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## What Has Happened Since *Chakrabarty*?

Jane M. Marciniszyn\*

### I. Introduction

"Biotechnology" refers to the use of biological organisms cast in the role of producers or manufacturers of useful goods. Biotechnology is based on the use of gene-splicing or recombinant DNA<sup>1</sup> to produce new products, cheaper products or purer products. Congress' Office of Technology Assessment has predicted that before the turn of the century, annual sales of chemicals and drugs that are produced by gene-splicing could exceed fifteen billion dollars.<sup>2</sup>

Sales of products which have arisen from biotechnology will come from virtually every area of manufacturing.<sup>3</sup> Eleven years ago it would have seemed implausible "that by 1984 an incredible \$2.5 billion dollars would have been invested in setting up more than one hundred new companies dedicated to pioneering new products from biotechnology."<sup>4</sup> Today, there are 700 U.S. companies engaged in biotechnology.<sup>5</sup>

New companies and older companies expanding into this area have relied on the Patent Act of 1952 to protect their investment.<sup>6</sup> This Act allows an inventor to exclude all others from making, using, or selling his invention for seventeen years.<sup>7</sup> Arthur R. Whale, in commenting on the pros and cons of the patentability of micro-organisms, stated:

It is conventional wisdom that the patent system is designed to undergird the investment in pushing technology forward. The patent system is innovation-oriented. And (sic) it functions most effectively in the expensive, breakthrough technologies, where uncertainties of suc-

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\* B.S., M.S., American University; J.D., Cleveland-Marshall College of Law. I wish to thank my husband, Dr. Joseph P. Marciniszyn and Richard Egan, Esq., Adjunct Professor, Cleveland-Marshall College of Law, for their contributions in preparation and analysis of this article.

<sup>1</sup>The DNA which results from the insertion of a whole or partial chain of DNA not originally/biologically present in that chain. *STEDMAN'S MEDICAL DICTIONARY* 1207 (5th ed. 1982). For a more detailed discussion of molecular biology, see Note, *Building a Better Bacterium: Genetic Engineering and the Patent Law After Diamond v. Chakrabarty*, 81 *COLOM. L. REV.* 159, 165-67 (1981).

<sup>2</sup>*Biotech Comes of Age*, *BUS. WEEK*, Jan. 23, 1984, at 84-85 [hereinafter *Biotech*].

<sup>3</sup>*Id.* at 85.

<sup>4</sup>*Id.* at 84.

<sup>5</sup>Fenyvesi, *Federal Rules May Trigger Biotech Boom*, *U.S. NEWS & WORLD REP.*, July 14, 1986, at 58.

<sup>6</sup>35 U.S.C. § 8 I-376 (1976). Biotechnology companies have swamped the United States Patent and Trademark Office with over a thousand patent applications. *Biotech*, *supra* note 2, at 86.

<sup>7</sup>35 U.S.C. §154 (1976).

cess or payback abound. If, in assessing the risk of commitment, the penalties of failure outweigh the prizes of success, the prudent money will go elsewhere. The patent system moves the equation to the right, not by better assuring success (for only public needs and market values can do that), but by aiding success through offering the innovator a temporary respite from non-innovative copying. However faulted and flawed our system might be, only the most compelling legal logic should deny this country its benefits in a nascent technology full of promise for so much good.<sup>8</sup>

## II. The *Chakrabarty* Decision

In 1980, the United States Supreme Court interpreted the scope of patentable subject matter, in the landmark case of *Diamond v. Chakrabarty*.<sup>9</sup> The Court held that a live, human-made microorganism is patentable subject matter under a statute providing for the issuance of a patent to a person who invents or discovers "any" new and useful "manufacture" or "composition of matter."<sup>10</sup>

In June, 1972, Ananda M. Chakrabarty, a microbiologist, filed a patent application assigned to the General Electric Company, asserting thirty-six claims relating to his human-made, genetically engineered *Pseudomonas* bacterium. Chakrabarty had created the bacterium by manipulating four rings of DNA plasmids from different bacteria strains into one host bacterium.<sup>11</sup> These plasmids would replicate when the host replicated. A super strain was created which would continue to reproduce its new self.

The new *Pseudomonas* bacterium was capable of degrading four different components of crude oil. The host *Pseudomonas* bacterium itself had no capacity for degrading oil. Each of the naturally occurring bacterial plasmids used to manufacture the new bacterium was capable of degrading only one component of crude oil. Chakrabarty sought to patent his microorganism

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<sup>8</sup>Whale, *Patentability of Microorganisms (Introduction)*, 7 AM. PAT. L.A. Q.J. 172, 174 (1979).

<sup>9</sup>447 U.S. 303 (1980).

