

# COMMENT

## PATENT PROTECTION AND RAW MATERIALS: THE CONVENTION ON BIOLOGICAL DIVERSITY AND ITS IMPLICATIONS FOR U.S. POLICY ON THE DEVELOPMENT AND COMMERCIALIZATION OF BIOTECHNOLOGY

CHERYL D. HARDY\*

### 1. INTRODUCTION

As the United States seeks to maintain its edge in an increasingly competitive and integrated world economy, biotechnology has become one of its most promising industries.<sup>1</sup> While there may be a consensus that the U.S. biotechnology industry has a great potential for profit and expansion,<sup>2</sup> the industry (still in its infancy)<sup>3</sup> is plagued with problems. For instance, it is difficult to apply existing patent laws to this technology, and this phenomenon has threatened even the most promising companies in the industry.<sup>4</sup> Fears

---

\* J.D. Candidate, 1994, University of Pennsylvania Law School; B.A., 1983, Temple University. I wish to thank my family and my husband, Willie L. Hardy, Jr., for their love and support. Also, this Comment is dedicated in loving memory of my parents.

<sup>1</sup> See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY 19 (1991) [hereinafter OTA-BIOTECHNOLOGY REPORT] (asserting that by many measures the United States is a preeminent force in biotechnology).

<sup>2</sup> See Ronald E. Yates, *Biotechnology Blossoms But Rivals Gaining on U.S.*, CHI. TRIB., Oct. 4, 1992, at C1 (noting that biotechnology is the "child prodigy" of the business world); JOHN NAISBITT & PATRICIA ABURDENE, MEGATRENDS 2000: TEN NEW DIRECTIONS FOR THE 1990'S 262 (1990) (stating the United States is a world leader in terms of biotechnology investment and sales).

<sup>3</sup> See NAISBITT & ABURDENE, *supra* note 2, at 242-43 (providing an overview of the rapidly changing biotechnology industry and the implications for future technological developments).

<sup>4</sup> For example, patent litigation caused tremendous fiscal loss to Genetics Institute, resulting in a fall in its stock price and the sale of a 60% stake in

abound that the biotechnology industry may go the route of the semiconductor industry<sup>5</sup> unless measures are taken to close existing loopholes in domestic and international patent laws.

Such fears motivated the Bush Administration's refusal to sign the Convention on Biological Diversity ("Biodiversity Treaty") at the 1992 Earth Summit in Rio de Janeiro, Brazil.<sup>6</sup> Biotechnology trade organizations, such as the Association of Biotechnology Companies, applauded the U.S. refusal to sign the Biodiversity Treaty.<sup>7</sup> These organizations objected to provisions of the Biodiversity Treaty that advocate a transfer and sharing of technology and profits with the developing nations that provide the raw materials that are essential to the biotechnology industry.<sup>8</sup> These provisions are aimed at ensuring these developing nations a share in the social and economic profits of biotechnological development and innovation.

This Comment will argue that the absence of a U.S. biotechnology policy resulted in the initial refusal of the United States to sign the Biodiversity Treaty. Now that the United States has signed the Biodiversity Treaty, however,<sup>9</sup>

---

the company to American Home Products. See Ronald Rosenberg, *Biotech Firm Split on Choice of New Backer*, BOSTON GLOBE, Jan. 10, 1992, at 45.

<sup>5</sup> The Office of Technology Assessment once noted that "America invented the videocassette recorder, [of which semiconductors and microprocessors are key components,] but now only sells 2% of them." Karen Tumulty, *Global Competition: Can U.S. Still Play By Its Rules?*, L.A. TIMES, June 8, 1992, at A8. There is evidence, however, that the U.S. semiconductor industry has made a comeback. See, e.g., *The Rising Sun in the West*, BOSTON GLOBE, Mar. 20, 1994, at 72 (noting the Japanese perception that the U.S. semiconductor industry is again competitive). The fear is that by the year 2000, Japan and the European nations will surpass the United States in developing products based on U.S. innovations in biotechnology, in the same way these nations once surpassed the United States in the development of products based on U.S. semiconductors. Tumulty, *supra*, at A8; see also Merrill Goozner, *Global Patents Pending*, CHI. TRIB., Apr. 13, 1992, at N1 (noting the problems of filing patents internationally and how the biotechnology industry may face patent wars similar to those faced by the U.S. semiconductor/microprocessor industries, unless measure are taken).

<sup>6</sup> See *Biodiversity Treaty Risks Interfering with Patent Protection*, *Official Says*, [Jan.-June] Int'l Trade Rep. (BNA) No. 25, at 1071-72 (June 15, 1992) [hereinafter *BNA-Patent Protection*].

<sup>7</sup> *Id.* at 1072.

<sup>8</sup> *Id.*

<sup>9</sup> See William K. Stevens, *Gore Promises U.S. Leadership on Sustainable*  
<https://scholarship.law.upenn.edu/jil/vol15/iss2/4>

it must aid the U.S. biotechnology industry by closing existing loopholes in both domestic and international patent laws. Such changes will encourage agreements between the developing nations that supply raw materials and U.S. biotechnology companies that stand to earn millions of dollars through commercially viable biotechnology products that use these materials.

Section 2 of this Comment will address the developing biotechnology industry, the profit potential of the industry through the globalization and commercialization of biotechnology-pharmaceutical products, and the potential loss of U.S. competitiveness to Europe and Japan. Section 3 will examine the concerns of the biotechnology industry regarding U.S. patent laws. Section 4 will discuss the role of developing nations in the biotechnology industry as well as U.S. objections to provisions of the Biodiversity Treaty concerning patent protections and the contributions of developing nations. Section 5 concludes that the U.S. biotechnology industry would be better served if the United States develops a comprehensive biotechnology policy that protects and promotes the U.S. biotechnology industry, in part by eliminating existing patent loopholes. Such a policy should also provide benefits to the developing nations that supply materials and resources for the development and commercialization of biotechnology products.

## 2. OVERVIEW OF THE BIOTECHNOLOGY INDUSTRY

### 2.1. *Biotechnology's Profit Potential*

Biotechnology is defined as "any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop micro-organisms for specific uses."<sup>10</sup> Aided by computer hardware and software and innovative bioprocessing techniques,<sup>11</sup> biotechnology is developing and expanding at a

---

*Development Path*, N.Y. TIMES, June 15, 1993, at C4; see also Elliot Dinger, *U.S. Suddenly a Leader on World Environment*, S.F. CHRON., June 14, 1993, at A1 (noting President Clinton's agreement to sign the Biodiversity Treaty after President Bush had rejected it).

<sup>10</sup> See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 268 app. F.

<sup>11</sup> See NAISBITT & ABURDENE, *supra* note 2, at 242 (noting that computer systems are used in biotechnology to "unlock the secrets of life").

rapid pace. One study reports that the United States remains preeminent in this industry, with the government spending more than \$3.4 billion in 1990 alone to support research and development ("R&D") in biotechnology.<sup>12</sup> Private industry in the United States has invested over \$2 billion in companies that were established slightly over twenty years ago.<sup>13</sup> Numbering over one thousand,<sup>14</sup> these dedicated biotechnology companies ("DBC's")<sup>15</sup> are considered a "uniquely American phenomenon."<sup>16</sup> DBCs have the potential to earn \$100 billion per year in sales by the year 2000.<sup>17</sup> Such projections undoubtedly account for the fact that Japan and Europe have chosen to target biotechnology as an industry of the future.<sup>18</sup>

Biotechnology, currently a U.S.-dominated industry, is becoming increasingly global as large Japanese and European companies clamor for their stake in the industry by acquiring, merging with, or investing in smaller DBCs.<sup>19</sup> Because of their size, scarce financial resources, and the high cost of litigation<sup>20</sup> arising out of patent disputes with other small companies, DBCs welcome and require a high infusion of

---

<sup>12</sup> See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 19.

