

1992

## The Regulation of Biotechnical Patented Imports Under the Omnibus Trade & Competitiveness Act

Lavanya Srivatsan

Follow this and additional works at: <http://digitalcommons.wcl.american.edu/auilr>



Part of the [International Law Commons](#)

---

### Recommended Citation

Srivatsan, Lavanya. "The Regulation of Biotechnical Patented Imports Under the Omnibus Trade & Competitiveness Act." American University International Law Review 7, no. 2 (1992): 345-365.

This Article is brought to you for free and open access by the Washington College of Law Journals & Law Reviews at Digital Commons @ American University Washington College of Law. It has been accepted for inclusion in American University International Law Review by an authorized administrator of Digital Commons @ American University Washington College of Law. For more information, please contact [fbrown@wcl.american.edu](mailto:fbrown@wcl.american.edu).

# THE REGULATION OF BIOTECHNICAL PATENTED IMPORTS UNDER THE OMNIBUS TRADE & COMPETITIVENESS ACT

Lavanya Srivatsan\*

## INTRODUCTION

The expanding<sup>1</sup> American biotechnology<sup>2</sup> industry advances significant financial and humanitarian support for the United States.<sup>3</sup> This newly emerging business competes in the economic marketplace as a profit-making enterprise.<sup>4</sup> Furthermore, the industry's increased globalization<sup>5</sup> assists United States competitiveness<sup>6</sup> at a period when the economy is faltering.<sup>7</sup> Innovation<sup>8</sup> in biotechnology also enhances the

---

\* Lavanya Srivatsan, J.D. Candidate, American University, May 1992 and M.S. Candidate, Johns Hopkins University, August 1992.

1. See G. S. BURRILL, *BIOTECH 90: INTO THE NEXT DECADE* 28 (1989) [hereinafter BURRILL] (noting that the biotechnology industry expects a twenty-five fold increase in sales in the next ten years).

2. See generally B. SATTELLE, *BIOTECHNOLOGY IN PERSPECTIVE* (1990) [hereinafter SATTELLE] (defining the uses of biotechnology). Biotechnology as used in this Comment, refers to an industry which uses living organisms and their subcellular, cellular or molecular components in environmental management technology and in the production of health-related goods. *Id.* at 4. Although biotechnology is at the forefront of present day applied science, many of the underlying biotechnological processes originated thousands of years ago and are the basis for the production of bread, cheese, beer, and wine. *Id.* at 6. Today, biotechnology comprises a full range of technologies in the mapping of proteins, including recombinant Deoxyribonucleic Acid (DNA) and cell fusion. See *id.* at 20 (outlining the uses of biotechnology); see also CENTER FOR SCIENCE INFORMATION, *BIOTECHNOLOGY, MICROBES AND THE ENVIRONMENT* 207-19 [hereinafter MICROBES AND THE ENVIRONMENT] (citing the tools used in environmental biotechnology and profiling renowned biotechnology experts).

3. See *infra* notes 9, 11, 13 and accompanying text (acknowledging United States efforts to preserve the environment and improve the Nation's health and food supply through the use of biotechnology).

4. BURRILL, *supra* note 1, at 125-27. Public biotechnological companies received \$1.36 billion in annual total sales and \$2.08 billion in annual total revenues. *Id.* at 125. In addition, the industry employs an estimated sixty thousand people. *Id.* This employment figure is expected to triple in the next five years. *Id.* at 18.

5. *Id.* at 30. American biotechnology companies are active in foreign markets. *Id.* More than fifty percent of all large companies and forty percent of all small companies have sales in Western Europe, Japan, and Canada. *Id.* at 87. In addition, exports are expected to soon equal imports. *Id.* at 87-88.

6. See BURRILL, *supra* note 1, at 144 (discussing the value of pharmaceutical compounds and noting that they generate more than \$1 billion in domestic revenues).

7. See Greenwald, *All Shook Up*, TIME, Oct. 15, 1990, at 30 (noting an increased unemployment rate and budget deficit).

quality of human lives.<sup>9</sup> For example, advancements in genetic engineering<sup>10</sup> have produced superior varieties of crops,<sup>11</sup> vaccines,<sup>12</sup> and environmental control technologies.<sup>13</sup> Although ethical issues exist regarding the utilization of some types of biotechnology,<sup>14</sup> the products of

---

8. Merges, *Commercial Success & Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803, 807 (1988) [hereinafter Merges] (defining "innovation" as the "functional version of a technology that is the first commercial product").

9. See generally MICROBES AND THE ENVIRONMENT, *supra* note 2, at 34-40 (maintaining that science and technology are intimately related to health and the preservation of the ecological environment); Jaworski, *Biotechnology: Prospects and Perspectives*, 34 U. KAN. L. REV. 655, 665-67, 660-61 (1986) [hereinafter Jaworski] (focusing on current research in tissue culture and microbial pesticides). Congressional studies indicate that "[t]he potential of biotechnology to improve the Nation's health, food supply, and the quality of the environment leads logically to questions about the adequacy of current funding levels." OFF. TECH. ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY, U.S. Investment in Biotechnology 1 (July 1988); see also Adler, *Controlling Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting*, 1 HARV. J.L. & TECH. 1, 17-22 (1988) (exploring biotechnology including the subject of transgenic animals).

10. See generally SATTELLE, *supra* note 2, at 16 (evaluating the principles of genetic engineering). Genetic engineering refers to the two techniques scientists use for internally altering the genetic structure of an organism: cell fusion and recombinant DNA. *Id.*; see Karney, *Regulation of Genetic Engineering: Less Concern About Frankensteins But Time for Action on Commercial Production*, 12 U. TOL. L. REV. 815, 819 n.23 (1981) (explaining the underlying principles of genetic engineering).

11. See Jaworski, *supra* note 9, at 655-57 (discussing the uses of microbial pesticides). Current technology can increase crop yields and decrease plant diseases and pests. *Id.*

12. See SATTELLE, *supra* note 2, at 25 (detailing the use of biotechnology in the development of vaccines). Vaccines enable the body to resist infection from diseases and have, thus, served to alleviate human suffering. *Id.* For example, twenty years ago, small pox was endemic in at least thirty different countries with more than ten million people infected. *Id.* Today, however, this major disease has been virtually eliminated. *Id.* Other viral diseases successfully treated by vaccines include polio, yellow fever, rabies, and rubella (German measles). *Id.*

13. See *Diamond v. Chakrabarty*, 447 U.S. 303, 304 (1980) (describing the role of bacterium capable of breaking down crude oil); MICROBES AND THE ENVIRONMENT, *supra* note 2, at 43-62 (acknowledging the types of microbes released into the environment). Microorganisms can be employed to purify waste water in sewage disposal. *Id.*; see SATTELLE, *supra* note 2, at 36-37 (addressing the role of microbes in environmental control). In addition, the waste sulfite liquid from paper-making mills can be purified by *paecilomyces* fungi. *Id.* at 37.