<sup>10</sup>*Id.*

<sup>11</sup>In bacteria, plasmids are circular DNA molecules that reproduce themselves and are thus conserved, apart from the chromosome, through successive cell divisions; heredity units physically separate from the chromosomes of the cell. THE SLOANE-DORLAND ANNOTATED MEDICAL-LEGAL DICTIONARY 555 (1987). For a more detailed discussion, see Novick, *Plasmids*, SCI. AM., Dec. 1980, at 102.

because this property is possessed by no naturally occurring bacterium and because this new microorganism is capable of mass production and use for more efficient and rapid control of destructive oil spills.

Chakrabarty's claims on the bacterium were rejected by the patent examiner on two grounds:<sup>12</sup> "1. that microorganisms are 'products of nature' and 2. that as living things they are not patentable subject matter under section 101 of the Patent Act of 1952."<sup>13</sup> Chakrabarty appealed the rejection of his claim to the Patent Office Board of Appeals (Board). The Board affirmed the examiner but only on the second ground.<sup>14</sup> The Court of Customs and Patent Appeals (C.C.P.A.) reversed, concluding that the fact that microorganisms are alive is without legal significance for purposes of the patent laws.<sup>15</sup> The United States Supreme Court granted certiorari in 1979.<sup>16</sup>

Article 1, section 8, clause 8 of the United States Constitution provides that "Congress shall have power [to legislate] . . . to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Clause 8 was intended to confer on inventors an exclusive right of ownership and use for a finite time. This right served as a reward for the benefit the public derived from the efforts of an individual, and as a stimulus to creativity. Individual reward is, of course, the inducement without which little "Progress of Science and useful Arts" could be expected. In 1790, Congress exercised this delegated power and enacted the Patent Act of 1790. In 1793, 1836, 1870, 1874, 1930 and 1952, amendments were made to the Patent Act.

As Chief Justice Marshall expressed, "to promote the progress of useful arts, is the interest and policy of every enlightened government."<sup>17</sup> "The authority of Congress is exercised in the hope that the productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens."<sup>18</sup>

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<sup>12</sup>*Chakrabarty*, 447 U.S. at 306.

<sup>13</sup>*Id.*

<sup>14</sup>*Id.*

<sup>15</sup>*In re Chakrabarty*, 571 F.2d 40, 43 (C.C.P.A. 1978).

<sup>16</sup>*Diamond v. Chakrabarty*, 444 U.S. 924 (1979).

<sup>17</sup>*Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 241 (1832).

<sup>18</sup>*Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974).

The Supreme Court in *Chakrabarty* defined the issue as whether Chakrabarty's microorganism, constituted a "manufacture" or "composition of matter" within the meaning of section 101 of the Patent Act of 1952.<sup>19</sup>

In determining the scope of section 101 the Supreme Court began with the language of the statute, interpreted words as taking their ordinary, contemporary common meaning, and was careful not to read into the patent laws limitations and conditions which the legislature had not expressed.<sup>20</sup>

The Supreme Court read the term "manufacture" in section 101 in accordance with its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties or combinations whether by hand-labor or by machinery."<sup>21</sup> "Composition of matter" was construed consistently with its common usage to include "all compositions of two or more substances and . . . all composite articles, whether they be the result of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."<sup>22</sup>

When Congress first selected the word "any" for section 101 of the Patent Act it intended that the statute be given wide scope, as reflected by the relevant legislative history.<sup>23</sup> The Patent Act was drafted by Thomas Jefferson and embodied his philosophy that "ingenuity should receive a liberal encouragement."<sup>24</sup> The Committee Reports accompanying the 1952 Act stated "[t]hat Congress intended [the] statutory subject matter to include anything under the sun that is made by man."<sup>25</sup>

The Supreme Court has created limits to patentable subject matter. The laws of nature, physical phenomena, and abstract ideas are not patentable as these discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."<sup>26</sup>

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<sup>19</sup>*Chakrabarty*, 447 U.S. at 307. 35 U.S.C. § 101 (1976) provides: 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 therefore, subject to the conditions and requirements of this title.

<sup>20</sup>*Chakrabarty*, 447 U.S. at 308.

<sup>21</sup>*American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1930).

<sup>22</sup>*Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 280 (D.C. 1957).

<sup>23</sup>*Chakrabarty*, 447 U.S. at 308.

<sup>24</sup>*Id.*

<sup>25</sup>S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess. 6 (1952).