<sup>13</sup> See COMMITTEE ON JAPAN NATIONAL RESEARCH COUNCIL, U.S.-JAPAN TECHNOLOGY LINKAGES IN BIOTECHNOLOGY: CHALLENGES FOR THE 1990S 1-2 (1992) [hereinafter U.S.-JAPAN TECHNOLOGY LINKAGES] (the \$2 billion dollar figure is for fiscal year 1990).

<sup>14</sup> *Id.* at 6 n.8.

<sup>15</sup> DBCs are companies devoted solely to biotechnology R&D.

<sup>16</sup> OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 19. The U.S. biotechnology industry consists mostly of small DBCs, whereas in Japan major corporations involved in other businesses account for the majority of companies involved in biotechnology. See U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 13, at 6-7 and n.8.

<sup>17</sup> See Yates, *supra* note 2, at C14.

<sup>18</sup> See *id.* at C1 (noting possible advances France, Britain, and Japan will have made in this area by the year 2000); see also Gale Eisenstodt, *A Different Kind of Drug Problem*, FORBES, Jan. 22, 1990, at 40 (noting that Japan has targeted biotechnology as a focus area for its economy); cf. Robert T. Yuan, *The Biotechnology Potential*, E. ASIAN EXECUTIVE REP., Aug. 15, 1988, at 8 (noting that Singapore, South Korea, and Taiwan have also targeted biotechnology as a priority area for industrial development).

<sup>19</sup> See THOMAS C. WIEGELE, BIOTECHNOLOGY AND INTERNATIONAL RELATIONS 72 (1991). Such firms usually are "large-scale enterprises or multinational corporations with significant resources to engage in research and the marketing of the products of biotechnology." *Id.*

<sup>20</sup> See *infra* notes 80-107 and accompanying text.

capital—capital that private industry and Wall Street seem willing to supply.<sup>21</sup> The U.S. biotechnology industry raised \$3 billion in public equity in 1991, and another \$2 billion in public equity financing in the first half of 1992.<sup>22</sup>

The U.S. biotechnology industry, and some market analysts, fear that the United States may lose its competitive edge in biotechnology. Some commentators speculate that biotechnology has been sold too cheaply.<sup>23</sup> Others assert that unless steps are taken to protect biotechnology through patent law modifications,<sup>24</sup> the United States will lose its competitive edge to Japan by the year 2000, and subsequently to Europe, especially where European nations have made significant progress in biotechnology development and commercialization.<sup>25</sup>

---

<sup>21</sup> See generally OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 45-68 (giving an overview of the financing process, strategic alliances, and tax gains of U.S. biotechnology companies).

<sup>22</sup> See Yates, *supra* note 2, at C14. Such activity led former U.S. Senator, now Vice President, Al Gore to proclaim that biotechnology is the "selling of the tree of knowledge to Wall Street." Senator Al Gore, *Planning A New Biotechnology Policy*, 5 HARV. J.L. & TECH. 19, 22 (1991).

<sup>23</sup> See U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 13, at 3.

<sup>24</sup> See Carlos A. Fisher, Comment, *Unfair Trade Practices in Biotechnology: The Legacy of In Re Durden*, 21 Sw. U. L. Rev. 1103, 1105 (1992) (noting the loopholes in processing patent claims); John C. Herman, Case Comment, *Biotechnology and Recently Amended Section 337: Federal Circuit Grants No Protection*, Amgen, Inc. v. United States International Trade Commission, 902 F.2d 1532 (Fed. Cir. 1990), 24 VAND. J. TRANSNAT'L L. 827, 841 (1991) (noting the judicial and legislative loopholes in the interpretations of patent law); Brandi L. Wickline, Note, *The Impact of the Deposit Requirement for Patenting Biotechnology: Present Concerns, Proposed Solutions*, 24 VAND. J. TRANSNAT'L L. 793, 822 (1991) (noting that legal flaws still leave microbiological inventors vulnerable).

<sup>25</sup> See Carol E. Curtis, *Rx: Made in Japan*, Forbes, Aug. 17, 1981, at 37 ("First television sets, cameras and steel. Then autos and computers. Now those tough competitors from across the Pacific are aiming at the drug industry."); Eisenstodt, *supra* note 18, at 40 (stating that Japanese firms are tapping U.S. pharmaceutical knowledge); Goozner, *supra* note 5, at N1 (noting that Japanese firms "dominate lists of leading patent-winning firms"); Tumulty, *supra* note 5, at A1, A8 (asserting that the Japanese and German governments' integration with and sponsoring of private industry puts these countries in a better position to compete on a global level); Yates, *supra* note 2, at C1 (noting that France and Britain are making significant gains against the U.S. biotechnology industry).

## 2.2. *Biotechnology Globalization And Commercialization*

The economic, legal, and social impact of biotechnology is most evident in the alliance that has formed between the pharmaceutical and biotechnology industries. Biotechnology-pharmaceutical sales<sup>26</sup> alone are expected to reach \$60 billion by the end of the decade.<sup>27</sup> Over a dozen biotechnology-pharmaceutical drugs have entered the commercial market, and an estimated 130 more are on their way.<sup>28</sup> Amgen, Inc., of Thousand Oaks, California, is clearly a leader among DBCs. Sales of Amgen's drug, Epogen ("EPO" or "Erythropoietin"), which treats anemia in end-stage renal disease patients, totaled over \$200 million during EPO's first full year of sales in 1990.<sup>29</sup> Sales of EPO in 1991 were expected to reach \$1 billion.<sup>30</sup> Other promising biotechnology drugs, including treatment for the side effects of chemotherapy,<sup>31</sup> growth deficiencies in children,<sup>32</sup> acute myocardial infarction (heart attacks),<sup>33</sup> and for AIDS-related anemia,<sup>34</sup> have entered the market. The enormous possibilities and potential profits<sup>35</sup> are attractive to both foreign and domestic transnational drug manufacturers.

Some DBCs,<sup>36</sup> such as Centcor,<sup>37</sup> continue to exist on

<sup>26</sup> The United States claims a surplus of exports over imports in pharmaceutical products. See Milt Freudenheim, *Though Markets Vary, Drugs Work Anywhere*, N.Y. TIMES, Jan. 1, 1992, at L49.

<sup>27</sup> *Promises, Promises, Promises*, ECONOMIST, Oct. 5, 1991, at 69.

<sup>28</sup> See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 7; *Promises, Promises, Promises*, *supra* note 27, at 69.

<sup>29</sup> See U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 13, at 6.

<sup>30</sup> See *Promises, Promises, Promises*, *supra* note 27, at 69.

<sup>31</sup> Neupogen, manufactured by Amgen, Inc., Thousand Oaks, California. PHYSICIAN'S DESK REFERENCE 605 (47th ed. 1993).

<sup>32</sup> Protopin, manufactured by Genentech, San Francisco, California. PHYSICIAN'S COMPENDIUM OF DRUG THERAPY 1993 at 15:18.

<sup>33</sup> Activase, manufactured by Genentech, San Francisco, California. *Id.* at 9:67.

<sup>34</sup> Procrit, manufactured by Ortho Biotech, Raritan, New Jersey. *Id.* at 9:86.

<sup>35</sup> See U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 13, at 2 (asserting that "[t]he biotechnology and pharmaceutical industries have been rated as second only to the computer software and services sector in terms of total value creation among U.S. high-technology companies founded since 1965").

