademarks (July 16, 1991). See also PAT. & TRADEMARK DAILY 2 (BNA)(Sept. 26, 1990). In addition, any provision providing for the expansion of ITC jurisdiction was eliminated because foreign countries have argued that § 1337(a) unfairly discriminates against foreign companies. Rochelle K. Seide & Aimee H. Weiss, *The Biotechnology Patent Protection Act of 1991: The Battle Lines Have Been Drawn*, J. PROPRIETARY RIGHTS 9 (Mar. 1992).

¹⁰⁵ Telephone Interview with Mr. Vanhorn, Director of Biotechnology and former Assistant Secretary and Commissioner of Patents and Trademarks (July 16, 1991).

¹⁰⁶ H.R. 5664, 101st Cong., 2d Sess. § 3 (1990).

¹⁰⁷ S. 654, 102d Cong., 1st Sess. (1991); H.R. 1417, 102d Cong., 1st Sess. (1991).

¹⁰⁸ 42 PAT. TRADEMARK & COPYRIGHT J. (BNA) 313 (August 1, 1991). Although all of the bills were drafted with the biotechnology industry in mind, the proposed changes in the patent laws should not be limited solely to the biotechnology industry. S. 654 as amended, unlike any of the prior bills, except for H.R. 5664, is not entitled the Biotech-

revised S. 654 both sections 103 and 282 of title 35 U.S.C. are to be amended.¹⁰⁹ On November 21, 1991 S. 654, as amended, was passed by the Judiciary Committee.

The redrafted bill incorporated the Bush Administration's concern that process patents granted under the proposed amendment expire on the same date as the product patents which formed the basis of the process claims.¹¹⁰ Of course applicants are free to seek a patent on a process under current law. Hence, the applicant may demonstrate that the patentability of the process is not dependent on the patentability of a particular

nology Patent Protection Act. There is no suggestion in the revised S. 654 that it should be limited to biological discoveries. Moreover, since the *Durden* decision can, in principle, apply to other industries apart from the biotechnology field, the impact of that decision poses a threat to the vitality of other American industries as well. All American industries deserve protection from unfair foreign competition. For these reasons the bill should not be construed as industry specific.

¹⁰⁹ Under § 1 of S.654, § 103 of title 35, U.S.C., is to be amended by adding at the end thereof the following new subsection:

(c) Notwithstanding any other provision of this section, a claimed process of making or using a machine, manufacture, or composition of matter is not obvious under this section if—

(1) the machine, manufacture, or composition of matter is novel under section 102 of this title and nonobvious under this section; and

(2)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same person or subject to an obligation of assignment to the same person; and

(B) claims to the process and to the machine, manufacture, or composition of matter, are entitled to the same effective filing date, and appear in the same patent or in different patents which are owned by the same person and are set to expire on the same date.

S.654, 102 Cong., 1st Sess. (1991).

Under § 2 of the bill entitled "Presumption of Validity" § 282 of title 35 is amended by inserting after the second sentence:

A claim issued under the provisions of section 103(c) of this title on a process of making or using a machine, manufacture, or composition of matter shall not be held invalid under section 103 of this title solely because the machine, manufacture, or composition of matter is determined to lack novelty under section 102 of this title or to be obvious under section 103 of this title.

Id.

Section 3 of the bill entitled "Effective Date" provides as follows:

The amendments made by this Act shall apply to all United States patents granted on or after the date of the enactment of this Act and to all applications for United States patents pending on or filed after such date of enactment, including any application for the reissuance of a patent.

Id.

¹¹⁰ BIOTECHNOLOGY PATENT PROTECTION ACT OF 1991, S. REP. NO. 102-260, 102d Cong., 2d Sess. 3, 14 (1991)

product.¹¹¹ In which case, a process patent, independently patentable, need not expire on the same day as the product patent.

B. Arguments Against The Proposed Legislation

Opponents of the proposed legislation advance one major argument against adoption of such legislation.¹¹² It is argued

¹¹¹ *Id.*

¹¹² Some opponents of the bill have suggested that the proposed legislation would encourage overclaiming, which is impermissible under the doctrine of *Lincoln Engineering Co. v. Stewart-Warner Corp.*, 303 U.S. 545 (1938). 40 PAT. TRADEMARK & COPYRIGHT J. (BNA) 462 (Sept. 27, 1990). However, *Lincoln Engineering* has very limited, if any, precedential value today.