<sup>26</sup>*See Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

Judged in this light, the Supreme Court found that Chakrabarty's microorganism "plainly qualifies as patentable subject matter."<sup>27</sup> Chakrabarty's claim "is not to a hitherto unknown natural phenomenon but to a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity having a distinctive name, character or use."<sup>28</sup>

In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,<sup>29</sup> decided in 1948, the Supreme Court invalidated a microbiological patent because the subject matter was a "product of nature." The subject matter was a mixture of several known strains of nitrogen-fixing *Rhizopus* bacteria. This mixture was considered useful because it could be used to inoculate several legumes rather than having a separate *Rhizopus* for a particular legume. The court distinguished *Funk* from *Chakrabarty* by noting that Funk made a mixture of bacteria wherein each bacterium in the culture would not inhibit the desired result of the others when used to inoculate seeds of leguminous plants. The mixed culture was nonpatentable, as the patentee had discovered "only some of the handiwork of nature."<sup>30</sup> No species acquired a different use. By contrast, Chakrabarty's bacterium was a new bacterium with markedly different characteristics from those found in nature.<sup>31</sup> "His discovery is not nature's handiwork but his own; accordingly it is patentable subject matter under section 101."<sup>32</sup>

The companion case to *Chakrabarty* was *In re Bergy*.<sup>33</sup> The examiner rejected the Bergy patent application on the basis that the microorganism culture, *Streptomyces vellosus*, was a "product of nature" and not within the subject matter of section 101 of the Patent Act of 1952.<sup>34</sup> Appeal to the Board affirmed the examiner's rejection, but the Board switched the basis of rejection: The Board concluded that section 101 precludes patenting any thing living.<sup>35</sup>

The C.C.P.A. reversed both the examiner and the Board and found the rejection based on "product of nature" to be wholly lacking merit.<sup>36</sup> The cul-

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<sup>27</sup>*Chakrabarty*, 447 U.S. at 309.

<sup>28</sup>*Id.*

<sup>29</sup>333 U.S. 127, 131 (1948).

<sup>30</sup>*Id.*

<sup>31</sup>*Chakrabarty*, 447 U.S. at 310.

<sup>32</sup>*Id.*

<sup>33</sup>596 F.2d 952 (C.C.P.A. 1979).

<sup>34</sup>*Ex parte Bergy*, 197 U.S.P.Q. (BNA) 78 (June 22, 1976).

<sup>35</sup>*Id.*

<sup>36</sup>*In re Bergy*, 563 F.2d 1031 (C.C.P.A. 1977).

ture "does not exist in, is not found in, and is not a product of, nature."<sup>37</sup> It is man-made and can be produced only under carefully controlled laboratory conditions.<sup>38</sup> In addition, the C.C.P.A. stated that the claim presented statutory subject matter and should not have been rejected on the ground that it was a living organism.<sup>39</sup> The United States Supreme Court granted certiorari but the appealed claim in the Bergy application was subsequently cancelled by the applicant in the Patent and Trademark Office. A motion was filed in the Supreme Court to dismiss the appeal as moot. The Supreme Court did dismiss *Bergy*.<sup>40</sup> Thus, *Diamond v. Chakrabarty* was left to be decided by the Supreme Court.

The inventor in *Bergy* had developed a purified culture of an old microorganism. He did not create a new one. This old microorganism, *Streptomyces vellosus*, was made capable of markedly increased production of an important antibiotic, lincomycin, without the concomitant production of lincomycin B. This microorganism did not exist as a pure culture in nature. It existed in the soil as a complex colony of microorganisms and this naturally occurring complex "could not be used to produce a desired product under any known fermentation conditions."<sup>41</sup> It was only by the discovery and skills of the microbiologist, that biologically pure cultures of microorganisms came into existence. The Bergy naturally-occurring microorganism was quite useless before it was purified.

When the "product of nature" rejection is used to reject as patentable the claiming of laws of nature, such as gravity or electricity, then there is longstanding judicial precedent for support.<sup>42</sup> However, when the "product of nature" is used to reject a claim to an entity, which as claimed does not occur in nature and cannot be considered a law of nature, this rejection could be ripe for reversal based on *Bergy* and *Chakrabarty*. Early in the case history of *Chakrabarty*, the Board expressly reversed the examiner; that withholding the Chakrabarty patent could not be based on the theory of a "product of nature" rejection, that one cannot take from the public that which the public already has the right to enjoy.<sup>43</sup>

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<sup>37</sup>*Id.*

<sup>38</sup>*Id.*

<sup>39</sup>*Id.*

<sup>40</sup>444 U.S. 1028 (1980).

<sup>41</sup>*In re Bergy*, 596 F.2d 952, 972 (C.C.P.A. 1979).

<sup>42</sup>*Id.* at 952.

<sup>43</sup>*In re Chakrabarty*, 571 F.2d 40, 42 (C.C.P.A. 1978).

The Supreme Court first defined "product of nature" in *American Fruit Growers, Inc. v. Brogdex Co.*<sup>44</sup> In this case, fruit was washed in borax, such that the rind of which became "impregnated with borax, through immersion in a solution, and thereby rendered resistant to blue mold decay."<sup>45</sup> The C.C.P.A. stated that the product, fruit, with its rind impregnated with borax, was an article of manufacture since the fruit was

the result of a process which is defined and described and not a natural product. The product is a combination of the natural fruit and a borax component carried by the rind or skin in an amount sufficient to render the fruit resistant to decay. The completed article is not found in nature and is thus an article of manufacture.<sup>46</sup>

The Supreme Court found the C.C.P.A.'s position untenable.

Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial use as theretofore.<sup>47</sup>

All that *American Fruit* requires for a patent is that the new article (fruit) possess "a new or distinctive form, quality or property" or "name, appearance or general character."<sup>48</sup>

In contrast to *American Fruit*, the Chakrabarty microorganism was a totally new super strain of bacterium created by the microbiologist who genetically engineered the insertion of four plasmids into a host bacterium. It was a product of human ingenuity having a distinctive name, character, and use. In comparison, the Bergy microorganism was a biologically pure culture of an otherwise unmodified microorganism capable of producing recoverable quantities of a useful antibiotic.

Even though the microorganism per se existed in soil, it could not therein "be used to produce the desired product under any known fermentation

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<sup>44</sup>283 U.S. 1 (1931).

<sup>45</sup>*Id.* at 11.

<sup>46</sup>*Id.*

<sup>47</sup>*Id.* at 11-12.

<sup>48</sup>*Id.* at 12-13.

condition."<sup>49</sup> In contrast, the borax treatment gave the oranges no new beneficial use; it merely protected the orange against deterioration by blue mold. The Bergy microorganism, however, was useless for production of lincomycin before the purification. This change in usefulness must be the type of new or distinctive quality or property that is required for a manufacture to be patentable purified natural product as envisioned by *American Fruit*. "The patent law does not proscribe patenting things which *exist* in nature, only the latter are things which all men may freely enjoy and which cannot be withdrawn from the public domain through patents."<sup>50</sup>

### III. What has happened since *Chakrabarty*?

Subsequent to *Chakrabarty*, the Board found maize plant technology to be within the subject matter of section 101 of the Patent Act of 1952.<sup>51</sup> The claims in *Ex parte Hibberd* relate to maize seed, maize plants capable of producing maize seed, and tissue culture capable of generating a plant capable of producing seeds containing an increased amount of tryptophan.<sup>52</sup>

The examiner rejected the claims solely under section 101, as the subject matter of seeds and plants is within the purview of the Plant Variety Protection Act of 1970 (PVPA).<sup>53</sup> The tissue culture patent application was rejected as subject matter inappropriate for protection under section 101 because it was in the purview of the Plant Patent Act of 1930 (PPA).<sup>54</sup> The examiner allowed patents for the hybrid seeds and plants.<sup>55</sup> The examiner's position was that the plant-specific Acts (PPA and PVPA) are exclusive forms of protection for plant life covered by those Acts.<sup>56</sup>

The Board held that the scope of patentable subject matter under section 101 of the Patent Act of 1952 has not been narrowed or restricted by the passage of PPA and PVPA, nor do these plant-specific Acts represent exclusive

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<sup>49</sup>*Bergy*, 596 F.2d at 972.

<sup>50</sup>Dunner & Lipsey, *The Patentability of Life Forms, New Technologies and Other Flocks of Nature*, 7 AM. PAT. L.A. Q.J. 190 (1979).

<sup>51</sup>*Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443 (Sept. 24, 1985).

<sup>52</sup>*Id.*

<sup>53</sup>*Id.* at 444.

<sup>54</sup>35 U.S.C. § 161 (1976).

<sup>55</sup>*Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 444 n.1 (Sept. 24, 1985).

<sup>56</sup>*Id.* at 444.

forms of protection for plant life covered therein.<sup>57</sup> The language of the PPA and PVPA does not exclude plant life, nor do the Acts' legislative histories exclude plant life as subject matter from protection under section 101 even though plant-specific Acts protect these plant forms.<sup>58</sup>

The *Hibberd* Court noted that the Supreme Court in *Chakrabarty* thoroughly examined the legislative history and purpose of both the PPA and PVPA. The Court stated that "prior to 1930, two factors were thought to remove plants from patent protection."<sup>59</sup> The first was the belief that plants, even though artificially bred "were products of nature not subject to patent protection."<sup>60</sup> The second was the fact that plants were not thought to be amenable to the "written description" requirements of the patent laws.<sup>61</sup> The Supreme Court in *Chakrabarty* stated that "in enacting the PPA, Congress addressed both of these concerns."<sup>62</sup> It explained at length its belief that the work of the plant breeder "in aid of nature" was a patentable invention, and it relaxed the written description requirement in favor of "a description . . . as complete as is reasonably possible."<sup>63</sup> The *Hibberd* Court felt the Supreme Court's analysis in *Chakrabarty* made it clear that these Acts were to extend patent protection to plant breeders under the PPA and PVPA when the two factors existed.<sup>64</sup>

The *Hibberd* Court reiterated the Borden Rule which provides that when there are two acts on the same subject, the rule is to give effect to both unless there is such a "positive repugnancy" or "irreconcilable conflict" that the statutes cannot coexist.<sup>65</sup> The Board found no "positive repugnancy" nor "irreconcilable conflict" between section 101 and the plant-specific Acts even though the subject matter under section 101 overlapped with the subject matter protectable under the plant-specific Acts. "[T]he overlap can be viewed as an indication that Congress intended the availability of both modes of protection."<sup>66</sup>

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<sup>57</sup>*Id.*

<sup>58</sup>*Id.*

<sup>59</sup>*Diamond v. Chakrabarty*, 447 U.S. 311 (1980).