<sup>36</sup> The top 10 U.S. biotechnology firms in R&D spending in 1990 were: Genentech; Amgen, Inc.; Genetics Institute; Cetus; Chiron; Centcor;

their own without the infusion of capital from larger pharmaceutical companies. A majority of DBCs, however, have opted through mergers, acquisitions, licensing, or various other agreements, to seek the assistance of larger pharmaceutical companies.<sup>38</sup> These alliances are beneficial for both parties. Larger pharmaceutical companies provide newly-formed biotechnology companies with much needed capital for R&D.<sup>39</sup> The established companies also have existing global sales forces, providing immediate access to the commercial market once a drug has been approved for sale. In return, DBCs supply major pharmaceutical companies with innovative techniques and products offering a vast potential for profit. In 1990, alliances with biotechnology companies accounted for fifty-five percent of the 304 strategic alliances formed by transnational drug companies.<sup>40</sup>

The larger U.S., European, and Japanese pharmaceutical companies form various types of alliances with smaller DBCs. U.S. and European companies usually opt for acquiring a majority share in a biotechnology company or entering into licensing/financing agreements. The larger company supplies the capital for the R&D, and the biotechnology company agrees to share any profits from the commercial marketing of a successful drug.<sup>41</sup> Sometimes the larger companies will

---

Biogen; Xoma; Immunex; and Genzyme. *Id.* at 15. Cetus has since merged with Chiron. See Emma Chynoweth, *Cetus Sells Diagnostics to Roche, Merges With Chiron*, CHEMICAL WK., July 31, 1991, at 12; Joan Hamilton, *Revenge of the Nerds in Biotech Land*, BUS. WK., Aug. 5, 1991, at 26.

<sup>37</sup> See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 84-85.

<sup>38</sup> See WIEGELE, *supra* note 19, at 92; see also *infra* notes 47, 49-53 and accompanying text. Based on overall sales, the top pharmaceutical companies in 1989 were: Merck & Co. (U.S.); Glaxo (U.K.); Bristol-Myers Squibb (U.S.); Bayer (Germany); Hoechst (Germany); Eastman Kodak (U.S.); Ciba-Geigy (Switzerland); SmithKline Beecham (U.S./U.K.); Sandoz (Switzerland); and American Home Products (U.S.). These companies have global operations, conducting research and manufacturing throughout the world. See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 85.

<sup>39</sup> It can take anywhere from five to ten years of R&D before a biotechnology product reaches the market. See U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 18, at 6 n.7. Estimates of the amount of capital required to fund R&D varies depending upon the outcomes of experiments, which makes estimating necessary capital quite difficult for these smaller companies.

<sup>40</sup> *Promises, Promises, Promises*, *supra* note 27, at 69.

<sup>41</sup> See *infra* notes 48-52 and accompanying text.

simply purchase a particular technology for their sole use and subsequent development.<sup>42</sup> Japanese pharmaceutical companies also acquire biotechnology companies and enter into licensing and sales agreements, but their primary mode of staking a claim in the industry is usually through funding universities<sup>43</sup> and private research institutions located throughout the United States.

The Japanese method of investing in U.S.-based biotechnology R&D has raised many concerns.<sup>44</sup> These linkages are viewed as creating a flow of information out of the United States into Japan, without a corresponding influx of technology from Japan. This phenomenon results in a strengthening of the Japanese market and a weakening of the U.S. ability to compete with, and commercialize, this technology.<sup>45</sup> Linkages between Japanese firms and U.S. academic and other research institutions include: Daiichi Pharmaceutical's \$1.2 million endowment of a chair at Vanderbilt University; Shiseido's establishment of an \$85 million dermatology research center at Massachusetts General Hospital ("MGH"); Japan Research and Development Corporation's grant of \$15 million (over five years) to Michigan State University for research on the evolution of microbes for environmental biotechnology; and Yamanouchi Pharmaceutical's collaboration with Mt. Sinai Medical Center to develop a transgenic mouse exhibiting Alzheimer's disease.<sup>46</sup>

While such R&D arrangements are utilized primarily by Japanese corporations, other foreign corporations have also utilized these methods. For example, Hoechst, A.G., a major

---

<sup>42</sup> For example, Cetus, a U.S. biotechnology company, sold its polymerase chain reaction diagnostics technology, which can aid in producing a test for the early detection of the HIV virus, to German-based Hoffman-LaRoche for \$300 million. See Chynoweth, *supra* note 36, at 12.

<sup>43</sup> University funding may be in the form of general funding for university research centers and departments and/or providing substantial endowments for biotechnology R&D chairs. See *infra* note 46 and accompanying text.

<sup>44</sup> See U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 13, at 52 (viewing such linkages as disadvantageous to U.S. interests).

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* at app. B (Examples of Linkages Between Japanese Companies and U.S. Academic Research Institutions).



German pharmaceutical corporation, entered into a ten-year agreement with MGH where Hoechst would invest \$50 million for R&D in return for "exclusive licenses to use any [forthcoming] patents . . . ."<sup>47</sup>

Acquisitions, mergers, and licensing agreements between foreign and U.S. biotechnology companies<sup>48</sup> within the past four years have included: Swiss-based Roche Holding Ltd.'s ("Roche") acquisition of a sixty percent share in Genentech, Inc.;<sup>49</sup> Sanofi's (France) acquisition of Genetic Systems Corp.;<sup>50</sup> the former West Germany's Schering AG's acquisition of Triton Biosciences Inc.;<sup>51</sup> and Japan's Chugai Pharmaceuticals Inc.'s ("Chugai") acquisition of Gen-Probe, Inc.<sup>52</sup>

Of the above transactions, Roche's acquisition of Genentech, Inc.<sup>53</sup> raised the greatest concern about the selling of U.S. technology to foreign companies. Roche quieted these concerns by pointing to its significant U.S. operations and the presence of its wholly-owned subsidiary, Hoffman-LaRoche, in Nutley, New Jersey.<sup>54</sup> Roche also assured investors that Genentech would continue to be independently operated.<sup>55</sup> Foreign acquisitions, agreements, and arrangements with U.S. biotechnology companies are regarded by some commentators as violating U.S. economic interests.<sup>56</sup> One commentator suggests that the United States should "export products, not processes or knowledge."<sup>57</sup>

---

<sup>47</sup> WIEGELE, *supra* note 19, at 77.

<sup>48</sup> From 1989 to 1990, there were at least 38 such mergers and acquisitions. See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 55.

<sup>49</sup> See Andrew Pollack, *U.S. Biotechnology Leader to Sell Swiss 60% Stake*, N.Y. TIMES, Feb. 3, 1990, at A1.

<sup>50</sup> See Polly Lane, *Seattle Biotechnology Company Sold*, SEATTLE TIMES, Apr. 20, 1990, at D10.

<sup>51</sup> See Sabin Russell, *Germany's Schering to Buy Triton: Sale Marks Another Foreign Acquisition of a Biotech Firm*, S.F. CHRON., Sept. 21, 1990, at C1.

<sup>52</sup> *Id.* Chugai acquired Gen-Probe to establish a U.S. presence. *Id.*

<sup>53</sup> Genentech was the first U.S. biotechnology company established to take commercial advantage of new developments in biotechnology. See Gore, *supra* note 22, at 21.

<sup>54</sup> See Pollack, *supra* note 49, at A1.

<sup>55</sup> See *Promises, Promises, Promises*, *supra* note 27, at 70.

<sup>56</sup> See U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 13, at 51.

<sup>57</sup> See WIEGELE, *supra* note 19, at 78 (warning that "the United States

The biotechnology industry's rate of expansion, its international scope, the financial complexities inherent in the industry, and present transfers of biotechnology have created anxiety over the globalization and commercialization of the U.S. biotechnology industry. Many commentators assert that one way the United States can maintain a competitive edge is to focus on strengthening domestic and international patent laws.<sup>58</sup> If it did so, the United States would be protected from biotechnology being exported internationally and manufactured into other products for later sale in the United States.<sup>59</sup>

### 3. U.S. PATENT LOOPHOLES AND THE BIOTECHNOLOGY INDUSTRY

U.S. patent laws provide protection for inventions and innovations and "promote the Progress of Science and useful Arts."<sup>60</sup> It was not until 1980, in *Diamond v. Chakrabarty*, that the U.S. Supreme Court ruled that organisms could be patented.<sup>61</sup> The organisms involved in *Chakrabarty* were genetically-engineered bacteria capable of digesting oil.<sup>62</sup> This decision was pivotal in the commercialization of

---

is in danger of becoming a knowledge colony for the world"). Some commentators have expressed concern over whether university-industry partnerships will hinder universities from maintaining their position as independent bodies of research and information, and whether such partnerships will impede a "wide exchange of information . . . between the university and society." Gore, *supra* note 22, at 27. Gore also argues that the extent to which public institutions are subsidizing private ventures ought to be examined. *Id.*

<sup>58</sup> See *supra* note 24 and accompanying text.