14. See Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 743-45 (1990) (suggesting that there are advantages in patenting parts of the human genome); OFF. TECH. ASSESSMENT, REPORT BRIEF, NEW DEVELOPMENTS IN BIOTECHNOLOGY, *Ownership of Human Tissues and Cells - Special Report* (March 1987) (defining the laws that relate to the ownership of human biological materials). Four issues are particularly controversial. *Id.* The first issue concerns the ownership and control of scientifically-generated information. *Id.* The second is the issue of mandatory genetic screening. See Capron, *Which Ills to Bear? Reevaluating the Threat of Modern Genetics*, 39 EMORY L.J. 665, 684-89 (1990) (elaborating on the ethical considerations associated with genetic screening). The third concern is the use of genetic information for reproductive decision making. See generally S. ELIAS & G. ANNAS, *REPRODUCTIVE GENETICS AND THE LAW* (1987) (considering the legal issues surrounding the use of

this industry are useful and essential.<sup>16</sup> In order to continue to provide beneficial technology, this industry merits adequate patent<sup>16</sup> protection.<sup>17</sup>

Patent laws are the primary means by which an inventor can protect new technology from infringement<sup>18</sup> within the United States.<sup>19</sup> Patent rights,<sup>20</sup> including the right to litigate for unauthorized use or manufacture, provide a critical competitive advantage in the biotechnology industry.<sup>21</sup> Development of one biotechnological product can cost mil-

---

genetic knowledge in selecting the characteristics of offspring); Knoppers & Sloss, *Recent Developments: Legislative Reforms in Reproductive Technology*, 18 OTTAWA L. REV. 663, 666-67 (1986) (examining emerging trends in the "medicalization" of reproduction and the "judicialization" of pregnancy in six countries). The fourth controversy is the patenting of animals whose hereditary genes have been augmented by the addition of Deoxyribonucleic Acid (DNA) by humans. See H.R. 1556, 101st Cong., 2d Sess. (1989); H.R. 1557, 101st Cong., 2d Sess. (1989) (addressing the scientific and regulatory questions involved in the patenting of transgenic animals).

15. See *supra* notes 9, 11, 13 and accompanying text (noting the use of biotechnology in the United States as a means by which to preserve the environment and to enhance the Nation's health and food supply).

16. See 35 U.S.C. §§ 161, 171 (1988) (denoting the three main types of patents: design, plant, and utility). Patents in biotechnology are an ancient practice. See *Louis Pasteur's Patents*, 86 SCI. 327, Oct. 8, 1937, reprinted in 19 J. PAT. OFF. SOC'Y 966 (1937). Many patents have been granted for the use of micro-organisms in fermentation and antibiotic production. *Id.* Louis Pasteur, for example, patented a number of yeast-related inventions. *Id.*; see also *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F.2d 453, 454-56 (2d Cir. 1908) (discussing the patent for the original bacteria-using septic tank), *cert. denied*, 209 U.S. 548 (1908). This Comment focuses on utility patents as related to biotechnology.

17. See Karney, *Biotechnology Licensing*, 8 LICENSING L. & BUS. REP. 1, 2 (1985) (commenting on the legal implications of the commercialization of biotechnology); Comment, *Enemies to Innovation: Protecting Biotechnology Inventions*, 5 SANTA CLARA COMPUTER & HIGH TECH. L.J. 435, 436 (1989) (evaluating proprietary rights in biotechnology).

18. *Autogiro Co. v. United States*, 384 F.2d 391, 400 (Cl. Ct. 1967). The critical test in any infringement suit is whether the allegedly infringing device does "the same work, in substantially the same way, and accomplish[es] substantially the same results" as the patented product or processes. *Id.* The largest infringement suit to date occurred when Polaroid Company was awarded \$910 million in a suit against Kodak. N.Y. Times, Oct. 22, 1990, at 4.

19. See 35 U.S.C. §§ 161, 171 (1988) (setting forth the means to enforce patent infringement claims within the United States).

20. See *infra* notes 77-79 and accompanying text (assessing the protection provided to an invention by the issuance of a patent).

21. See Note, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100, 101-04 (1988) (commenting on the United States rising competitive position in the biotechnology industry) [hereinafter Note, *Genetic Engineering*]; OFF. TECH. ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY, PATENTING LIFE 29 (1989) [hereinafter *Patenting Life*] (noting that patent law is of increasing importance to biotechnology research and concluding that patent protection of biotechnology products is an issue that presents a potential barrier to commercialization). Patents benefit commercial entities by attracting venture capital and collaborative arrangements. *Id.* Investors monitor biotechnological patent developments and often respond

lions of dollars and span several years.<sup>22</sup> The patent system encourages innovation<sup>23</sup> by providing an incentive to invest in such costly research and development.<sup>24</sup> In the absence of effective intellectual property rights, there would be little incentive to innovate in biotechnology.<sup>25</sup>

Section 337 of the Omnibus Trade and Competitiveness Act<sup>26</sup> (OTCA) is the principal means by which an inventor may protect a process patent<sup>27</sup> from foreign infringement. Congress enacted the OTCA, in part, in an effort to confront the issue of effective intellectual

quickly to the news. *Id.* For example, in 1980, Genentech set a Wall Street record for the fastest price per share increase in an initial offering of stock. *Id.* at 30. The stock price increased from \$35.00 to \$89.00 in twenty minutes. *Id.* That same year, Cetus set the record for the largest sum of money raised in an initial public offering - \$115 million. *Id.*

Since Italy began providing patent protection in 1978, Italian companies have increased their market share of pharmaceutical products from thirty-six percent to forty-four percent. *Patents Stimulate the Development of Pharmaceutical Companies in Italy*, 7 Int'l Trade Rep. (BNA) at 1201 (Aug. 1, 1990). Prior to 1978, only one Italian company was among the fifty larger pharmaceutical companies in the world. *Id.* In 1991, there are seven. *Id.*

22. *Process Patent Amendments of 1990: Hearings on H.R. 3957, 5664 Before the Subcomm. on Courts, Intellectual Property and the Administration of Justice of the House Comm. on the Judiciary*, 101st Cong., 2d sess. (1990) [hereinafter *Hearings*] (testimony of David Beir, Vice-President Government Affairs, Genentech, Inc.). The current cost of developing a new biopharmaceutical therapy can easily exceed \$230 million. *Id.* Amgen, Inc. spent eight years and over \$100 million to develop erythropoietin, a drug useful to people suffering from anemia. *See id.* (testimony of Gordon Binder, Chairman & Chief Executive Officer, Amgen, Inc.).

23. *See Sony Corp. v. Universal City Studios*, 464 U.S. 417, 426 (1984) (reasoning that the monopoly privileges authorized by Congress are intended to motivate the creativity of authors and inventors by means of a "reward"); STAFF OF SENATE COMM. ON THE JUDICIARY, 85th CONG., 2d SESS., STUDY OF THE SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS - AN ECONOMIC REVIEW OF THE PATENT SYSTEM 15 (Comm. Print 1958) (providing a general discussion of the relationship between innovation and patents and of the "exchange for secrets thesis" of the patent system by the noted economist Fritz Machlup); *see also* Merges, *supra* note 8, at 807 (contending that the patent system encourages and rewards innovation).

24. *See supra* note 22 (addressing the costliness of biotechnology research and development).

25. Merges, *supra* note 8, at 876 (detailing the history of patent law); *see* Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 174 (1986) (interpreting the results of an empirical study regarding the interrelationship between patents and innovation).

26. Omnibus Trade and Competitiveness Act of 1988, 19 U.S.C. § 1337(a)-(j) (1988) [hereinafter OTCA]; *see* 134 CONG. REC. H5520 (daily ed. July 13, 1988) (referencing the debate over the OTCA amendments). Section 337 of the Tariff Act of 1930 has carried over to present day use despite changes in the actual section numbers; thus, section 1337 is generally referred to as section 337. Note, *Overview of Amendments in the 1988 Omnibus Trade Bill: Sections 301, "Super 301" and 337*, 730 B.Y.U.L. REV. 729, 729 n.1 (1989).