<sup>60</sup>*Id.*

<sup>61</sup>*Id.* at 312.

<sup>62</sup>*Id.*

<sup>63</sup>*Id.*

<sup>64</sup>*Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443, 445 (Sept. 24, 1985).

<sup>65</sup>*United States v. Borden Co.*, 308 U.S. 189, 198-99 (1939).

<sup>66</sup>*Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443, 446 (Sept. 24, 1985).

#### IV. Expanding Biotechnology

It is noteworthy that without changes in legislation the judiciary has altered the interpretation of statutory subject matter to adapt to the developments in technology. As discussed above, both plant and animal technology are now held firmly within the scope of section 101 of the Patent Act of 1952. Ownership of patents in the biotechnology area has increased the commercial potential of biotechnology.<sup>67</sup>

Recombinant-DNA and gene-splicing can be used to turn the body's proteins into potential drugs and provide new routes for the industrial chemist. Biotech industries have successfully used their expertise to produce products ranging from human insulin for diabetes (instead of animal insulin) to new varieties of corn and tomatoes which are both hardier and more nutritious.<sup>68</sup>

Before they can be marketed, genetically engineered pharmaceuticals, food additives and cosmetics must be approved by the Food and Drug Administration (FDA). The FDA has approved five biotechnology therapeutics: human insulin (1982),<sup>69</sup> human growth hormone (1985),<sup>70</sup> alpha interferon (1986),<sup>71</sup> monoclonal antibody (1986)<sup>72</sup> and hepatitis B vaccine (1986).<sup>73</sup>

Genentech, Inc.'s human insulin, licensed to Eli Lilly and Co., became the first recombinant-DNA drug to reach the market.<sup>74</sup> Genentech markets the second FDA approved therapeutic, human growth hormone, under the tradename of Protropin.<sup>75</sup> This is the first drug taken from discovery to market six years later by a biotechnology company. Genentech sought FDA approval to market the human growth hormone in 1983.<sup>76</sup> Protropin is used to

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<sup>67</sup>For a discussion of pending federal legislation which offers the hope of renewed incentives for new animal health care products development, see *Research Encouragement Offered — But Heavily Qualified — In Legislation*, 7 *Animal Drug News* (Animal Health Inst.) No. 4, at 2 (July-Aug. 1986).

<sup>68</sup>*Biotech*, *supra* note 2, at 84.

<sup>69</sup>FDA Approves New Drug to Halt Rejection of Kidney Transplants, *Cleveland Plain Dealer*, June 20, 1986, at 5-A, col. 1 [hereinafter *FDA Approves New Drug*].

<sup>70</sup>*Id.* See also Hamilton, *Biotech's First Superstar*, *BUS. WEEK*, Apr. 14, 1986, at 68, 69.

<sup>71</sup>*Interferon Approved for Marketing by FDA*, *CHEM. & ENG'G NEWS*, June 9, 1986, at 7 [hereinafter *Interferon*].

<sup>72</sup>*FDA Approves New Drug*, *supra* note 69, at 5-A.

<sup>73</sup>*Lab-produced Vaccine Against Hepatitis OK'd*, *Cleveland Plain Dealer*, July 24, 1986, at 12-A, col. 1 [hereinafter *Vaccine*].

<sup>74</sup>Hamilton, *supra* note 70, at 69.

<sup>75</sup>*Id.*

<sup>76</sup>*Id.*

counteract a deficiency that causes some children to become dwarfs.<sup>77</sup> In June, 1986, Genentech sought FDA approval to expand the use of Protopin to treat short stature associated with Turner's Syndrome, a chromosomal disorder which affects approximately 8,000 young girls.<sup>78</sup>

In June, 1986, the FDA issued its first approval to market a recombinant DNA product for use against cancer.<sup>79</sup> The product, alpha interferon, which is the third FDA approved therapeutic, will be marketed by two companies, Hoffman-La Roche and Schering-Plough.<sup>80</sup> Both companies appeared to be heading for a clash over patent rights for their slightly different versions of alpha interferon. However, in May, 1985, the two firms agreed to cross-license the rights in the United States, thus avoiding both costly patent litigation and a delay in the introduction of the product.<sup>81</sup>