<sup>59</sup> The United States is the world's largest market for pharmaceutical sales. See U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 13, at 27.

<sup>60</sup> U.S. patent laws are enacted under art. I, § 8, cl. 8 of the U.S. Constitution.

<sup>61</sup> "Congress intended statutory subject matter to include anything under the sun made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952); H. REP. NO. 1923, 82d Cong., 2d Sess. 6 (1952)).

<sup>62</sup> This organism has since been used in the clean-up of the *Exxon Valdez* oil spill. See Bill Kaczor, *Use of Oil-Eating Bacteria on Spills is Successful But Short of A Cure-All*, L.A. TIMES, Dec. 30, 1990, at B4; John Lancaster, *Oil-Eating Microbes Tested on Spill; EPA Calls Results in Valdez 'Promising'*, WASH. POST, July 8, 1989, at A3.

biotechnology.<sup>63</sup>

Patent protection is vital to the biotechnology industry, particularly because small biotechnology companies invest large sums of money in R&D. It can take anywhere from five to ten years to research and develop a product before that product enters the commercial market.<sup>64</sup> Patent laws usually provide protection for seventeen years.<sup>65</sup> If a product takes ten years to reach the market, the patentee has only seven years in which to recoup gains from sales of a commercially viable product. As a result, the patentee may not recover all of the capital expended to develop, produce, and market the product.<sup>66</sup>

### 3.1. *The Deposit Requirement And Section 271(e)(1)*

Before a patent may be issued, U.S. patent laws require full disclosure of the “manner and process of making [an invention]” in a context sufficient to enable others to make use of this information.<sup>67</sup> For biotechnology, usually the organism itself is the novel invention to be patented. Therefore, descriptions of recombinant DNA processes, or cell fusion and resulting by-products, and other techniques of genetic engineering may not suffice to give a clear understanding of the “manner and process” of arriving at the result. Hence, the U.S. Patent and Trademark Office (“PTO”) requires<sup>68</sup> the patent application to include a deposit of the

---

<sup>63</sup> See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 214.

<sup>64</sup> Amgen's EPO drug took six years from development to marketing. See U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 13, at 6.

<sup>65</sup> 35 U.S.C. § 154 (1988).

<sup>66</sup> The U.S. Drug Price Competition and Patent Term Restoration Act of 1984 provides patent term extensions for pharmaceuticals meeting certain criteria. See Gary Lee, *House Favors Patent Extensions for 3 Firms*, WASH. POST, Aug. 5, 1992, at A21 (reporting that the U.S. House of Representatives voted to extend patents on fat substitute food additives and anti-inflammatory drugs). Japan has a similar act and the European Commission is considering proposed legislation that would allow for extension of pharmaceutical patents. See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 93, Box 5-I.

<sup>67</sup> This is the “enabling requirement” of U.S. patent law. See 35 U.S.C. § 112 (1988).

<sup>68</sup> While not formally requiring it, the PTO strongly suggests compliance with the deposit requirement. See *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1210 (Fed. Cir. 1991) (noting that “ [t]he deposit

organism.<sup>69</sup>

The PTO may deny the patent if a deposit is not made. The PTO, however, will accept a patentee's written argument and oral interview regarding whether or not the invention (i.e., the organism) requires a deposit.<sup>70</sup> Patent validity and claims of infringement may depend upon whether the patentee complied with the deposit requirement.

By drawing a distinction between known and unknown sources of genetic material, the U.S. Court of Appeals for the Federal Circuit has attempted to clarify the question of whether a deposit of genetically-engineered subject matter is required. If the biological material is unknown and "obtained from nature," others cannot replicate the invention without having access to the organism.<sup>71</sup> In such cases, a deposit of the organism is required.<sup>72</sup> On the other hand, if the organism is created by inserting genetic material into "generally [known and] available sources," no deposit is required.<sup>73</sup> A description of how to replicate the invention will suffice.<sup>74</sup>

Once an organism is deposited, third parties can have access to the culture for a minimum fee.<sup>75</sup> The patentee no longer has physical control over her invention, and the self-replicating nature of the organism provides third parties with the "capability of producing an unlimited supply of the organism."<sup>76</sup>

---

requirement is a nonstatutory mechanism for ensuring compliance with the enabling provision under 35 U.S.C. § 112.'") (quoting Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 569, 607 (1985)).

<sup>69</sup> The United States currently has three internationally-recognized depositories to collect and house organisms. The three U.S. depositories recognized under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure are: American Type Culture Collection (Maryland); Northern Regional Research Laboratory (Illinois); and InVitro International, Inc. (Maryland). See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 208.

<sup>70</sup> See *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d at 1211.

<sup>71</sup> See *id.*

<sup>72</sup> See *id.*

<sup>73</sup> See *id.*

<sup>74</sup> See *id.*

<sup>75</sup> See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 222.

<sup>76</sup> Wickline, *supra* note 24, at 807; see also Fisher, *supra* note 24, at 1111

Since there is no protection of the deposited samples, a debate has surfaced over the domestic and international use of the samples once they have been deposited.<sup>77</sup> Under U.S. patent law, a research exemption<sup>78</sup> provides third parties with an experimental-use defense against a patentee's claim of infringement. A third party need only assert that she is conducting experiments with the organism for strictly scientific purposes that do not infringe upon the rights of the patentee to qualify for the research exemption.

The experimental-use defense is a court-created doctrine.<sup>79</sup> In 1984, in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,<sup>80</sup> the Federal Circuit held that the use of a patented drug during the term of the patent for testing purposes related to FDA drug approval constituted infringement.<sup>81</sup> Thus, the experimental-use defense was no longer a viable defense to claims of infringement. The U.S. Congress responded to *Roche Products* by amending the patent

---

(suggesting that since it is the actual organism that is patented, "unauthorized propagation of a patented [o]rganism may itself constitute infringement of the patent").

<sup>77</sup> See Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1241 [hereinafter Budapest Treaty]. The Budapest Treaty provides for internationally recognized depositories where a patentee who is applying for a patent in more than one country can make a single deposit of the microorganism which will fulfill the deposit requirement under each country's patent laws. The treaty does not address the use of deposited samples. Therefore, the patent office of a signatory country can request, or authorize third parties to request, a sample of the deposited microorganism, and the substantive law of that country will govern the use of the sample. The fact that so many parties have access to these samples led to the debate over whether or not adequate protection against infringement exists for a patentee's deposited "invention." See *id.* at 1258; see also Wickline, *supra* note 24, at 804. Wickline suggests that acts of patent infringement can be curtailed if countries afforded greater protection to patentees by allowing the patentee to restrict access to its deposited samples. See *id.* at 823-25.

<sup>78</sup> See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 222-23.

<sup>79</sup> The experimental-use defense against a patentee's claim of infringement originated in *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C. Mass. 1813) (No. 17,600). *Whittemore* held that an act of infringement does not exist where a party merely experiments with a patented invention absent an intent to use the patented invention for profit. *Id.*

<sup>80</sup> 733 F.2d 858 (Fed. Cir. 1984).