In *Lincoln Engineering* a plaintiff brought a suit for contributory infringement against a supplier of fittings for lubrication guns. *Lincoln Engineering Co.*, 303 U.S. at 547. The fittings, which were well known to the art, were included in plaintiff's combination patent. *Id.* at 546. Save the patentable improvement in the "chuck" or coupler, the other elements of plaintiff's combination patent — a lubrication gun and hose — were also known to the art. *Id.* at 549, 551.

The Court held that the plaintiff's patent was void because it claimed more than the plaintiff invented. *Id.* The court added that "the improvement of one part of an old combination gives no right to claim that improvement in combination with other old parts which perform no new function in the combination." *Id.* at 549-50. The principle applies not only in cases of contributory infringement but also in cases where it is alleged that defendant is infringing upon the improved element of the combination. *Great A. & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 150 (1950).

The policy underlying the Court's decision in *Lincoln Engineering* stems from the 1822 Supreme Court decision *Evans v. Eaton*. 20 U.S. (7 Wheat.) 356 (1822); *Holstensson v. V-M Corporation*, 325 F.2d 109, 125 (1963). In *Evans* the court invalidated a patent to a "Hopper Boy," a machine used in the manufacturing of flour, because the patent comprehended the whole machine and was thus broader than the invention. *Id.* at (7 Wheat.) 428-31.

After reviewing the requirements of the then existing patent law, the Court reasoned: "the party cannot entitle himself to a patent for more than his own invention; . . . the patent should be limited to such improvement, for if it includes the whole machinery, it includes more than his invention and therefore cannot be supported." *Id.* at 430-31 (7 Wheat. at 430-31).

From *Lincoln Engineering* and its progeny grew the principle that for a combination of old and new elements to be patentable the old elements in conjunction with the new element must perform some new function and thus add to the utility and novelty of the product to justify patentability for the total combination. *Ansul Company v. Uniroyal, Inc.*, 301 F.Supp. 273, 282 (S.D.N.Y. 1969) (citing *Great A & P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 152 (1950); see also *Holstensson v. V-M Corporation*, 325 F.2d 109, 120 (6th Cir. 1963) (citing *Lincoln Engineering*; *DeBurgh v. Kindel Furniture Co.*, D.C., 125 F. Supp. 468, 476 (W.D.Mich. 1954), *aff'd*, 229 F.2d 740 (6th Cir. 1956)). "[O]nly when the whole in some way exceeds the sum of its parts is the accumulation of old devices patentable." *Great A. & P. Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 152 (1950). In addition, the combination of the old elements must not have been obvious to those skilled in the art prior to the date of the invention. *Ansul Company v. Uniroyal*,

that the legislation is unnecessary because the Federal Circuit decision in *In re Pleuddeman*¹¹³ clarified the confusion surrounding the *Durden* decision.¹¹⁴

Inc., 301 F.Supp. 273, 282 (S.D.N.Y. 1969).

Yet even from its genesis the doctrine of *Lincoln Engineering* has been criticized. The dissenter in *Evans* rejected the majority's holding as unfair because the penalty of total forfeiture of a patent was viewed as too harsh a rule. 20 U.S. (7 Wheat) 448.

The Court of Customs and Patent Appeals in *In re Bernhart*, 417 F.2d 1395, 163 U.S.P.Q. 611 (1969), in a well reasoned opinion reversed a patent examiner's decision to deny a combination patent, on the ground that *Lincoln Engineering* should not be followed. *Id.* at 1402. The court pointed out that the effect of an inventor claiming old elements in combination with an improved element creates a lesser monopoly than if the inventor patented the improved element alone. *Id.* Implicitly, the court reasoned that an inventor has a lesser monopoly because the patent is only infringed when another seeks to use the whole product, the new element in combination with the old. If someone found another use for the new element separate from its use in combination with the old elements, the combination patent would not be infringed.

Similarly, the Patent and Trademark Office Board of Appeals in *Ex Parte Barber*, 187 U.S.P.Q. 244 (1974), also declined to follow *Lincoln Engineering*. *Id.* at 246. There the court held that the examiner erroneously denied patent protection to an improved muffler claimed in combination with old elements forming an internal combustion engine. *Id.* at 244-45. The court reasoned that because 35 U.S.C. section 271(c) provides that it is a defense to contributory infringement that a product is capable of substantial non-infringing use, the rationale of *Lincoln Engineering* has been eliminated by the legislature and therefore is no longer good law. *Id.* at 246.