Interferon is the first of a new generation of synthetic anticancer agents, known as biologicals.<sup>82</sup> These natural substances exist in small quantities in the body, but now can be mass produced through genetic engineering.<sup>83</sup> La Roche developed its alpha interferon, tradenamed Roferon-A, in collaboration with Genentech, and Schering-Plough licensed its product, Intron A, from Biogen.<sup>84</sup> The FDA approved both versions specifically for the treatment of hairy cell leukemia, a disease which affects 1000 Americans.<sup>85</sup> At present these companies are seeking FDA approval to expand the use of alpha interferon against multiple myeloma, a cancer that attacks plasma cells; Kaposi's sarcoma, a cancer associated with AIDS; malignant meloma, a skin cancer; and venereal warts.<sup>86</sup> The companies are also testing alpha interferon for treatment of non-Hodgkin's lymphoma, a lymph gland cancer; laryngeal papillomatosis, the growth of warts in the throat; and the common cold.<sup>87</sup>

Of great importance to the developers of recombinant DNA therapeutics was the fact that the FDA approved alpha interferon within six months after

<sup>77</sup>*Biotech*, *supra* note 2, at 84.

<sup>78</sup>GENENTECH, INC., SECOND QUARTER REPORT 1 (1986).

<sup>79</sup>*Interferon*, *supra* note 71, at 7.

<sup>80</sup>*Id.*

<sup>81</sup>*Id.*

<sup>82</sup>*A Cancer Drug Wins Its Spurs*, U.S. NEWS & WORLD REP., June 16, 1986, at 7.

<sup>83</sup>*Id.*

<sup>84</sup>*Interferon*, *supra* note 71, at 7.

<sup>85</sup>*Id.*

<sup>86</sup>*Id.*

<sup>87</sup>*Id.*

the companies filed new drug applications; even on fast-track, FDA approval normally takes an average of two years.<sup>88</sup>

The fourth bioengineered drug to receive FDA approval is monoclonal antibody, which is being used to reverse the rejection of newly transplanted kidneys.<sup>89</sup> Each year about 7,000 Americans receive kidney transplants and about two-thirds have symptoms of acute rejection.<sup>90</sup> Unchecked, the rejection will lead to a shutdown of renal function and the patient's return to dialysis.<sup>91</sup> Federal health officials have said the new drug could also make kidneys available to more people.<sup>92</sup> The approval is the first world-wide for therapeutic use of a product of animal origin developed by biotechnology.<sup>93</sup> Monoclonal antibody is produced by fusing and cloning cells in a laboratory and not through the process of gene-splicing.<sup>94</sup> It is marketed by Ortho Pharmaceutical Corporation under the tradename, Orthoclone OKT3.<sup>95</sup>

Until recently, monoclonal antibody technology has been used primarily for diagnostic purposes, such as pregnancy testing, AIDS screening and tumor detection.<sup>96</sup> Research has indicated, however, that monoclonal antibodies may help purge bone marrow of tumor cells, thus enhancing the effectiveness of bone marrow transplants.<sup>97</sup>

In July, 1986, the FDA approved the first commercialized genetically engineered human vaccine, Recombivax HB. The vaccine, which prevents hepatitis B, is administered by three injections over an eight month period to those considered at risk of contracting hepatitis B from contaminated blood, semen, or saliva.<sup>98</sup> Recombivax HB is replacing the hepatitis vaccine made from human blood components.<sup>99</sup> It is estimated that seventy percent of those people who need inoculations do not get them out of fear of AIDS con-

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<sup>88</sup>*Id.* See also *Is Red Tape Tying Up High Tech? Keeping the Genie in the Bottle*, U.S. NEWS & WORLD REP., Apr. 21, 1986, at 50.

<sup>89</sup>*FDA Approves New Drug*, *supra* note 69, at 5-A.

<sup>90</sup>*Id.*

<sup>91</sup>*Id.*

<sup>92</sup>*Id.*

<sup>93</sup>*Id.*

<sup>94</sup>*Id.*

<sup>95</sup>*Id.*

<sup>96</sup>*Id.*

<sup>97</sup>*Id.*

<sup>98</sup>*Vaccine*, *supra* note 73, at 12-A.

<sup>99</sup>*Id.*

tamination.<sup>100</sup> Recombivax HB contains no blood ingredients and is produced by fermentation and modification of a special type of yeast.<sup>101</sup>

Hepatitis B can lead to liver cancer and cirrhosis of the liver.<sup>102</sup> The vaccine is expected to prevent many cases of these diseases, which annually claim the lives of approximately 5,000 Americans.<sup>103</sup> The vaccine was developed with gene-splicing techniques.<sup>104</sup> Scientists hope to use these techniques to develop similar vaccines against malaria, snail fever, and other diseases that result in millions of deaths throughout the world each year.<sup>105</sup>

Genentech is presently seeking approval of a tissue type plasminogen activator (t-PA), tradename Activase.<sup>106</sup> Genentech received its first patent on this drug in Britain in February, 1986.<sup>107</sup> Investors believe that Activase will be the second billion dollar drug.<sup>108</sup> FDA approval is expected in 1987.<sup>109</sup> Activase, a gene-splicing protein, sparks enzymes which will dissolve blood clots almost immediately in the treatment of heart attacks.