<sup>81</sup> See *id.* at 865 (stating that courts will no longer fashion an experimental-use defense where Congress has not expressly provided for this exception under U.S. patent law).

law to add section 271(e)(1).<sup>82</sup> The language of section 271(e)(1) is specific to the biotechnology industry.<sup>83</sup> Indeed, section 271(e)(1) has caused much concern about a biotechnology patentee's rights to his inventions under the patent laws. The Supreme Court has interpreted section 271(e)(1) as "allow[ing] competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval"<sup>84</sup> through a U.S. government agency such as the FDA. Courts remain divided<sup>85</sup> on the activities permissible under section 271(e)(1), a fact which offers no assurance to small biotechnology companies that they necessarily will be able to reap the benefits of a product they have spent years developing.<sup>86</sup>

### 3.2. *Section 1337 Of The Tariff Act Of 1930 And The Durden Dilemma*

Section 1337 of the Tariff Act of 1930 makes it unlawful to import into the United States articles that are made or

---

<sup>82</sup> Section 271(e)(1) provides:

It shall not be an act of infringement to make, use, or sell a patented invention (. . . which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .

35 U.S.C. § 271(e)(1) (1988 & Supp. 1993).

<sup>83</sup> *See id.*

<sup>84</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990).

<sup>85</sup> *See id.* at 661. This case did not specifically address the infringement of a drug patent. The Supreme Court, however, utilized section 271(e)(1) and held that experimentation with the patented invention for the purpose of producing a cardiac defibrillator was not an act of infringement against the original patentee. *But see* *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). This litigation involved a biotechnology-produced substance known as human Factor VIII:C—a blood clotting drug used by hemophiliacs. Scripps had the initial patent and Genentech was conducting experiments with the patented material as the patent neared its expiration in order to produce its own version of the drug. The court found such activities to be an impermissible act of infringement. Thus, the section 271(e)(1) experimental-use exception would not apply. *See id.* at 1583-84.

<sup>86</sup> *See Cetus Wins Patent Fight*, *CHEMICAL. WK.*, Mar. 13, 1991, at 52.

produced from a *process* covered by a U.S. patent.<sup>87</sup> In *In re Durden*,<sup>88</sup> the Federal Circuit held that an *obvious* process is not patentable even if the “material” employed and the resultant product are “novel and non-obvious.”<sup>89</sup> Under *Durden*, no patent should be issued for an obvious process. U.S. patent examiners frequently deny process patents on this basis.<sup>90</sup> *Durden*, combined with section 1337, results in the “*Durden* Dilemma.” The *Durden* Dilemma means that a patentee may obtain a patent for a new organism, yet be denied a patent for the *process* of making the organism. Thus, a patentee would have no claim of infringement when a company outside of the United States uses an unpatented process, but imports back into the United States products made with a patented organism. The perils of the *Durden* Dilemma are illustrated by a series of cases involving Amgen, Inc. and Genetics Institute (“GI”).<sup>91</sup>

In 1987, both Amgen and GI were granted different patents

---

<sup>87</sup> Section 1337 provides:

(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with . . . as provided in this section:

(B) The importation into the United States . . . or the sale within the United States after importation by the owner . . . of articles that . . .

(ii) are made, produced, processed, or mined under, or by means of, a *process* covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337(a)(1)(B)(ii) (1988) (codifying amendments under the Trade Act of 1988) (emphasis added).

<sup>88</sup> 763 F.2d 1406 (Fed. Cir. 1985).

<sup>89</sup> See *id.* Under 35 U.S.C. § 103, obviousness is a question of law. See *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991).

<sup>90</sup> See OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 221.

<sup>91</sup> See *Fisher*, *supra* note 24, at 1111-12. This series of cases, involving patent infringement and the drug EPO, commenced with *Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532 (Fed. Cir. 1990) and *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991). It continued when Ortho Pharmaceuticals sued both Amgen and Chugai/GI for infringement of an EPO licensing agreement. See *Ortho Pharmaceutical Corp. v. Genetics Institute, Inc.*, 808 F. Supp. 894 (D. Mass. 1992) (holding that Ortho lacked standing to sue both GI and Amgen because Ortho's licensing agreement with Amgen covered the sale of EPO in Europe, not in the United States).

for EPO.<sup>92</sup> EPO is best described as a "biotechnology-made copy of a human protein that circulates in the bloodstream and triggers production of red blood cells."<sup>93</sup> EPO is used primarily for treating anemia in end-stage renal disease patients.<sup>94</sup> GI licensed its technology to a U.S. joint venture between Upjohn Co. and Chugai.<sup>95</sup> Chugai began importing back into the United States, for sale, the EPO drug it manufactured abroad using Amgen's patented genes and host cells.

In 1988, Amgen filed a complaint with the U.S. International Trade Commission ("USITC") against GI and Chugai<sup>96</sup> for infringement of Amgen's EPO patent under section 1337. The USITC ruled that Chugai's process for EPO production did not infringe upon Amgen's patent, and, therefore, no violation of section 1337 had occurred. In *Amgen, Inc. v. United States Int'l Trade Comm'n* ("*Amgen I*"),<sup>97</sup> the Federal Circuit upheld the USITC's finding that Amgen could not bar importation of goods made outside of the United States that used a *product* patented in the United States if no U.S. *process* patent existed. The court held that not only must the organism itself be patented, but the *process* of creating the organism must also be patented before a violation can be found to exist under section 1337.<sup>98</sup> Therefore, according to the

---

<sup>92</sup> Both companies arrived at the same result through different methods. An Amgen scientist isolated the EPO-producing gene, and by splicing it with hamster cells, was able to produce EPO. Amgen patented the gene and host cell that begins the EPO biotechnology process. GI's patent covered producing EPO through urine. Later, GI was able to manufacture the drug using biotechnology and licensed it to Chugai Pharmaceutical of Japan. See Barry Stavro, *Amgen Prevails in Patent Fight Over Its Anemia Drug*, L.A. TIMES, Oct. 8, 1991, at D1. This drug is estimated to have sales of over \$1 billion per year. See *Promises, Promises, Promises*, *supra* note 27, at 69.

<sup>93</sup> Stavro, *supra* note 92, at D1.

<sup>94</sup> See *id.* Patients with kidney disease are "chronically" anemic due to an inability to produce enough red blood cells. EPO is a biotechnology copy of the human protein that triggers production of the red blood cells, thus restoring the patient's lost energy.

<sup>95</sup> See *id.* at D9.

<sup>96</sup> Amgen had established a joint venture with Kirin Brewery Co. of Japan to market EPO, and GI had a similar agreement with Chugai. See *Ortho Pharmaceutical Corp. v. Genetics Institute, Inc.*, 808 F. Supp. 894, 897 (D. Mass. 1992); see also *supra* note 86.

<sup>97</sup> 902 F.2d 1532 (Fed. Cir. 1990).

<sup>98</sup> There is pending legislation to correct this loophole, but some people



court, both Amgen and Chugai possessed valid EPO patents.

Even if Amgen filed for a *process* patent concurrently with its application for a *product* patent, however, it is conceivable that the PTO may have denied Amgen a patent for its process of producing EPO. In subsequent litigation, Amgen argued that by using its patented genes and host cells, EPO could be obtained by a “‘routine limited dilution cloning procedure[]’ well known in the art.”<sup>99</sup> An expert testified that the process was “standard.” These assertions may be interpreted to mean that the process was “obvious.” Thus, *Amgen I* illustrates the problem of the *Durden* Dilemma: under *Durden*, Amgen likely would not have been able to obtain a patent for its “obvious” process, but at the same time, Amgen could not prevail in a section 1337 claim against GI, because Amgen did not hold a process patent.