27. *See supra* note 16 and accompanying text (focusing on the three patent categories).

property protection.<sup>28</sup> The OTCA was intended to eliminate the unauthorized importation of patented goods into the United States.<sup>29</sup> The biotechnology industry depends on the OTCA to uphold the value of its patents and prevent infringement by foreign manufacturers.<sup>30</sup>

This Comment discusses the effectiveness of patent protection under the OTCA. The Court of Appeals for the Federal Circuit<sup>31</sup> clarified the scope of the OTCA in *Amgen, Inc. v. United States International Trade Commission*.<sup>32</sup> The court held that the OTCA does not prohibit the importation of foreign goods produced by a process in which a starting product claimed in a United States patent is used.<sup>33</sup> The court declined to assess the adequacy of available patent protection, reasoning that such an issue should be resolved by the legislature.<sup>34</sup> *Amgen* illustrates the inadequacy of biotechnical patent protection provided by the OTCA.

Part I of this Comment discusses the purpose and privileges of patent laws. Part I also briefly explores the dependence of the biotechnology industry on patents. Part II details the evolution of the OTCA and the limited protection accorded by section 337 against the infringement of process patents. Part III discusses the underlying issues and implications of the *Amgen* decision. Part IV analyzes the scope of section 337 of the OTCA and illustrates the failure of the OTCA to stimulate innovation and provide adequate protection of intellectual property rights. This section also addresses the consequences of such deficiencies on the biotechnology industry. Finally, Part V urges Congress to strengthen and extend the OTCA's reach in an effort to protect *all* types of patent claims. Part V contends that such strengthening would advance fundamental goals that are the essence of intellectual property rights.

---

28. See *infra* notes 102-105 (discussing the reasons the OTCA was enacted).

29. See Newman, *infra* note 96, at 575-80 (reviewing the history of the OTCA).

30. See *Hearings, supra* note 22, at 2-7 (demonstrating the importance of patents to the biotechnology industry).

31. See *Merges, supra* note 8, at 806 (noting that Congress established the Court of Appeals for the Federal Circuit in 1982 in an effort to improve and create conformity in the patent system).

32. 902 F.2d 1532 (Fed. Cir. 1990).

33. *Id.* at 1539.

34. *Id.* at 1540.

## I. AN OVERVIEW OF PATENT LAW

### A. PATENTS ENDEAVOR TO PROMOTE INNOVATION IN BIOTECHNOLOGY

The Constitution provides the basis for the concept of American intellectual property rights.<sup>35</sup> Article I of the Constitution grants Congress broad legislative power "[t]o promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited [t]imes to [a]uthors and [i]nventors the exclusive right to their respective [w]ritings and [d]iscoveries."<sup>36</sup> Congress chose to achieve this goal by issuing patents to deserving authors and inventors.<sup>37</sup>

The granting of patents advances the collective goals of disclosure and reward.<sup>38</sup> Inventors disclose their inventions to society, and in return society rewards such efforts through the issuance of limited property rights in each invention.<sup>39</sup> This reciprocal relationship is essential for three reasons. First, the development of new technologies alleviates the impact of increased foreign competition.<sup>40</sup> New technology fosters United States growth and productivity.<sup>41</sup> Second, society as a whole benefits by the introduction of new inventions.<sup>42</sup> Third, the disclosure and reward method promotes further innovation because researchers can improve on the patented inventions of others.<sup>43</sup>

Some commentators erroneously assert that the patent system does not impact the development of innovation.<sup>44</sup> These critics allege that

---

35. U.S. CONST. art. I, § 8, cl. 8. The concept of intellectual property protection originates from English common law. *Patenting Life*, *supra* note 21, at 3.

36. U.S. CONST. art. I, § 8, cl. 8.

37. 35 U.S.C. §§ 100-104 (1988).

38. *Merges*, *supra* note 8, at 808; *see also* Waltersheid, *The Need for a Uniform Government Patent Policy: The D.O.E. Example*, 3 HARV. J.L. & TECH. 103, 184 (1990) (emphasizing the tendency of courts to favor disclosure as the ultimate goal of the federal patent system).

39. *Merges*, *supra* note 8, at 809.

40. *See* Clark, *The Future of Patent-Based Investigations Under Section 337 After the Omnibus Trade and Competitiveness Act of 1988*, 38 AM. U.L. REV. 1149, 1150-51 (1989) [hereinafter Clark] (characterizing the effects of increased technological development); *see also* Perry, *The Surprising New Power of Patents*, FORTUNE, June 23, 1986, at 57 (acknowledging the recent growth in the financial power of patents) [hereinafter Perry].

41. Clark, *supra* note 40, at 1150-51.

42. *See* *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (maintaining that the introduction of new technologies provides increased employment opportunities and improvements in the standard of living).

43. *Merges*, *supra* note 8, at 808. A researcher is able to examine and improve upon another's invention, thus, fostering additional product innovation. *Id.*

44. *See* Note, *Genetic Engineering*, *supra* note 21, at 101 (outlining the arguments of patent reform critics).

the patent system results in commercial monopolization<sup>45</sup> and frustrates technological advancement.<sup>46</sup> This argument, however, is flawed; a patent in itself does not constitute a monopoly.<sup>47</sup> Moreover, a patentee engaging in monopolistic behavior, in acquiring or using the patent, is accountable to antitrust laws.<sup>48</sup> Critics also contend that the general economic climate impacts the development of technology more than any other specific measure.<sup>49</sup> This reasoning is inconclusive because it fails to address specific industry issues.

Patents are a critical element in promoting innovation in biotechnology.<sup>50</sup> The average biotechnology firm spends a tremendous amount of funds on research and development.<sup>51</sup> Commercial biotechnology, more than any other high technology industry, depends on research and development to generate revenue.<sup>52</sup> A company generates income on patented products through exclusivity in marketing.<sup>53</sup> Patents offer the op-

---

45. *Id.*

46. *Id.*

47. *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186 (1933). In *Dubilier Condenser Corp.*, the Supreme Court reasoned that an inventor does not deprive society of anything that it enjoyed prior to his or her discovery; instead, the inventor aids society by "adding to the sum of human knowledge." *Id.*

48. *United States v. Studiengesellschaft Kohle*, 670 F.2d 1122, 1127-28, 1133-34 (D.C. Cir. 1981).

49. *BUS. WEEK*, June 15, 1990, at 35.

50. See *Patent Life*, *supra* note 21, at 3 (asserting that patents are vital to protecting commercial interests in biotechnology); Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1045-46 (1989) (noting that although patents are justified as a means of providing incentives, there are no clear answers to the empirical questions of when these incentives are needed); see also BURRILL, *supra* note 1, at 94-95 (reviewing the number of patents held by various biotechnological firms).

51. See *Hearings*, *supra* note 22, at 1 (testimony of Robert Armitage, Vice President, The Upjohn Company) (estimating that Upjohn's expenditures on research for 1990 amounted to more than \$400 million). The start-up costs of a biotechnological company, which include basic research and development, are usually so high that most companies can only achieve profitability as they expand. BURRILL, *supra* note 1, at 104. Research and development costs vary depending on the size of the company. *Id.* at 107. Small companies spend 40 percent of total costs while large companies spend 41 percent of total costs. *Id.* For example, research costs can amount to as much as \$8.6 million per year. *Id.*; see also *BUS. WEEK*, *supra* note 49, at 207-08 (providing research and development statistics for the pharmaceutical industry). The United States biotechnology industry spends more than \$2.0 billion annually in research and development. *U.S. Investment in Biotechnology*, *supra* note 9, at 3.