While the issue of whether *Lincoln Engineering* is still a viable doctrine is not totally free from doubt, it would be fair to say that beyond providing an incentive to comply with 35 U.S.C. § 112, *Lincoln Engineering* is no longer good law today. *Radio Steel & MFG. Co. v. MTD Products, Inc.*, 731 F.2d 840, 845, 221 U.S.P.Q. 657 (Fed. Cir. 1984) (the doctrine is no longer good law beyond the requirement that a patent directed to a combination of old elements must comply with § 112); *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 199 U.S.P.Q. 641, 647 (1978) (court declined to reach issue whether *Lincoln Engineering* is still valid). *But see Duplan Corp. v. Deering Milliken, Inc.*, 444 F.Supp. 648, 717-18 (1977) (*Lincoln Engineering* continues to remain good law and patent was declared invalid on ground it is directed to old combination with only one new element).

¹¹³ 910 F.2d 823, 15 U.S.P.Q.2d 1738 (Fed. Cir. 1990).

¹¹⁴ 42 PAT. TRADEMARK & COPYRIGHT J. (BNA) 184, 187 (June 20, 1991).

The statement in *In re Dillion*, 919 F.2d 688, 16 U.S.P.Q.2d 1897 (Fed. Cir. 1990), by judge Lourie regarding *Durden* did not help clarify the issue: "*Durden* did not hold that all methods involving old process steps are obvious . . . and [*Durden*] refused to adopt an unvarying rule that the fact that nonobvious starting materials and nonobvious products are involved *ipso facto* makes the process nonobvious." *In re Dillion*, 919 F.2d at 695, 16 U.S.P.Q.2d at 1903.

Although *Dillion* may be said to provide support for the proposition that *Durden* does not create an absolute bar to every method claim on an old process based on obviousness, the issue still remains muddled, because how is one to determine whether *Durden* or *Pleuddemann* applies with any degree of predictability. Furthermore, at least two commentators have noted that three concurring judges refused to join the dicta regard-

In re Pleuddeman dealt with patentability of a process of using a silane coupling agent, a bonding/priming compound for certain polymers and fillers.¹¹⁵ The PTO had allowed claims to the coupling agents and had allowed claims to the new articles produced by using the new agents, but had rejected claims of using the agents in a conventional process.¹¹⁶ The court held that since the process claims concerned the process of using the bonding/priming agents rather than the process of making the said agents, the applicant was entitled to patent protection.¹¹⁷ The court relied upon *In re Kuehl*,¹¹⁸ wherein the court permitted patent claims to the process of using a new zeolite, ZK-22, as a catalyst for cracking hydrocarbons.¹¹⁹ Process patent protection in *Kuehl* was granted because, although the product, ZK22, was used in the same manner as other zeolites found in the prior art, the ZK-22 was not sufficiently similar to the zeolites known to the prior art as to render the use of ZK-22 to crack hydrocarbons, obvious to one of ordinary skill in the art.¹²⁰

The court in *Pleuddeman* grounded its decision upon the fact that the patentee in that case sought a patent on the process of using the novel starting material. The court distinguished the *Durden* decision on the ground that *Durden* involved the obvious process of making a new insecticide, despite the fact that both the starting materials and the final product were novel;¹²¹ whereas, the patent at issue in *Pleuddeman* involved a process of using novel bonding/priming agents.¹²² The court reasoned that, since the use of the novel starting materials is an inherent part of the materials, it cannot be separated from the materials themselves, and therefore, the use of the materials

ing *Durden* and that three dissenting judges also stated that they could not join judge Lourie's statement regarding *Durden*. Harold C. Wegner, *Biotechnology Process Patents: Judicial or Legislative Remedy*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 24 (1991); Louis S. Sorell & Susan K. Lehnhardt, *Current State of Law Regarding Biotechnology Process Patents* (1991) (unpublished, on file with author).

¹¹⁵ 910 F.2d at 824, 15 U.S.P.Q.2d at 1739.

¹¹⁶ *Id.* at 825, 15 U.S.P.Q.2d at 1740.

¹¹⁷ *Id.* at 827-28, 15 U.S.P.Q.2d at 1741-42.