Amgen, unable to win its battle over EPO under section 1337, subsequently chose an alternative route to invalidate Chugai’s patent. Since GI had licensed its EPO patent to Chugai, Amgen sued GI directly, alleging infringement of its *product* patent. Amgen argued that its patent covered GI’s biotechnology version of EPO because GI and Chugai were utilizing Amgen’s patented host cell and genes. In December 1989, a district court judge ruled that both patents were valid.<sup>100</sup> Amgen appealed, and in *Amgen, Inc. v. Chugai Pharmaceutical Co.* (“*Amgen II*”),<sup>101</sup> the Federal Circuit upheld Amgen’s EPO patent and invalidated GI’s patent.<sup>102</sup>

After the court’s ruling in *Amgen II*, GI employed renowned U.S. lawyer Lawrence Tribe to represent GI before the Supreme Court.<sup>103</sup> The Supreme Court, however, refused to hear GI’s appeal.<sup>104</sup> On the day the Supreme Court denied

---

question whether the proposed legislation will correct this problem. See Herman, *supra* note 24, at 843-44.

<sup>99</sup> *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1211 (Fed. Cir. 1991) (alteration in original).

<sup>100</sup> *Amgen, Inc. v. Chugai Pharmaceutical, Co.*, No. 87-2617Y, 1989 U.S. Dist. LEXIS 16110 (D. Mass. Jan. 30, 1990).

<sup>101</sup> 927 F.2d at 1200.

<sup>102</sup> See *id.*

<sup>103</sup> See Stavro, *supra* note 92, at D9.

<sup>104</sup> *Genetics Institute, Inc. v. Amgen, Inc.*, 112 S. Ct. 169 (1991).

GI's appeal, Amgen's stock rose and GI's stock declined.<sup>105</sup> Subsequently, GI sold sixty percent of its shares to American Home Products Corporation, with the president of GI acknowledging that "[t]he outcome of the lawsuit was a complete surprise to us and is one of major disappointment."<sup>106</sup>

The patent loopholes embodied in section 271(e)(1) and section 1337 lead to costly, although necessary, litigation within the biotechnology industry. Companies fear their inventions are not adequately protected and realize that if legal action is not taken to secure patent rights, the results can be catastrophic, particularly for newly-formed companies. Because the viability of biotechnology companies hinges, in part, upon patent protection, and given the high costs of patent litigation, in 1992 the Bush Administration refused to sign the Biodiversity Treaty because the treaty contains provisions that lessen the already scarce protection of patented biotechnology.<sup>107</sup>

#### 4. THE BIODIVERSITY TREATY

The Biodiversity Treaty was first presented to the international community at the Earth Summit in Rio de Janeiro, Brazil, in June 1992.<sup>108</sup> The Biodiversity Treaty is designed to "stem the loss of animal and plant species,"<sup>109</sup> but, in addition, contains provisions which have been interpreted as advocating payment of royalties to developing nations if commercially viable products are produced from plants or other organisms found in that nation.<sup>110</sup>

The Biodiversity Treaty calls for establishing and maintaining efforts to preserve the estimated ten million plants, animals, and other organisms found in the tropical forests of developing nations.<sup>111</sup> These organisms supply the

---

<sup>105</sup> See Stavro, *supra* note 92, at D9.

<sup>106</sup> See Rosenberg, *supra* note 4, at 47.

<sup>107</sup> See *BNA-Patent Protection*, *supra* note 6, at 1072.

<sup>108</sup> See *id.*

<sup>109</sup> See Alex Barnum, *Taking Stock In The Rain Forest*, S.F. CHRON., Dec. 22, 1992, at C1.

<sup>110</sup> See *Third World Seeks a Share of Biotech Profits*, 24 NAT'L J. 1830 (1992).

<sup>111</sup> See Reid G. Adler, *Biotechnology Development and Transfer*:

raw materials for biotechnology R&D.<sup>112</sup> Although the United States may be regarded as the competitive leader in the biotechnology industry,<sup>113</sup> the United States nevertheless has been characterized as a gene-poor nation,<sup>114</sup> and should, therefore, recognize the strategic importance of preserving, maintaining, and obtaining access to these raw materials.<sup>115</sup> The plant material alone represents a value to the pharmaceutical industry of "five to forty billion dollars annually."<sup>116</sup> Countries that attended the Earth Summit and actually signed the Biodiversity Treaty in 1992 recognized the vast profit-potential of these materials.<sup>117</sup>

#### 4.1. U.S. Objections To The Biodiversity Treaty

The Bush Administration cited articles 16(3) and 19(2), two provisions of the Biodiversity Treaty regarding the transfer and sharing of patented biotechnology, as the primary reason for the U.S. refusal to sign the Biodiversity Treaty. These two articles provide the following:

Article 16(3): Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are *developing countries, which provide genetic resources* are provided access to and transfer of technology which makes use of those resources, on *mutually agreed* terms, including technology protected by *patents* and other intellectual

---

*Recommendations for an Integrated Policy*, 11 RUTGERS COMPUTER & TECH. L.J. 469, 471 (1985).

<sup>112</sup> *Id.* at 471-72.

<sup>113</sup> See, e.g., OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 3; U.S.-JAPAN TECHNOLOGY LINKAGES, *supra* note 13, at 1.

<sup>114</sup> See Adler, *supra* note 111, at 472.

<sup>115</sup> *Id.*

<sup>116</sup> *Id.* at 476; see also *id.* at 473-74 (emphasizing the importance to biotechnology of the "gene library" in the developing nations' natural resources).

<sup>117</sup> See *BNA-Patent Protection*, *supra* note 6, at 1072 (noting that during final negotiations on the proposed Biodiversity Treaty, the Europeans wanted to proceed despite the patent language contained in the draft); see also Graeme Browning, *Biodiversity Battle*, 24 NAT'L J. 1827 (1992) (noting that 114 countries, including Japan and various European countries, initially signed the Biodiversity Treaty).

property rights . . . ."<sup>118</sup>

Article 19(2): Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on *mutually agreed* terms.<sup>119</sup>

The Association of Biotechnology Companies' announcement that the provisions would lead to a loss of patent protection for the biotechnology industry mirrored the U.S. objections to these provisions.<sup>120</sup> U.S. concerns about these provisions of the Biodiversity Treaty were substantially the same under the Clinton Administration.<sup>121</sup> When the U.S. representative to the United Nations, Madeleine Albright, signed the Biodiversity Treaty on June 4, 1993,<sup>122</sup> U.S. officials appended an interpretive statement<sup>123</sup> addressing the biotechnology industry's technology transfer and patent protection concerns.<sup>124</sup> In this interpretive statement, the

<sup>118</sup> Convention on Biological Diversity, S. DOC. NO. 20, 103d Cong., 1st Sess. 12 (1993) (emphasis added).

<sup>119</sup> *Id.* at 13 (emphasis added).

<sup>120</sup> *BNA-Patent Protection*, *supra* note 6 at 1072.

<sup>121</sup> See Richard L. Berke, *Clinton Declares New U.S. Policies for Environment*, N.Y. TIMES, Apr. 22, 1993, at 1. (stating that President Clinton expressed concerns similar to those of former President Bush over certain provisions of the Biodiversity Treaty regarding the transfer of biotechnology). President Clinton, however, unlike President Bush, signed the Biodiversity Treaty once a compromise was reached between biotechnology-pharmaceutical companies and environmental groups. *See id.*

<sup>122</sup> See Stevens, *supra* note 9, at C4.

<sup>123</sup> The Clinton Administration characterizes the interpretive statement as a detailed report of the Clinton Administration's position on Articles 16(3) and 19(2) of the Biodiversity Treaty. See Convention on Biological Diversity, Letter of Submittal, *supra* note 118, at iv.

<sup>124</sup> The interpretive statement also accompanied the Biodiversity Treaty when the treaty was sent to the U.S. Senate for ratification. See Convention on Biological Diversity, Letter of Submittal, *supra* note 118, at v-xix. President Clinton's Letter of Submittal states, "The Administration will therefore strongly resist any actions taken by Parties to the Convention that lead to inadequate levels of protection of [patent] rights, and will continue to pursue a vigorous policy with respect to . . . adequate and effective [patent] protection . . ." *Id.* at iv.