52. See BURRILL, *supra* note 1, at 28 (proposing that biotechnology companies are supported and driven by the potential for future commercial success). Two-thirds of the biotechnology industry's total revenue is generated by product sales. *Id.* Large companies typically earn as much as \$57.7 million in sales. *Id.* at 105. Contract and collaborative research are the other major sources of revenue. *Id.*

53. See *Patenting Life*, *supra* note 21, at 3 (stressing the vital role of patents in protecting commercial interests in biotechnology).



portunity to procure substantial profits from new inventions.<sup>54</sup> The reward of a patent, thus, justifies the enormous financial risks of research and development.<sup>55</sup> Adequate patent protection is, therefore, crucial in an effort to encourage innovation in biotechnology.<sup>56</sup> The lack of adequate patent protection jeopardizes essential economic and humanitarian benefits provided by this industry.

## B. PATENT STANDARDS & LITIGATION RIGHTS

An invention must meet specific criteria to merit a patent award.<sup>57</sup> The invention must be new,<sup>58</sup> non-obvious,<sup>59</sup> and useful.<sup>60</sup> The subject matter of the invention must also be considered patentable.<sup>61</sup> Product and process patents are the two predominant categories of patentable subject matter.<sup>62</sup> A product is a physical entity such as a machine,

---

54. See BURRILL, *supra* note 1, at 144 (opining that "[t]here has never been on the face of this earth a product more profitable than a blockbuster pill"). Furthermore, "[a]n effective pill is probably one of the best creations of capitalism because . . . the customer receives incredible value, and the reward to the investor who took risk to create that pill is enormous." *Id.*

55. *Id.*

56. See *id.* at 210 (noting that "[i]f the invention is truly valuable and cannot be protected except by a patent, then a patent is well worth having, despite the expense") (quoting Howard C. Birndorf, President of Progenx Inc.).

57. 35 U.S.C. §§ 100-04 (1988). Title 35 delineates the measures that must be taken in securing a patent application and grant. *Id.*

58. *Id.* at § 102(a)-(g). An invention is not patentable under this section if it is described in a printed publication or another patent prior to the patent applicant's date of invention, or if it is otherwise known or used in the United States prior to that date. *Id.* There are several other detailed provisions denoting when an invention is not considered novel. *Id.*

59. *Id.* at § 103; see *Graham v. John Deere Co.*, 383 U.S. 1, 14-17 (1966) (concluding that section 103 requires an independent determination of nonobviousness as a prerequisite to patentability). Three indicia are considered in determining nonobviousness. *Id.* at 17. First, the state of the prior art before the invention must be found. *Id.* Second, the ordinary level of skill in the inventor's field is assessed. *Id.* Third, the difference between the invention and the prior art is examined. *Id.*

60. 35 U.S.C. § 101 (1988). The utility requirement is derived from two sources. First, the Constitution mandates protection for the "useful Arts." U.S. CONST. art 1, § 8, cl. 8. Second, the Patent Act specifies that an invention must be useful. 35 U.S.C. § 101 (1988). An invention must be of some benefit qualitatively, but no particular quantum benefit is required. *Anderson v. Natta*, 480 F.2d 1392, 1395 (C.C.P.A. 1973). Utility cannot be presumed. 35 U.S.C. § 112 (1988). It must be disclosed as an integral part of the patent specification. *Id.*

61. 35 U.S.C. § 101 (1988). "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." *Id.*

62. See D. CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT §§ 1.02-.03 (1988) [hereinafter CHISUM] (discussing the different categories of patents).

manufacture or composition.<sup>63</sup> A process, however, is defined as a "means to an end."<sup>64</sup> For example, assume an invention contains a patented process that isolates a precise protein through a sequence of steps incorporated in a machine. The machine itself is patentable as a process patent.<sup>65</sup> Essential starting materials may or may not be patentable.<sup>66</sup> Additionally, the end-product of the process - the isolated protein - may warrant an independent product patent.<sup>67</sup>

A patent, regardless of its classification, accords particular privileges to its owner.<sup>68</sup> It grants a limited property right<sup>69</sup> in the invention for a term of seventeen years.<sup>70</sup> A patentee<sup>71</sup> is entitled to litigate<sup>72</sup> against unauthorized individuals<sup>73</sup> who make, use, or sell, the invention within the United States.<sup>74</sup> A patent entitles a patentee to bring suit against a foreign importer that manufactures an American product patent abroad and sells that product in the United States.<sup>75</sup> The patentee has a viable cause of action in such a case because the patent is materially infringed in the United States.<sup>76</sup>

Prior to the OTCA, an infringement suit could not be filed against foreign manufacturers who made, used, or sold an American process patent abroad and then exported the resulting end-product into the

---

63. *Id.* § 1.02.

64. *Id.* § 1.03.

65. 35 U.S.C. §§ 100-01 (1988).

66. CHISUM, *supra* note 62, § 1.02.

67. *Id.* Naturally occurring substances are not usually considered patentable. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Substances or organisms that have been humanly modified may qualify for patentability. *Id.* at 309-10.

68. See 35 U.S.C. §§ 261-62 (1988) (delineating the rights of the patentee).

69. See 35 U.S.C. § 261 (1988) (stating that patents have the attributes of personal property).

70. *Id.* § 154. Section 154, entitled "Contents and term of patent," states:

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, subject to the payment of fees as provided for in this title, of the right to exclude others from making, using, or selling the invention throughout the United States . . . .

*Id.*

71. See *id.* § 100(d) (defining the term "patentee" as including the individual to whom the patent was issued as well as any successors in title). *Id.*

72. See *id.* § 281 (stating that a patentee is entitled to bring a civil action for patent infringement).

73. See *id.* § 271(a) (providing that "whoever without authority makes, uses, or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent."). Even an innocent infringer who develops the same invention independently can be prevented from using the patent. *Id.* § 154.

74. *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972) (holding that the United States patent system has no extraterritorial effect).

75. *Id.*

76. *Id.*

United States.<sup>77</sup> These foreign manufacturers were not concerned with infringement actions because the physical infringement of the process patent occurred outside the United States and American patent laws did not provide a remedy in such a case.<sup>78</sup> Meanwhile, an injured process patentee's sole recourse was existing trade legislation allowing a claim for an unfair action.<sup>79</sup> Injured patentees filed suits under section 337 of the Tariff Act of 1930<sup>80</sup> at the International Trade Commission (ITC).<sup>81</sup>

## II. EVOLUTION OF THE OTCA

### A. THE INEFFECTIVE PRE-OTCA REMEDY: SECTION 337 OF THE TARIFF ACT

Section 337 of the Tariff Act of 1930<sup>82</sup> (Tariff Act) is the predecessor of section 337 of the OTCA.<sup>83</sup> The Tariff Act's drafters intended to stimulate the growth of industry and protect American labor by preventing unfair tactics or methods of competition in the importation

---

77. See Tariff Act of 1930, 19 U.S.C. § 1337 (1982 & Supp. IV 1986), *amended by* OTCA, 19 U.S.C. § 1342 (1988) (denoting the rights available to the patentee).

78. *Id.* The Contributory Infringement Doctrine also did not provide the patentee with a form of relief. *Id.* Contributory infringement requires direct infringement "unauthorized use of the process within the United States." *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972). A manufacturer using an infringing process patent outside the United States was able to export that product into the United States without directly infringing the process patent. *Id.*

79. See 19 U.S.C. § 1337 (1988) (demonstrating the inadequate protection accorded by federal law). Section 337(a) of the Tariff Act of 1930, as amended, prohibits unfair methods of competition and unfair acts regarding imports as follows:

Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade or commerce in the United States, are declared unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provisions of law, as provided in this section.