¹¹⁸ 475 F.2d 658, 177 U.S.P.Q. 250 (C.C.P.A. 1973).

¹¹⁹ *In re Pleuddemann*, 910 F.2d 823, 827, 15 U.S.P.Q.2d 1738, 1741 (Fed. Cir. 1990).

¹²⁰ *In re Kuehl*, 475 F.2d 658, 663, 177 U.S.P.Q. 250, 254 (C.C.P.A. 1973)).

¹²¹ *Pleuddeman*, 910 F.2d at 828, 15 U.S.P.Q.2d at 1741.

¹²² *Id.*

must also be novel.¹²³

In an effort to clarify the alleged distinction between the instant case and *Durden*, the *Pleuddeman* court emphasized that the patentee did not attempt to claim the process of making a final product, filled resins, but of only using starting materials; whereas, the patentee in *Durden* attempted to claim the process of making a final product, novel insecticide. This point is puzzling, because is the court suggesting that the patent applicant in *Durden* would have been awarded method claims if the applicant had argued he or she sought to claim the use of the starting material to produce the final product. The court further maintained that the applicant in *Pleuddeman* did not seek to patent the process of making starting material.¹²⁴ This argument is inapposite, because the applicant in *Durden* also did not seek to patent the process of making starting material.

Furthermore, it is not at all clear how the court in one breath can accept the reasoning in *Durden* and in another implicitly accept the reasoning of *In re Mancy*.¹²⁵ The *Durden* court reasoned that a process is obvious if the novel starting material and the starting material well known in the art, intended for the same purpose, are so similar, it would have been obvious to one skilled in the art to use the former in place of the latter in the process of making the final product. The *Mancy* court reasoned that a conventional process employing novel starting material is not obvious, because one skilled in the art would elect to use novel starting material in lieu of conventional starting material only after one is apprised of its nature and composition, based on the patentee's application.¹²⁶ Therefore, it is solely because of the distorting effects of hindsight that one would make such a substitution. The *Plueddeman* court accepted the rationale of *In re Mancy* by its approval of the rationale of *In re Kuehl*.¹²⁷ The *Plueddeman* court found both ap-

¹²³ *Id.* at 825-26, 827, 15 U.S.P.Q.2d at 1741.

¹²⁴ *Id.* at 827, 15 U.S.P.Q.2d at 1741.

¹²⁵ 499 F.2d 1289, 182 U.S.P.Q. 303 (1974).

¹²⁶ *In re Mancy*, 499 F.2d 1289, 1292-93, 182 U.S.P.Q. 303, 305-06 (1974).

¹²⁷ *Plueddeman*, 910 F.2d at 828, 15 U.S.P.Q.2d at 1741-42. The acceptance of *In re Kuehl* necessarily involves the acceptance of *In re Mancy* because, in both cases it was the starting material that was novel and because of the court's view in both cases that no

proaches to be sound, and intimated that both approaches can be reconciled if one distinguishes between use and make. However, both *Durden* and *Mancy* dealt with the patentability of conventional processes to *make* a final product.

Before embarking on a discussion of the wisdom of the "make" and "use" distinction, an underlying premise of the following argument must be brought to the surface. There is a distinction between a method of making a novel final product that employs no novel starting materials in the process and a method of making a final product, novel or not, employing novel starting material in the process of making the resulting product. It is the latter form of making which Amgen Inc. sought a patent and which is referred to throughout the discussion below.

The patentability of a process should not hinge upon whether one is "using" starting material or "making" a final product, because, in effect, the patentee is receiving process patent protection for the same thing. The coupling agents are in essence starting material used in making the final products, filled resins. If the patentee can only use the starting material for one purpose, to make filled resin, then the patentee, when the patentee's starting material is used, is actually receiving a patent on the process of making filled resin in the usual way, which according to *Durden* is impermissible. Even assuming the starting material has other purposes, if one of them is to make filled resins in a conventional manner, the patentee is still receiving a patent on the process of making filled resins in the usual way when the patentee's starting material is used.

The distinction between "make" and "use" is further obfuscated when one examines *Plueddeman* in light of *Ex Parte MacAdams*.¹²⁸ *Ex Parte MacAdams* held that claims drawn to a conventional method of using a novel composition are patentable.¹²⁹ There the court reasoned that it is not proper to determine the obviousness of a process solely on whether the physical manipulative steps, as applied to a known set of ingredients, are con-

one could decide to use new material in place of a similar starting material since the new starting material was unknown before the applicant invented it.