United States adopts the position that commercially viable products will not make it to the market if patent protection is not afforded companies that discover and develop new biotechnology.

#### 4.2. *Developing Nations Under The Biodiversity Treaty*

There are existing treaties that offer general patent protection and other treaties that specifically protect biotechnology patents. An example of a general patent protection treaty is the Paris Convention for the Protection of Industrial Property, which provides basic rights for patent protection.<sup>125</sup> Additionally, the Patent Cooperation Treaty outlines procedures that simplify international patent filing requirements.<sup>126</sup> A treaty that specifically addresses biotechnology patent protection is the Budapest Treaty, which concerns international depositories that receive deposits of organisms in order to fulfill patent application requirements.<sup>127</sup> Another such treaty is the International Convention for the Protection of New Varieties of Plants, which provides patent protection for breeders of new plant species.<sup>128</sup>

The existing patent treaties,<sup>129</sup> combined with proposed patent treaties under negotiation or revision,<sup>130</sup> demonstrate that "the industrialized world is in the process of 'locking up' patents for biotechnology and bioprocesses so that its position in the coming decades will be unassailable."<sup>131</sup> With the exception of the Paris Convention, few, if any, developing nations are parties to these treaties.<sup>132</sup> More significantly, under the existing treaties, no benefits accrue to nations supplying the raw materials for biotechnology.

Articles 16(3) and 19(2) of the Biodiversity Treaty do not

---

<sup>125</sup> Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 161 Consol. T.S. 409-417 [hereinafter Paris Convention].

<sup>126</sup> Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645.

<sup>127</sup> Budapest Treaty, *supra* note 77, at 1242.

<sup>128</sup> International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 815 U.N.T.S. 89.

<sup>129</sup> See *supra* notes 125-28 and accompanying text.

<sup>130</sup> See *BNA-Patent Protection*, *supra* note 6, at 1072.

<sup>131</sup> See WIEGELE, *supra* note 19, at 105.

<sup>132</sup> *Id.* at 87-89.

provide for a mandatory means of sharing benefits with developing countries, but specifically provide that contracting parties should share the technology on *mutually agreed upon terms*.<sup>133</sup> Although commentators initially interpreted these provisions as mandating "compulsory licensing arrangements"<sup>134</sup> (in alleged contravention of proposed patent provisions of the General Agreement on Tariffs and Trade treaty),<sup>135</sup> the current position of the United States is that articles 16(3) and 19(2) concern intellectual property rights, not licensing arrangements.<sup>136</sup>

Given the U.S. interpretation of articles 16(3) and 19(2), developing nations are unlikely to receive patented biotechnology under the Biodiversity Treaty. Under the U.S. interpretation of article 16(3), voluntary transfer of technology from private industry will not occur if a developing country is without "effective" levels of patent protection and a legal system which protects and enforces patent rights.<sup>137</sup> Since few developing countries are signatories to the international patent treaties,<sup>138</sup> it is unlikely that a developing nation will be viewed as providing adequate and effective patent protection sufficient to encourage "voluntary transfer of technology."<sup>139</sup> Even if a developing country is, or becomes, a party to existing international patent treaties and develops its domestic patent laws, it is still unlikely, under the U.S. interpretation of article 19(2), that technology transfer will occur. The United States has opted to leave to the sole discretion of private industry the determination of when and if it is appropriate for a developing country to participate in

<sup>133</sup> See Convention on Biological Diversity, *supra* note 118, at 13.

<sup>134</sup> Richard Wilder, of the Association of Biotechnology Companies, takes this position. See *BNA-Patent Protection*, *supra* note 6, at 1072. The interpretive statement makes clear that the United States understands that the Biodiversity Treaty does not advocate the use of compulsory licensing laws that would require the U.S. government to "compel private companies to transfer technology." See Convention on Biological Diversity, Letter of Submittal, *supra* note 118, at xiii.

<sup>135</sup> See *BNA-Patent Protection*, *supra* note 6, at 1072.

<sup>136</sup> See *id.* (citing a May 29, 1992 State Department press memorandum).

<sup>137</sup> See Convention on Biological Diversity, Letter of Submittal, *supra* note 118, at xii-xiii.

<sup>138</sup> See *supra* notes 125-28 and accompanying text.

<sup>139</sup> Convention on Biological Diversity, Letter of Submittal, *supra* note 118, at xii-xiii.

the research and development of new products. Arguably, this is contrary to the language of articles 16(3) and 19(2), which requires signatories to legislate or administer with regard to the transfer of and access to developed technologies.<sup>140</sup>

Articles 16(3) and 19(2) may have been aimed at avoiding situations such as the one that arose between the United States's Eli Lilly & Co. and Madagascar. In Madagascar, folk healers used a plant, the rosy periwinkle, for various medicinal purposes. Eli Lilly discovered that cancer-fighting drugs could be made from the plant. Eli Lilly set up farms in Madagascar to grow additional plants, manufactured its cancer-fighting drug, and subsequently made millions of dollars, while Madagascar received nothing.<sup>141</sup> Under the U.S. interpretation of articles 16(3) and 19(2), however, countries like Madagascar are unlikely to receive their share of the benefits and profits from such products. Thus, as it now stands, the Biodiversity Treaty can merely encourage, but not mandate, that biotechnology companies share the profits from innovative and commercially successful products with the developing countries that provide the raw materials for those products.<sup>142</sup>

Under the Clinton Administration, however, the U.S. position regarding royalty payments apparently has changed. The Administration agrees in principle that benefits should accrue to developing nations for the use of their genetic resources, and that such benefits can take the form of "monetary compensation."<sup>143</sup> The Clinton Administration's position appears to reflect a new willingness on the part of the biotechnology industry to view articles 16(3) and 19(2) as

---

<sup>140</sup> See Convention on Biological Diversity, *supra* note 118, at 11, 13. This language can be read as an unwillingness to leave to the free market the task of arranging technology transfer and sharing of benefits.

<sup>141</sup> See *Third World Seeks Share of Biotech Profits*, *supra* note 109, at 1830.

<sup>142</sup> For an extensive examination of strategies that developing nations can utilize to benefit from biotechnology products that use their environmental resources, see David Dembo et al., *Biotechnology and the Third World: Some Social, Economic, Political and Legal Impacts and Concerns*, 11 RUTGERS COMPUTER & TECH. L.J. 431 (1985). Dembo et al. propose many strategies for developing nations to implement when contracting with transnational corporations. *Id.* at 463-66.

<sup>143</sup> See Convention on Biological Diversity, Letter of Submittal, *supra* note 118, at 7.

recommending royalty payments, rather than as requiring technology transfers.

Biotechnology trade organizations, which no longer oppose, in theory, the sharing of benefits and profits with developing nations,<sup>144</sup> currently advocate the use of agreements such as the one between Merck Co.<sup>145</sup> and the National Institute of Biodiversity of Costa Rica ("INBIO").<sup>146</sup> Merck will pay \$1 million to INBIO in return for access to the plants and other organisms of Costa Rica; if a commercial product is subsequently developed using these materials, Merck will pay royalties to INBIO.<sup>147</sup> The Merck agreement clearly indicates the direction in which a biotechnology company must go in order to retain a competitive share of this market. It remains to be seen, however, whether \$1 million in royalty payments will be perceived by the developing nations as an adequate sharing of benefits if a commercially-successful product generates, for example, over \$100 million in profits. In any event, widespread use of voluntary agreements may be a long time in coming, and beneficial arrangements for both industrialized and developing nations may effectively be arrived at only through provisions such as those contained in the Biodiversity Treaty.

#### 4.3. *Emerging U.S. Biotechnology Policy And Developing Nations*

Progress with respect to globalization and commercialization will not alone ensure that the U.S. biotechnology industry retains its competitive edge.<sup>148</sup> The

---

<sup>144</sup> See *BNA-Patent Protection*, *supra* note 6, at 1072.