*Id.*

80. *Id.*

81. See *id.* § 1330. (describing the organization of the International Trade Commission). The administrative process for obtaining protection under section 337 is designed to provide efficient and expeditious relief. See H. KAYE, P. PLAIA & H. HERTZBERG, *INTERNATIONAL TRADE PRACTICE* § 2.02 (1987) [hereinafter *INTERNATIONAL TRADE PRACTICE*] (detailing the establishment of Revenue Commission of 1865).

82. Tariff Act of 1930, 19 U.S.C. § 1337 (1982 & Supp. IV 1986), *amended by* OTCA, 19 U.S.C. § 1342, at 1212-15 (1988).

83. 19 U.S.C. § 1337(a) (1988).

of articles into the United States.<sup>84</sup> The drafters sought to hold foreign importers to the same standards of fairness that were expected of domestic industries.<sup>85</sup> Thus, the Tariff Act prohibited foreign importers from engaging in unfair acts that damage, restrain or inhibit United States businesses.<sup>86</sup> In interpreting the Tariff Act, courts included patent infringement within the meaning of an unfair act.<sup>87</sup>

The designation of a patent infringement as an unfair act, however, did not protect all patentees, as demonstrated by the case *In re Amtorg Trading Corp.*<sup>88</sup> The court in *Amtorg* held that the importation of a product produced outside the United States using a patented process was not an infringement under United States patent law.<sup>89</sup> In response, Congress amended section 337 of the Tariff Act to prohibit the unauthorized importation of products, produced under a valid United States process patent.<sup>90</sup> This statute gave the ITC<sup>91</sup> two options upon establishment of the unlawful act.<sup>92</sup> First, the ITC had the authority to exclude articles from entry.<sup>93</sup> Second, the ITC had the power to order persons, over whom it had jurisdiction, to cease and desist from import-

84. Wineburg, *Litigating Intellectual Property Disputes at the International Trade Commission*, 68 J. PAT. OFF. SOC'Y 473, 473-74 (1986). Section 337 reaches unfair acts involving a wide variety of intellectual property causes of action as well as many business torts and antitrust problems. *Id.* at 477. The most commonly asserted unfair trade practice, however, is unauthorized patent use. *Id.*

85. INTERNATIONAL TRADE PRACTICE, *supra* note 81, at § 4.01.

86. See section 337(a) of the Tariff Act of 1930, 19 U.S.C. § 1337 (1988) (providing the standards by which to judge the damage of an unfair act).

87. *Frischer & Co. v. Bakelite Corp.*, 39 F.2d 247, 259-60 (C.C.P.A.), *cert. denied*, 282 U.S. 852 (1930).

88. *In re Amtorg Trading Corp.*, 75 F.2d 826, 832-34 (C.C.P.A.), *cert. denied*, 296 U.S. 576 (1935).

89. *Id.* The court noted that protection granted by a United States patent right is confined to the United States and infringement of this right cannot be established by acts performed in a foreign country. *Id.* at 831-32.

90. See 19 U.S.C. § 1337(a) (1982) (repealed 1988) (describing that imported products made by a process covered by a claim of a valid United States patent are governed by that patent just as competing domestic products are covered).

91. See *supra* note 81 and accompanying text (providing background information on the ITC). Anyone, including a nonparty, who was adversely affected by the ITC's final determination could appeal the decision to the Court of Appeals for the Federal Circuit. 19 U.S.C. § 1337(c) (Supp. IV 1982).

92. 19 U.S.C. § 1337(c) (Supp. III 1985). Section 337 requires establishment of the following:

- (1) an unfair act of authorized use and importation;
- (2) existence of a domestic industry exploiting the patent, or the potential for such an industry;
- (3) that such U.S. industry, if existing, is efficient and economically operated;
- (4) an effect or tendency of such importation is to destroy or substantially injure that industry, or prevent the establishment of such an industry.

*Id.*

93. *Id.* § 1337(d).

ing such articles.<sup>94</sup> The ITC's ruling was subject to a policy review by the President.<sup>95</sup>

Despite congressional intent, the Tariff Act provided minimal relief to process patentees against infringing imports.<sup>96</sup> In addition, parties found the Tariff Act to be cumbersome, costly, and ineffective.<sup>97</sup> Moreover, injured process patentees still could not bring infringement suits under statutory patent laws.<sup>98</sup> Claims could only be filed under the trade laws.<sup>99</sup> In response to these inadequacies, Congress enacted the OTCA<sup>100</sup> to improve the Tariff Act and to extend the reach of patent protection.<sup>101</sup>

## B. OTCA AMENDS PATENT LAW AND THE TARIFF ACT

The OTCA resulted from more than three years of deliberation by both Congress and the Reagan Administration.<sup>102</sup> Senator Lautenberg, one of the original sponsors of the OTCA, emphasized that the intent of the Act was to encourage innovation and enhance American industry's ability to compete globally.<sup>103</sup> Congress intended the OTCA to

94. *Id.* § 1337(f).

95. *Id.* § 1337(j). Parties who were adversely affected by a Presidential veto did not have the remedy of appeal. *Duracell, Inc. v. United States Int'l Trade Comm'n*, 778 F.2d 1578, 1581-82 (Fed. Cir. 1985).

96. See Newman, *The Amendments to Section 337: Increased Protection for Intellectual Property Rights*, 20 LAW & POL'Y INT'L BUS. 571, 573-87 (1989) [hereinafter Newman] (discussing the inadequacies of the Tariff Act of 1930 and detailing subsequent amendments to increase its effectiveness).

97. *Id.*

98. *Id.* at 572.

99. *Id.*

100. OTCA, 19 U.S.C. § 1337 (1988).

101. NEWMAN, *supra* note 96, at 572-73.

102. *Id.* at 572. The amendments reflect a concern that section 337 was becoming increasingly ineffective "in addressing the growing problems being faced by U.S. companies." H.R. REP. NO. 40, 100th Cong., 1st Sess., pt. 1, at 155 (1987).

103. 134 CONG. REC. S10,714 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg). According to Senator Lautenberg:

[a] continuing goal of Congress is to encourage innovation by providing meaningful protection for the inventions and discoveries of American inventors and for the manufacture of innovative products made by American workers. The emerging biotechnology industry has pioneered a revolutionary genetic engineering technology that produces recombinantly derived materials used to make previously unavailable products.

With respect to section 1342 of the Trade Act (title 19), this bill reenacts prior section 337a of the Tariff Act of 1930 (as 337(a)(1)) which addresses protection of United States businesses from importation of products made outside of the United States by a process covered by claim of a United States patent.

Section 337(a)(1) (a reenactment of section 337a) will provide the assistance necessary for emerging U.S. industries, such as the biotechnology industry, to compete in a marketplace without interference due to the unfair acts of foreign competitors. The continued broad jurisdiction of the International Trade Com-

counter an escalating trade deficit and the country's falling competitive position.<sup>104</sup> Congress had realized that international competitiveness depends largely on the technological developments of domestic industries.<sup>105</sup>

The OTCA revised both statutory patent law and the Tariff Act of 1930.<sup>106</sup> These revisions were designed to stimulate innovation by expanding intellectual property protection.<sup>107</sup> The OTCA expands section 154 of the Tariff Act by prohibiting the use or sale within the United States, or importation into the United States, of products made by an American *process patent*.<sup>108</sup> The OTCA also allows an injured process patentee to bring an infringement suit for an injunction or damages in federal district court.<sup>109</sup>

Section 337 of the OTCA's description of unlawful activities remains essentially the same as the Tariff Act.<sup>110</sup> The OTCA altered, however, several central provisions.<sup>111</sup> The drafters revised these provisions in or-

---

mission will help U.S. industry address the unfair activity of foreign competitors who, for example, *import products manufactured using patented genetic engineering technology*. Merely moving manufacture offshore does not absolve the wrongdoer from the requirement to compete fairly. This Trade Act protection prohibits the foreign enterprise from taking jobs from American workers by doing offshore that which they could not lawfully do in the United States.