A report given at the American College of Cardiology in March, 1986, indicated that Activase cleared blocked arteries in seventy-five percent of the patients treated.<sup>110</sup> These findings were so significant that the National Institute of Health has decided it would be unethical to withhold Activase from the patients who were getting placebos in the clinical trials.<sup>111</sup> Now every patient in the trials will receive Activase as standard therapy.<sup>112</sup> The results of these trials will be submitted to FDA as part of the Product License Application.<sup>113</sup>

An antiviral drug, Azidothymidine (AZT) is the first drug shown to have prolonged the survival of AIDS patients.<sup>114</sup> The drug was developed and

<sup>100</sup>*Id.*

<sup>101</sup>*Id.*

<sup>102</sup>*Id.*

<sup>103</sup>*Id.*

<sup>104</sup>*Id.*

<sup>105</sup>*Id.*

<sup>106</sup>GENENTECH, INC., FIRST QUARTER REPORT 1 (1986) [hereinafter FIRST QUARTER REPORT].

<sup>107</sup>Hamilton, *supra* note 70, at 69.

<sup>108</sup>SmithKline Beckman Corp.'s antiulcer drug Tagamet was the first. *Id.*

<sup>109</sup>Webber, *Biotechnology Stocks Outraced Stock Market in First Half*, CHEM. & ENG'G NEWS, July 14, 1986, at 17.

<sup>110</sup>FIRST QUARTER REPORT, *supra* note 106, at 1.

<sup>111</sup>*Id.*

<sup>112</sup>*Id.*

<sup>113</sup>*Id.*

<sup>114</sup>*Experimental Drug for AIDS Shows Promise, Officials Say*, Cleveland Plain Dealer, Sept. 19, 1986, at 8-A, col. 1.

manufactured by the Burroughs Wellcome Company.<sup>115</sup> AZT was originally obtained from the sperm of herring and salmon. Today, methods have been developed to produce it synthetically through genetic engineering.<sup>116</sup> While most drugs take eight to ten years before the FDA clears them for general use, AZT emerged from testing in two years.<sup>117</sup>

Although AZT shows major promise in the battle against AIDS, it is not a cure.<sup>118</sup> AZT is now in the same class as other drugs whose trials were suspended when patients clearly improved.<sup>119</sup> The reason for the suspension was to allow those who took part in the study, but who had received a placebo, to begin taking AZT. The present course is to increase the size of the test group for new clinical trials.

In the race between the search for a cure and the spread of the nation's most feared infectious disease, doctors hope that advances can be made to stem the new threat of AIDS striking beyond-risk groups to the general population. Genentech is investigating the development of an AIDS vaccine which could prevent a widespread epidemic and eliminate the threat of the disease.<sup>120</sup> The results of Genentech's *in vitro* experiments have been encouraging, and the use of an animal model, such as the chimpanzee, will be a necessary next step.<sup>121</sup>

A new form of interferon was patented during the first week of October, 1986, for Damon Biotech, Inc.<sup>122</sup> Tradenamed Interferon Epsilon, the new form is produced from human epithelial cells and has a marked anti-viral activity in such cells.<sup>123</sup> Epithelial cells are abundant in the body and are major targets of virus infection and cancer.<sup>124</sup> The invention's use is still in the developmental stages.<sup>125</sup>

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

<sup>116</sup>Carey, *An AIDS Pill That Offers Hope*, U.S. NEWS & WORLD REP., Sept. 29, 1986, at 69.

<sup>117</sup>AZT emerged from testing in two years — an unusually brief period. Most drugs take eight to ten years before the FDA clears them for general use. Experimental drugs first are tested for safety in a dozen or so patients, which usually takes less than a year. It takes two years to test for effectiveness in a patient sample of about 200. Three more years of trials with up to 3,000 patients fine-tunes the dosages. Final FDA approval can take three years or more. *Id.*

<sup>118</sup>*Id.*

<sup>119</sup>*Id.*

<sup>120</sup>FIRST QUARTER REPORT, *supra* note 106, at 4.

<sup>121</sup>Lasky, *Neutralization of the AIDS Retrovirus by Antibodies to a Recombinant Envelope Glycoprotein*, 233 SCIENCE 209, 212 (1986).

<sup>122</sup>*A New Interferon*, N.Y. Times, Oct. 4, 1986, at 18, col. 3.