<sup>145</sup> In 1989, Merck Company (U.S.) was the leader in pharmaceutical sales, ranking number one among all multinational pharmaceutical companies. See *OTA-BIOTECHNOLOGY REPORT*, *supra* note 1, at 85.

<sup>146</sup> See *BNA-Patent Protection*, *supra* note 6, at 1072.

<sup>147</sup> See Lynn Shapiro, *Plant Derived*, 241 *CHEMICAL MARKETING REP.*, Mar. 9, 1992, at SR38. Other similar agreements exist. For example, Shaman Pharmaceutical, Inc., backed by Eli Lilly & Co., plans to compensate people and countries who offer materials and assistance with a portion of royalties and profits if a commercially viable drug is developed. See Barnum, *supra* note 108, at C1.

<sup>148</sup> See *OTA-BIOTECHNOLOGY REPORT*, *supra* note 1, at 211-14; see generally OFFICE OF TECHNOLOGY ASSESSMENT, *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS* 263-502 (1984) (detailing 10 <https://scholarship.law.upenn.edu/jil/vol15/iss2/4>



absence of a comprehensive U.S. biotechnology policy for the development of the U.S. biotechnology industry<sup>149</sup> will result in a decrease of U.S. competitiveness in the industry. The U.S. government's aim should be the promotion of biotechnology by "consider[ing] [its] future path . . . and [by] anticipat[ing] any problems that technology might present."<sup>150</sup> The emergence of a U.S. biotechnology policy is suggested by the Clinton Administration's decision to draft an interpretive statement of the Biodiversity Treaty.<sup>151</sup> The U.S. government, however, must take further steps to aid the biotechnology industry.

Existing U.S. patent laws are problematic for the biotechnology industry.<sup>152</sup> Application of these laws to biotechnology products and processes has led to inconsistent results. Patent validity and infringement litigation, in addition to being costly, can have other serious effects on small biotechnology companies. The loss of a patent claim may impede a company's ability to raise capital through public markets, force mergers with larger companies that may otherwise not have resulted,<sup>153</sup> or ultimately serve to

---

factors influencing competitiveness in biotechnology). These reports, while focusing on the U.S. competitive edge in the commercialization and globalization of biotechnology, are primarily concerned with patent problems and maintaining this competitive edge. The developing nations that supply raw materials to the biotechnology industry, and the role these raw materials play in driving the biotechnology industry, are scarcely mentioned, if at all.

<sup>149</sup> See Gore, *supra* note 22, at 19; Senator Albert Gore, Jr. & Steve Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336, 348 (1985).

<sup>150</sup> Gore & Owens, *supra* note 149, at 357.

<sup>151</sup> See Alex Barnum, *Companies, Environmentalists United on Treaty*, S.F. CHRON., Apr. 24, 1993, at B1.

<sup>152</sup> See *supra* note 24 and accompanying text.

<sup>153</sup> For example, American Home Products acquired its 60% stake in GI after litigation in which GI's EPO drug was held to be an infringement of Amgen, Inc.'s patent. See discussion *supra* § 3.2. Cetus' merger with Chiron and the selling of its polymerase chain reaction technology to Hoffman-La Roche came on the heels of a patent infringement suit with E.I. DuPont de Nemours Co. regarding this technology. See *E.I. DuPont de Nemours & Co. v. Cetus Corp.*, No. C 89-2860 MHP, 1990 U.S. Dist. LEXIS 18382, (N.D. Cal. Dec. 11, 1990); Chynoweth, *supra* note 36, at 12. Eastman Kodak, which had research and development agreements with Cetus for the polymerase chain reaction technology, unsuccessfully sought to enjoin the sale of the technology to Hoffman-La Roche. This also added to Cetus'

decrease the incentives for start-ups in the biotechnology industry. The absence of a clear U.S. biotechnology policy has meant, in part, that the courts have been required to apply patent laws that do not necessarily contemplate the particular issues raised by biotechnology to biotechnology cases, a phenomenon that may, over time, hinder the biotechnology industry.

A comprehensive U.S. biotechnology policy should close existing domestic and international patent law loopholes, such as section 1337 of the Tariff Act of 1930 (the *Durden Dilemma*), the deposit requirement, and the experimental-use provision of section 271(e)(1). The effect of these loopholes is that the biotechnology industry is inadequately protected against acts of patent infringement, which can result in a company's unwillingness to share profits from a commercially successful product with a developing nation that supplied the raw materials for the product, if the possibility exists that those profits will be consumed by subsequent costly patent litigation.

The position of the United States in 1992 regarding the Biodiversity Treaty may have reflected a lack of awareness of the U.S. biotechnology industry's dependence on the organisms supplied by developing nations. Perhaps the Bush Administration was unaware that the developing nations had recourse against the refusal of the U.S. biotechnology industry to share benefits and profits, such as forming more advantageous alliances with European nations and Japan. It may be the case, with the first suggestion of an emerging U.S. biotechnology policy, that the United States finally believes "that developing countries will curtail or restrict access to the United States and other world leaders in biotechnology unless the developing nations foresee some direct benefits from [permitting] such access."<sup>154</sup>

A loss of U.S. competitiveness in the biotechnology industry will not result from U.S. biotechnology companies sharing the benefits and profits from patented products with developing nations.<sup>155</sup> A loss of U.S. competitiveness in this industry

---

litigation costs. See *Eastman Kodak Co. v. Cetus Corp.*, No. 12,249, 1991 Del. Ch. LEXIS 197, at \*1-\*3 (Dec. 3, 1991).

<sup>154</sup> See Adler, *supra* note 111, at 474.

<sup>155</sup> See generally WIEGELE, *supra* note 19, at 105-120 (outlining problems  
<https://scholarship.law.upenn.edu/jil/vol15/iss2/4>

will result, however, from alliances between developing nations and other industrialized nations, such as Europe and Japan, which may be more willing to share the benefits of biotechnology products with these developing nations.<sup>156</sup> Europe's and Japan's access to the raw materials needed to make biotechnology products, coupled with their recent acquisitions of U.S. biotechnology knowledge and processes, will undoubtedly place these countries in a position to become leading manufacturers and exporters of biotechnology products in the near future.<sup>157</sup>

## 5. CONCLUSION

Both patent protection and raw materials are vital to the U.S. biotechnology industry. The United States must adopt a comprehensive biotechnology policy that recognizes both factors if it is to reap the benefits of what promises to be one of the next decade's most profitable industries. The United States arguably has moved in this direction by appending an interpretive statement to the Biodiversity Treaty. The United States, however, must do more to aid the U.S. biotechnology industry. A comprehensive U.S. biotechnology policy should close loopholes in existing patent laws. Currently, these loopholes create fears within the U.S. biotechnology industry that prevent U.S. biotechnology companies from sharing the benefits of, and profits from, innovative biotechnology products with the developing nations that supply the raw materials for these products. If the developing nations are not permitted to share in the social and economic profits to be gained from U.S. biotechnology products, they soon may refuse to supply U.S. biotechnology companies with the raw materials necessary to manufacture these products. Developing nations may be

---

with the developing nations' biotechnology).

<sup>156</sup> See generally, OTA-BIOTECHNOLOGY REPORT, *supra* note 1, at 53-64 (describing foreign participation in biotechnology mergers and acquisitions, as well as various strategic alliances used to raise finances).

<sup>157</sup> For example, one commentator suggests that the nature of the German and Japanese business and economic systems make these countries more effective competitors in the biotechnology industry. Since government and industry in these countries are so highly integrated, these nations will be better able to develop and retain technology "that would otherwise spread rapidly to trading rivals." Gavin Boyd, STRUCTURING INTERNATIONAL ECONOMIC COOPERATION 119 (1991).

induced to supply raw materials instead to Europe and Japan, which will lead to a loss of business for the U.S. biotechnology industry and a subsequent loss of U.S. competitiveness in this highly profitable, and expanding, industry.