*Id.* (Emphasis added.)

104. See Clark, *Patent Based Investigations Under Section 337 After the Omnibus Trade and Competitiveness Act of 1988*, 38 AM. U.L. REV. 1149, 1150-51 (1989) [hereinafter Clark] (noting that almost every country in the world has investments in American industry).

105. *Id.* at 1151.

106. OTCA, 19 U.S.C. § 1337(a)(2)(B) (1988), *amending* 35 U.S.C. § 154 (1952). Title IX, subtitle A of the OTCA amended the Patent Act to extend protection against infringement to process patentees. *Id.* Under the OTCA, "unlawful activities" include the following:

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

*Id.* § 1342(a)(1)(B); see 134 CONG. REC. H5,520 (daily ed. July 13, 1988) (referencing the debate over the OTCA amendments).

107. OTCA, 19 U.S.C. § 1101(a)(10) (1988).

108. *Id.* § 9002; see Note, *supra* note 26, at 739-44 (outlining the new and old provisions of section 337).

109. OTCA, 19 U.S.C. § 9006(c) (1988). Section 9006 expressly preserves the remedies available under the Tariff Act. *Id.*

110. The Tariff Act of 1930, 19 U.S.C. § 337 (1982 & Supp. IV 1986); see Newman, *supra* note 100, at 575 (providing a history of the Tariff Act of 1930 and comparing it to the OTCA).

111. OTCA, 19 U.S.C. § 1337(a). Specifically, the new section 337 mandates that "[i]f intellectual property rights are registered under United States law, injury need not be shown." *Id.* The showing of injury by a United States industry is still required,

der to ease a patent holder's burden of proving foreign process patent infringement and to limit the remedies against United States parties.<sup>112</sup> Congress recognized the need to protect American industries from unfair acts and process patent infringements by improving the scope of patent law and the provisions of the Tariff Act.<sup>113</sup>

### III. THE EFFECT OF THE OTCA ON AMGEN

Even though Congress conceived OTCA to protect against intellectual property piracy and promote United States industry,<sup>114</sup> the Court of Appeals for the Federal Circuit cast doubt upon the OTCA's ability to address these concerns with its decision in *Amgen, Inc. v. United States Int'l Trade Comm'n.*<sup>115</sup>

#### A. BACKGROUND OF *Amgen*

Amgen, Inc. is a company dedicated to the development of human pharmaceuticals through the advancement of recombinant DNA<sup>116</sup>

---

but the requirement that it must be an economic injury was eliminated. *Id.* § 1337(a)(3).

112. See 134 CONG. REC. H5,520, H5,529 (daily ed. July 13, 1988) (statement of Rep. Fish) (emphasizing the importance of process patent protection to the stability of United States industry).

113. *Id.*

114. See *id.* (supporting of the enactment of the OTCA amendments); Newman, *supra* note 100, at 575 (providing arguments in favor of the OTCA amendments).

115. 902 F.2d at 1532. This case was one of first impression for the court. See *id.* at 1540 (acknowledging that Congress had not contemplated the specific patent issue presented).

116. See *Engineering, Genetic Style*, 15 NAT'L J. 2097, Oct. 15, 1983 (1983) (defining recombinant deoxyribonucleic acid (DNA) and discussing its use in genetic engineering); see also D. VOET & J. VOET, *BIOCHEMISTRY* 772-86 (1990) [hereinafter *BIOCHEMISTRY*] (providing a detailed discussion of DNA); SATTELLE, *supra* note 2, at 20 (describing recombinant DNA technology); L. STRYER, *BIOCHEMISTRY* 117 (3d ed. 1988) (specifying the function and structure of enzymatic and protein activity in recombinant DNA); Dressler & Potter, *Molecular Mechanisms in Genetic Recombination*, ANN. REV. *BIOCHEMISTRY* 727, 727-61 (1982) (detailing current innovations in gene splicing and recombination); Stahl, *Genetic Recombination*, SCI. AM., Feb., 1987, at 90-101 (discussing the recent developments in genetic engineering).

Genes contain information necessary for the composition of a particular protein. *BIOCHEMISTRY*, *supra*, at 772-86. The recombinant-DNA method begins with the isolation of a specific genetic sequence. *Id.* Scientists look for a specific trait in a donor organism's genes for transfer to a host organism and isolate the specific segment of the donor's DNA that produces that trait. *Id.* These segments are then joined with other fragments of DNA. *Id.* The reconstructed DNA is transferred to a microorganism. *Id.*

Viral DNA was first spliced into recombinant molecules by Paul Berg of Stanford University in 1972. MICROBES AND THE ENVIRONMENT, *supra* note 2, at 191. In 1973, Stanley Cohen and Herbert Boyer launched the era of biotechnology when they spliced toad genes and recombined bacterial DNA. *Id.*

technology.<sup>117</sup> Amgen invested eight years and over \$100 million to develop recombinant erythropoietin<sup>118</sup> (rEPO).<sup>119</sup> This product helps to treat patients suffering from anemia.<sup>120</sup> Scientists at Amgen unraveled the genetic mystery of erythropoietin (EPO).<sup>121</sup> Amgen successfully produced genetically-altered cells (host cells) capable of manufacturing large amounts of EPO far more quickly than normal human cells.<sup>122</sup> Because the amount of EPO available free in nature is minimal, the unique host cells and recombinant DNA sequences are vital as starting materials to manufacture rEPO for pharmaceutical purposes.<sup>123</sup>

Amgen succeeded in obtaining a patent for its rEPO developments in 1987.<sup>124</sup> The patent, known as '008, protects Amgen's developments in recombinant DNA sequences and host cells used to produce rEPO.<sup>125</sup> Amgen's claims, however, do not extend to the product rEPO itself, to any process of making rEPO, or to any other related process.<sup>126</sup> Patent laws did not allow rEPO itself to be patented.<sup>127</sup> In sum, Amgen has a patent only on the *starting material* needed to make rEPO. Unauthorized use of Amgen's starting material within the United States constitutes unlawful infringement.<sup>128</sup>

---

117. *Hearings, supra* note 22, at 2 (statement of Gordon Binder, Chairman and Chief Executive Officer, Amgen, Inc.).

118. *See* Amgen, Inc., 902 F.2d at 1533 (describing "erythropoietin" as a protein that controls the synthesis of red blood cells in bone marrow).

119. *Id.*; *see* BURRILL, *supra* note 1, at 195 (observing that researchers have reported that the production of recombinant products, as compared to other biotech products, is particularly difficult and expensive).

120. Amgen, Inc., 902 F.2d at 1533.

121. *See Hearings, supra* note 22, at 3 (statement of Gordon Binder, Chairman and Chief Executive Officer, Amgen, Inc.).