<sup>123</sup>*Id.*

<sup>124</sup>*Id.*

<sup>125</sup>*Id.*

Biotechnology is also important in the area of livestock production. At least ninety-two companies in the United States are now engaged in veterinary biotechnology activity of some type, and 171 separate veterinary biotechnology projects are known to be underway in industry.<sup>126</sup> Research efforts are currently centered on developing growth hormones, vaccines, and what is known as "probes and vectors."<sup>127</sup> The latter category includes products and processes that use biotechnology to diagnose disease, as well as regulate and enhance the animal's immune system.<sup>128</sup>

The bovine growth hormone (bGh) can increase milk yields up to twenty-five percent; field trials of this recombinant DNA growth hormone are now underway to demonstrate their safety and effectiveness.<sup>129</sup> Use of the bGh is expected to cause an increase in milk production and will eventually lower the price of milk.<sup>130</sup> The use of bGh is not without controversy, however. Jeremy Rifkin, an avowed foe of genetic engineering, has petitioned the FDA to block approval of the hormone.<sup>131</sup> Rifkin wants to compel the agency to perform an environmental impact statement as part of its review process, on the grounds that the hormone will affect land use and the cow's "internal environment."<sup>132</sup> He asserts that cows injected with the hormone will be subject to more stress and disease. The Humane Society of the United States was among co-signers of the petition.<sup>133</sup>

At a recent United States House of Representative hearing, representatives of the four hormone manufacturers of bGh argued that the hormone will help the farmer stay competitive, and that, over the short-term, treated cows do not differ from untreated controls with regard to disease, temperament and reproduction.<sup>134</sup> Long-term studies are still being conducted.<sup>135</sup> FDA approval of the hormone is not expected until 1989 or 1990.<sup>136</sup>

A recombinant DNA vaccine for pseudo-rabies is now available, and vaccines for foot-and-mouth disease, scours and coccidiosis may be available

<sup>126</sup>FDA Report *Outlines Future of Biotechnology*, 7 Animal Drug News (Animal Health Inst.) No. 4, at 1 (July-Aug. 1986) [hereinafter *FDA Report*].

<sup>127</sup>*Id.*

<sup>128</sup>*Id.*

<sup>129</sup>*Id.*

<sup>130</sup>Sun, *Will Growth Hormone Swell Milk Surplus?*, 233 SCIENCE 150 (1986).

<sup>131</sup>*Id.* at 151.

<sup>132</sup>*Id.*

<sup>133</sup>*Id.*

<sup>134</sup>*Id.*

<sup>135</sup>*Id.*

<sup>136</sup>*Id.*

between 1988 and 1991.<sup>137</sup> Jeremy Rifkin is also opposing the use of pseudo-rabies vaccine.<sup>138</sup>

Animal health officials in Minnesota claim that pseudo-rabies is costing hog farmers one million dollars a month. Nationally, it is estimated that about ten percent of the country's fifty-four million swine are infected with the pseudo-rabies virus. The annual cost to pork producers may be as high as sixty million dollars.<sup>139</sup>

In comparing the present state of veterinary biotechnology with the prospects for the future, growth hormones and vaccines will continue to dominate research activities. However, inventors are moving in all directions, producing an astounding number of useful products including pharmaceuticals, improved plant varieties, pesticides and chemical feedstocks.

Moreover, gene-splicing will lead to patent applications on living organisms more complex than a virus or bacterium. It could eventually lead to genetically engineered humans. A Canadian Patent Appeal Board stated in the case of *In re Abitibi*:

If an inventor creates a new and unobvious insect which did not exist before (and thus is not a product of nature), and can recreate it uniformly and at will, and it is useful (for example to destroy, the spruce bud worm), then it is every bit as much a new tool of man as a microorganism. With still higher life forms it is of course less likely that the inventor will be able to reproduce it at will and consistently, as more complex life forms tend to vary more from individual to individual. But, if it eventually becomes possible to achieve such a result, and the other requirements of patentability are met, we do not see why it should be treated differently.<sup>140</sup>

Thus far both plant and animal technology are within the subject matter of section 101 of the Patent Act of 1952. The frontiers of biotechnology are yet to be explored. With *Chakrabarty* as the basis, man is finding the capability of making anything and everything — all possibly patentable. As reiterated by Chief Justice Warren Burger, statutory subject matter should "include anything under the sun that is made by man."<sup>141</sup>

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<sup>137</sup>FDA Report, *supra* note 126, at 1.

<sup>138</sup>Science Seen as Primary in Government-Industry Dialogue, 7 Animal Drug News (Animal Health Inst.) No. 5, at 4 (Sept.-Oct. 1986).

<sup>139</sup>*Id.*

<sup>140</sup>*In re Abitibi*, 24 Pat. Trademark & Copyright J. (BNA) No. 592, at 394 (Mar. 18, 1982).

<sup>141</sup>*Diamond v. Chakrabarty*, 447 U.S. 309 (1980).