¹²⁸ 206 U.S.P.Q. 445 (1978).

¹²⁹ *Id.* at 448.

ventional.¹³⁰ Rather, the court determined that since the novel composition (the starting material) was unknown to the art before the applicant invented it, the process of using it must be nonobvious. However, as mentioned earlier, *Durden* overruled *Ex Parte MacAdams*. Is *MacAdams* now to be regarded as sound law and thus carry precedential value given the holding of *Plueddeman*?

The word "make" is defined as "to cause to exist, occur, or appear; to bring into being by forming, shaping, or altering material: fashion; to put together from components: constitute."¹³¹ The word "use" is defined as "the act or practice of employing something; a method or manner of employing or applying something."¹³² For the purpose of determining the patentability of a process, the distinction between make and use essentially amounts to clever word juggling. Indeed the words are not synonymous, and arguably there may be some conceptual difference in terms of how the words are employed in the English language. For example, one may "use" bricks to "make" a wall. One may also "use" a wall to "make" a house. The terms are used differently depending on whether one is referring to a starting material or an end product. Yet, the distinction between the two words relates only to semantics and should be irrelevant for patentability purposes.

To draw two separate categories of processes resting on the distinction between the terms "make" and "use" would be subordinating substance to form. In order to avoid serious harm to fledgling American Industry, rather than simply labeling a process as either "make" or "use", the court should carefully ascertain whether an inventor seeks to patent a process in which novel starting material is brought into play or employed to produce some final product, regardless of the patentability of that final product.

The legislature should establish patent protection for a process of producing or making a product, if the starting material in the process is novel and patentable. First, the patent monopoly is narrowed when a claim to a conventional process is added to a

¹³⁰ *Id.* at 447.

¹³¹ WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1363 (1976).

¹³² *Id.* at 2523.

claim to a new starting material.¹³³ A patent to a well-known process would not pre-empt the use of that process. Rather, such a patent would only foreclose from others the use of that process in conjunction with the patented starting material. Second, patent infringement litigation is not encouraged,¹³⁴ because a patent holder would not seek to prevent others from using an old process as it was practiced in the prior art, but would attempt to prevent others from using only an old process when it involves patented starting material. Third, the inventor deprives society of nothing which it enjoyed before his or her discovery, yet society still enjoys the fruits of the invention and the inventor adds to the sum of human knowledge. Finally, the proposed law will not discourage any American firm from enterprise in a particular field any more so than they are now, because American firms are presently foreclosed from experimentation with respect to a given process when it involves patented starting material. It is worth repeating that, on the other hand, to date, foreign corporations do not risk a patent infringement suit if they appropriate and infringe starting material when that is the only element of a product which is patented. They are free to use and exploit any patented starting material as long as the process or end product is not patented. For this reason the present law permits a foreign corporation to deny an American inventor the fruits of his or her invention and also to gain an unfair advantage over American industry.

¹³³ In *Bernhart* the court observed:

Many cases have said that the combination claim reciting only one new element with no new result is overclaiming or claiming more than the applicant invented. Such statements are indeed puzzling in view of the fact that the addition of elements to a claim *narrows* its scope and thereby creates a lesser monopoly. Others have said the combination is not new, or is obvious, if no new coaction or result is obtained. This too is unsound, since it is not the result which is to be patented but the recited machine, composition, etc. If the prior art does not show or suggest the improved element itself, it defies logical reasoning to say that the same prior art suggests the use of that improved element in a combination.

In re *Bernhart*, 417 F.2d 1395, 1402, 163 U.S.P.Q. 611, 618 (C.C.P.A. 1969).

¹³⁴ One author suggests problems may arise due to multiple patents covering the same process and due to more complicated licensing arrangements. Kevin Kelly, *The Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents?*, 24 J. MARSHALL L. REV. 263, 290 (1990)

VI. THE AFTERMATH FOLLOWING LEGISLATIVE CHANGE

The most obvious question is how would this case have been decided under the proposed amendment to the patent laws. Amgen would have applied for this new type of process patent, just as it did originally. Yet, whereas before the PTO denied the patent application on the authority of *Durden*, under the proposed amendment Amgen would be awarded a patent on an old process since the starting materials are novel (the host cells).