122. Amgen, Inc., 902 F.2d at 1533.

123. *Hearings, supra* note 22, at 3. Before the development of host cells, erythropoietin was found only in minute quantities in urine. *Id.* It still cannot be purified in amounts large enough for human use. *Id.*

124. *Id.* at 4. Amgen obtained United States Patent Number 4,703,008 (the '008 patent). Amgen, Inc., 902 F.2d at 1533.

125. Amgen, Inc., 902 F.2d at 1533-34. The "claims" section of any patent is important to define the exact property rights of a patentee. *See* Duft, *Patent Infringement and Biotechnology*, 16 AIPLA Q.J. 339, 343-89 (1988) (explaining claim interpretation, the basis for infringement, and available remedies).

126. Amgen, Inc., 902 F.2d at 1533-34. The original patent application contained process claims for the production of rEPO, but the Patent and Trademark Office rejected these claims. *Id.* These claims were considered to be for the application of an old process to new starting materials. *Id.* Thus, the process itself was not patentable. *In re Durden*, 763 F.2d 1406, 1411 (Fed. Cir. 1985).

127. Amgen, Inc., 902 F.2d at 1533-34.

128. *Id.* at 1538.



In January 1988, Amgen initiated an unfair action<sup>129</sup> suit before the ITC against Chugai Pharmaceutical Co. of Japan (Chugai) and its subsidiary, Chugai Pharma U.S.A., alleging that they had imported rEPO manufactured in Japan.<sup>130</sup> Amgen claimed that Chugai used recombinant technology protected by patent and maintained that the rEPO Chugai imported was made by a process, which if practiced in the United States, would infringe the '008 patent.<sup>131</sup> During the ensuing ITC investigation,<sup>132</sup> Congress passed the OTCA,<sup>133</sup> thus, Amgen's complaint fell under the jurisdiction of section 337 of the new OTCA.<sup>134</sup>

The primary question was whether Chugai engaged in unfair activities as defined by section 337 of the OTCA.<sup>135</sup> The Court of Appeals for the Federal Circuit stated the issue as whether Chugai's imported rEPO was made employing a process protected by a claim of Amgen's patent.<sup>136</sup> Thus, the answer depended upon the court's interpretation of section 337's language concerning "a process covered by the claims of a . . . patent."<sup>137</sup> The court employed a two-step analytical approach to determine the scope of section 337 and to interpret the relevant language.<sup>138</sup> The court first examined the plain meaning of the OTCA's statutory language to determine whether section 337's language prohibited the importation of products that used patented American starting materials.<sup>139</sup> After finding that the plain language of section 337 only referred to process claims and not patented starting materials,<sup>140</sup> the court used a second approach. The court focused on the OTCA's legislative history in an effort to determine the scope of section 337.<sup>141</sup>

---

129. See *supra* notes 82-113 and accompanying text (defining the term "unfair action").

130. Amgen, Inc., 902 F.2d at 1534.

131. *Id.* at 1534, 1538.

132. *Id.* at 1534; see 19 C.F.R. § 210.53 (1988) (detailing the infringement claim procedure). When a complaint is filed, an administrative law judge at the ITC holds a preliminary hearing to examine the unfair acts and economic aspects of the foreign importation or sale. *Id.*

133. OTCA, 19 U.S.C. § 1337(a)-(j) (1988). The OTCA was passed on August 23, 1988. Amgen, Inc., 902 F.2d at 1534.

134. *Id.*

135. *Id.*

136. *Id.* Amgen requested that the issue be phrased as "whether section 1337(a)(1)(B)(ii) requires conventional process claims." *Id.* The court was limited, however, to using only the language contained in the OTCA. *Id.*

137. *Id.* at 1538.

138. *Id.*

139. *Id.*

140. Amgen, Inc., 902 F.2d at 1538.

141. *Id.*

The Court of Appeals for the Federal Circuit held that section 337 of the OTCA applies only to patents containing a process claim.<sup>142</sup> The court found that the OTCA does not prohibit the importation of articles made by a process in which a product claimed in a United States patent is used.<sup>143</sup> The court ruled that Chugai's rEPO was not made employing a process protected by a claim of Amgen's patent.<sup>144</sup> Chugai's rEPO may have used Amgen's starting materials, but, Amgen's host cells are not covered under a process patent claim; therefore, the patented host cells are not protected under section 337 of the OTCA.<sup>145</sup>

#### IV. THE INADEQUACIES OF THE OTCA

The *Amgen* decision illustrates the minimal protection accorded by the OTCA. By confining its scope exclusively to process claims,<sup>146</sup> the OTCA inadequately addresses the problems it was designed to rectify.

##### A. THE OTCA FAILS TO ENCOURAGE INNOVATION & INDUSTRY

Despite Congress' intention to use the OTCA to protect United States intellectual property rights and to encourage the development of new American technology,<sup>147</sup> the legislation has had a disappointing effect upon American industry.<sup>148</sup> As illustrated by *Amgen v. Chugai*, the OTCA has two different standards of intellectual property protection.<sup>149</sup> The OTCA guards against the infringement of process patents,<sup>150</sup> while abandoning patents lacking a process claim. Inventors can not prevent the importation of a product made abroad by a process which uses a starting material patented in the United States.<sup>151</sup> This type of relief from patent infringement is neither consistent, adequate, nor does it promote the OTCA's policy to safeguard intellectual property rights. The inconsistency of American intellectual patent law results in both disfavor and distrust in the effectiveness of a patent. Fur-

---

142. *Id.* at 139.

143. *Id.*

144. *Id.* at

145. *Id.* at 1540. The court vacated the Commission's Order which dismissed the claim for lack of jurisdiction, and remanded the case for entry of a final determination dismissing the complaint on the merits. *Id.* The ITC should have made a determination that Amgen's patent did not cover a process claim. Instead, they refused to hear it. *Id.*

146. *Id.* at 1537.

147. Clark, *supra* note 104, at 1511.

148. *Id.*

149. *Amgen, Inc.*, 902 F.2d at 1540.

150. *Id.*; see Clark, *supra* note 104, at 1151.

151. *Amgen, Inc.*, 902 F.2d at 1540.

thermore, current patent law places an unfair burden on inventors by forcing them to obtain process patents in order to properly guard their invention. These factors hinder rather than bolster American ingenuity.

Inadequate patent protection translates into a tremendous loss of revenue for American industry.<sup>152</sup> The biotechnology industry, whose commercial success depends upon a patent's ability to generate income,<sup>153</sup> is especially vulnerable. Without adequate patent protection, biotechnology companies are likely to lose much of their income.<sup>154</sup> The OTCA has the potential to harm the very industry Congress intended to protect.<sup>155</sup> As a result, American competitiveness in the international marketplace will be inhibited in an era when the trade deficit<sup>156</sup> is soaring and American leadership<sup>157</sup> in world markets is diminishing.

The OTCA also fails to promote the Constitutional goal of encouraging the arts and sciences.<sup>158</sup> Congress chose to stimulate innovation by granting patent rights.<sup>159</sup> Inadequate patent rights restrain the development of innovation in industries such as biotechnology.<sup>160</sup> Thus, the minimal protection provided by OTCA discourages, rather than encourages, the development of particular arts and sciences.

The OTCA is inadequate because it fails to provide infringement remedies for imported products that use patented starting materials abroad. The failure to provide these remedies brings irreparable consequences - it deters innovation, exposes biotechnological companies to financial ruin, and harms the American economy.

---

152. BURRILL, *supra* note 1, at 94.

153. *Id.*; see also Perry, *supra* note 40, at 57 (noting increased recognition in the value of patents).

154. See *supra* notes 50-56 (demonstrating the importance of patents to the continued success of the biotechnology industry).

155. See BUS. WEEK, *supra* note 49, at 35 (stating that innovation is a weapon of economic leadership and that laws should encourage economic leadership by protecting American ingenuity).

156. See Freadhoff, *August Trade Deficit Expanded, Reflecting Higher Oil Import Bill*, INVESTOR'S DAILY, INC., Oct. 19, 1990, at 25 (stating that the trade deficit for August 1990 was \$9.34 billion). Analysts predict a \$12 billion monthly deficit soon. *Id.*

157. See BUS. WEEK, *supra* note 49, at 35. (indicating that the fall in American leadership is evidenced by a decline in capital investments, funding of industrial research, and import penetration of domestic markets). According to renowned political scholar Don E. Kash, if America does not exploit its scientific assets more efficiently, the nation's competitiveness will gradually erode or there will be a severe economic disruption. *Id.*

158. U.S. CONST. art. I, § 8, cl. 6.

159. See *supra* notes 35-43 and accompanying text (describing the rationale behind Congress' decision to use patent rights to stimulate innovation).

160. See *supra* notes 21-25 (describing the importance of patents to the biotechnology industry).

## V. RECOMMENDATIONS

The holding in *Amgen v. Chugai* evinces a significant weakness in patent laws that were drafted prior to the emergence of the biotechnology industry.<sup>161</sup> Congress is considering amending the OTCA with the Process Patent Amendments of 1990.<sup>162</sup> This proposal attempts to meet the contemporary needs of the biotechnical industry.<sup>163</sup>

The Process Patent Amendments empower the ITC to ban foreign products that are made using a biotechnological material covered by a United States patent.<sup>164</sup> The proposed amendments would allow the ITC to exclude imported products that are made, produced, or processed using a biotechnological material covered by a valid and enforceable United States patent.<sup>165</sup> Unlike prior legislation, this proposal would also make infringement claims actionable in a district court.<sup>166</sup>

The OTCA must be amended in an effort to provide effective regulation of intellectual property rights.<sup>167</sup> The Process Patent Amendments provide an opportunity to protect American industry against unfair foreign patent infringement by expanding intellectual property rights so that patents on novel starting materials are guarded.<sup>168</sup>

Although the proposed amendments are beneficial to United States industry,<sup>169</sup> they are likely to arouse strong opposition from other trading nations.<sup>170</sup> The enactment of stronger intellectual property laws

---

161. *Amgen, Inc.*, 902 F.2d at 1540. The Federal Circuit noted:

[i]t is our impression from study of this case that the possibility of doing what Chugai is doing in Japan - using Amgen's patented host cells - is something which was not considered by the Congress in connection with the 1988 revision of section 1337. Consequently it did nothing to deal with the situation, which it certainly did not discuss.

*Id.* Commentators suggest that because biotechnology is a novel industry, it requires novel legal solutions. Brannigan, *Biotechnology and the Law*, 16 HOFSTRA L. REV. 545, 546 (1988).

162. H.R. 3957, 101st Cong., 2d Sess., 165 CONG. REC. 16,746 (1990); *see also Hearings, supra* note 22 (describing the debate over the need for additional protection for the biotechnology industry).

163. H.R. 3957, 101st Cong., 2d Sess., 165 CONG. REC. 16,746 (1990).

164. *Id.*

165. H.R. 5664, 101st Cong., 2d Sess., 136 CONG. REC. 116 (1990).

166. *Id.*

167. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 168 (1989) (prohibiting the state of Florida from providing a patent for boat hulls). Federal preemption of patent laws limits most state action in this area, and Congress therefore has the burden to impose effective regulation. *Id.*

168. H.R. 3957, 101st Cong., 2d Sess., 165 CONG. REC. 16,746 (1990).

169. *See Hearings, supra* note 22 (arguing that American industry must be protected from inherent violations of intellectual property law).

170. Bello & Homer, *United States Trade Law and Policy Series No. 16: Settling Disputes in the GATT: the Past, Present and Future*, 24 INT'L L. 519, 529 (1990) [hereinafter Bello & Homer]. Trading partners have protested prior changes to section

could breach United States international obligations under the General Agreement on Tariffs and Trade<sup>171</sup> (GATT).<sup>172</sup> The United States has taken measures to ensure that the OTCA conforms with GATT provisions.<sup>173</sup> An amendment, however, that safeguards United States industry and patents against foreign manufacturers may be construed as discriminatory against other nations.<sup>174</sup>

Nevertheless, the fear of opposition is not a sufficient reason to abandon the Process Patent Amendments. Large parts of the world are not subject to GATT rules.<sup>175</sup> Moreover, GATT dispute settlement mechanisms do not provide adequate protection for the United States.<sup>176</sup> GATT is also ineffective in terms of expediency and enforceability.<sup>177</sup> Furthermore, GATT's deficiencies will not be remedied soon.<sup>178</sup> Members of the GATT negotiating group on trade-related intellectual property rights disagree on the strategy that should be taken in resolving patent piracy problems.<sup>179</sup> The United States can not relinquish unilateral methods of protecting American industry and settling trade disputes absent a showing that GATT is an effective and timely forum for the redress of unfair trade practice complaints.<sup>180</sup> Because the international community fails to provide an operative method of preventing unfair trade acts, Congress must amend the OTCA to reflect adequate intellectual property right protection.

### CONCLUSION

In passing the OTCA, Congress ventured to protect American ingenuity in a global marketplace. The court's ruling in *Amgen*, however,

---

337 of the OTCA claiming that the changes are not compatible with article III of the General Agreement on Tariffs and Trade. *Id.*

171. General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A3, T.I.A.S. No. 1700, 55 U.N.T.S. 194 (1948) [hereinafter GATT]. GATT is a multilateral trade agreement designed to ensure fair trade, competition, and nondiscrimination throughout the world. *Id.*

172. Clark, *supra* note 104, at 1149.

173. See *Nothing To Lose But Its Chains; The ITO That Never Was*, ECONOMIST, Sept. 22, 1990, at 1 (acknowledging United States efforts to insure compliance with GATT) [hereinafter *Nothing to Lose*]. Legal scholars have proposed that the creation of a single district court to hear all foreign and domestic patent infringement cases. *Id.* Such a proposal, however, has received a great deal of criticism. *Id.*

174. Bello & Homer, *supra* note 170, at 529.

175. FED. NEWS SERVICE, Sept. 25, 1990. One-third of international commerce is not governed by internationally-recognized rules. *Id.*

176. *Id.*

177. *Id.* (quoting Carla Hills from the Meeting of the International Trade Society).

178. *Nothing To Lose But its Chains: The Economics of Managed Trade*, ECONOMIST, Sept. 22, 1990, at 20.

179. *Id.*

180. FED. NEWS SERVICE, Sept. 25, 1990.

demonstrates that this goal will not be realized under the current legislative scheme. While section 337 protects the claims of a process patentee, it does not defend other types of claims, such as patented biotechnological starting materials. This deficiency in trade law leaves patents prey to foreign avarice.

The inadequacy of protection provided by American trade and intellectual property laws is detrimental to society. Such minimal intellectual property protection inhibits innovation, threatens the financial stability of biotechnology companies, and stifles the growth of the American economy. In addition, consumers suffer the ultimate loss in foregone product innovation. Resolution of these issues will determine the development and availability of a broad range of biotechnological products. Innovation, creativity, and risk-taking must be nurtured and rewarded in the global marketplace. Congress must amend the OTCA to reflect just protection for patents.