Thereafter, if Chugai Pharmaceutical Co., Ltd. of Japan were to import rEPO into the United States, Amgen would file a complaint with the ITC alleging unfair trade practices. In turn, the Commission would institute an investigation under section 1337(a). Amgen would be entitled to relief and the Commission would issue an order excluding the importation of rEPO.

The question then becomes what new problems will present themselves after the exclusion order goes into effect. Even assuming the patent holder, Amgen, licenses the patent to some companies, there will still be fewer suppliers of rEPO than there were before the order went into effect.¹³⁵ Assuming Amgen does not license the patent, there would only be one supplier of rEPO, viz., Amgen.¹³⁶ Assuming demand remains unchanged from its present figure, the limited supply of rEPO would cause the price of the product to increase.¹³⁷ In turn, hospitals and dialysis centers will have to pay more for the product.¹³⁸ Accordingly, the increased cost would be transferred to patients. Hence, fewer persons may have access to the product.

There can be no doubt that this result is indeed a disadvan-

¹³⁵ There will be less suppliers of rEPO assuming the exclusion order applies to all foreign producers not just a particular defendant.

¹³⁶ Currently, Amgen only licenses the Johnson & Johnson, Corp. to manufacture rEPO. Telephone interview with Sally Crampton, supervisor in Trade Relations at Amgen (July 19, 1991).

¹³⁷ Demand pull inflation, as opposed to cost push inflation, should cause the price of the product to rise since the market demand will exceed the supply. M. SPENCER, CONTEMPORARY MACROECONOMICS, at 118-19 (6th. ed. 1986). For a full discussion of the competing interests of providing incentives to inventors and ensuring that the public has access to medical products, see Note, *Patents For Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145 (1990).

¹³⁸ The Amgen Corporation sells to drug wholesalers, who then sell the product to hospitals and dialysis centers. Telephone interview with Sally Crampton, supervisor in Trade Relations at Amgen (July 19, 1991); AMGEN INC., 1991 ANNUAL REPORT 44 (1991).

tage of the exclusion order. If the proposed amendment which would give rise to such an exclusion order had no countervailing advantages it would be undesirable as a matter of policy. However, the proposed amendment does have countervailing advantages which outweigh any negative effects.

In the first place, the laws should afford Amgen fair treatment. Amgen, like most other corporations, is in business for a profit. In a free-enterprise, capitalistic system, society expects an enterprise to strive to become profitable and grow. As such, a corporation should be allowed to reap the benefits of its efforts.¹³⁹ Foreign competition is free to apply for the same type of patent protection as domestic industry.¹⁴⁰ Indeed foreign competitors are already afforded the type of patent protection at issue here, in their own countries.¹⁴¹

Further, the law should provide inventors an incentive to develop new products and processes in the biotechnology field.¹⁴² If the law is to remain consonant with the goal of providing inventors an incentive to labor in endeavors fraught with the risk of financial loss, additional proprietary protection is necessary in this field. A single corporation may spend millions on a project that may not prove successful at all or at best not provide a marketable item until after years of research.¹⁴³

¹³⁹ For a discussion of the justifications of the patent system and of the costs and benefits attributable to the system, see A. Samuel Oddi, *A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Beyond Obviousness: Invention Protection in the Twenty-First Century*, 38 AM. U. L. REV. 1097 (1989).

¹⁴⁰ As long as a foreign based corporation has money to pay lawyers it has the same opportunities for patent protection and can apply for that protection just as easily as a domestically-based firm. Japan retains almost as many District of Columbia-based lobbying/public relations law firms as those of Canada, Britain and the Netherlands combined. Walter Shapiro, *Is Washington in Japan's Pocket?*, TIME, Oct. 1, 1990 at 106, 107. Japan spends approximately \$100 million a year lobbying in Washington. *Id.*

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

¹⁴² At least one scholar has observed that a patent monopoly is the best inducement available to encourage technological innovation. Donald F. Turner, *The Patent System and Competitive Policy*, 44 N.Y.U. L. REV. 450, 445 (1969) (Professor Turner argues that patent monopolies result in wasted resources to some extent, because others attempt to solve the same problem while attempting to avoid infringement.). Other commentators have pointed to empirical studies which indicate that patent protection is the primary incentive to technological development. Reid G. Adler, *Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium On Animal Patenting*, 1-2 HARV. J.L. & TECH. 1, 15 (1988-89).

¹⁴³ Research in the field of biotechnology almost by definition requires an eye for

The government has a strong interest in encouraging American companies to produce biotechnological products and to maintain the lead in that field. Additional patent protection would advance those government interests. If foreign competition eclipses the United States in biotechnology, the United States may suffer from loss of jobs, loss of control of technology, and a lower standard of living.¹⁴⁴ While it may be beneficial to society to have many manufacturers of a medical drug,¹⁴⁵ if Europe or Japan surpasses the United States in the biotechnology industry, control of the price and supply of the products will be in the hands of foreign competition. Thus, if the dominant companies in this field are foreign corporations, the risk is created that not only will there be fewer manufacturers of medical products, but that the United States will be at the beckon call of these foreign corporations.

Of course the Act is intended to help American companies, but this advantage does not mean that the proposed change to the patent laws is somehow tainted with protectionism. It simply provides certainty of reward. It acts as an incentive to American biotechnological companies to aggressively find new applications for genetic engineering.¹⁴⁶ Thus, it furthers the Constitutional

the long-term view. A Wall Street Journal article on the Japanese plans in the biotechnology field was made part of the December 18, 1987 Congressional Record. 133 CONG. REC. S18399 (daily ed. Dec. 18, 1987). A portion of that article reads as follows:

For the U.S. recently bloodied by the Japanese in semiconductors, there is reason for concern in [the Biotechnology] field, too. Biotech research consumes much time and money, with any payback far in the future. This isn't a problem for most of the Japanese players, because they tend to be huge corporations loaded with cash from their other operations. But many of the most promising American biotechnology firms are small and don't have any profitable business to sustain them.

Equally important, in the Japanese corporate world a manager is free to take a long-term approach, investing for years without showing any results.

Bernard Wysocki Jr., *Gene Squad: Japanese Now Target Another Field The U.S. Leads: Biotechnology*, WALL ST. J., Dec. 17, 1987, at 1.

¹⁴⁴ "America's ability to compete in a global marketplace is inextricably bound to her capacity to protect creativity, inventors, and the established reputation of her products." 133 CONG. REC. E984 (daily ed. Mar. 17, 1987) (statement of Rep. Hou).

¹⁴⁵ While Drug firms may be among the most profitable in the United States, limited patent protection is not an intelligent measure to combat the high cost of certain pharmaceuticals. One suggestion is to set maximum reimbursement levels for high-cost pharmaceuticals. Janice Castro, *Condition: Critical*, TIME, Nov. 25, 1991, at 42.

¹⁴⁶ "[T]o have science flourish you want people who take chances." Leon Jaroff, *Crisis in the Labs*, TIME, Aug. 26, 1991, at 49 (quoting Physicist Nicholas Samious, direc-

mandate that Congress promote "the Sciences and the Useful Arts."¹⁴⁷

V. CONCLUSION

The *Angen* case provides in crystalline form the problem in U.S. trade laws. If our society expects inventors to improve our standard of living, increase the number of jobs for our citizens, and even help maintain our liberty, it must provide domestic innovators protection against the unfair trade practices of foreign importers.¹⁴⁸

We expect our biotechnology industry to produce prosthetic devices, pharmaceutical products and industrial chemicals. If we expect scientists and investors to actively seek to develop these products, the laws must provide incentives and protection to encourage these groups to practice their art. If as a society we determine that the biotechnology industry is not of sufficient social utility to warrant more extensive patent protection, we may have unwittingly chosen to stand by and watch another U.S. industry disappear in a tidal wave of foreign competition.

After the sun sets on another American industry, the critics can point fingers and tirelessly write volumes about what should have been done decades earlier.

John Christopher Hunt*

tor of Brookhaven National Laboratory in New York). But people do not take chances if the rewards do not outweigh the risks.

¹⁴⁷ Art. I, § 8, cl. 8. The Act would also further the policy behind the Process Patent Amendments of 1988. 35 U.S.C. § 271(g).

¹⁴⁸ Leon Jaroff, *Crisis in the Labs*, TIME, Aug. 26, 1991, at 45 (quoting VANNEVAR BUSH, SCIENCE: THE ENDLESS FRONTIER (1945)).

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