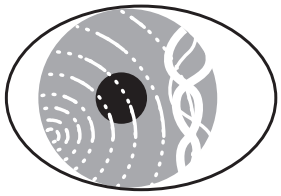
European Group
on Ethics in Science
and New Technologies
to the European Commission

European Commission

A history of patenting life in the United States with comparative attention to Europe and Canada

This study has been carried out at the request of the European Group on Ethics in Science and New Technologies during the preparatory work of its opinion on ethical aspects of patenting inventions involving human stem cells



European Group
on Ethics in Science
and New Technologies
to the European Commission

European Commission

A history of patenting life in the United States with comparative attention to Europe and Canada

Daniel J. Kevles

Department of History
Yale University

A report to the
European Group on Ethics in Science
and New Technologies

12 January 2002

This study has been carried out at the request of the European Group on Ethics in Science and New Technologies during the preparatory work of its opinion on ethical aspects of patenting inventions involving human stem cells

A great deal of additional information on the European Union is available on the Internet.
It can be accessed through the Europa server (http://europa.eu.int).

Cataloguing data can be found at the end of this publication.

Luxembourg: Office for Official Publications of the European Communities, 2002

ISBN 92-894-2063-4

Printed in Luxembourg

PRINTED ON WHITE CHLORINE-FREE PAPER

CONTENTS

.

I. Patents and Products of Nature

During a congressional hearing on patenting animals in 1987, the late Congressman Mike Synar, a wry Democrat from Oklahoma, remarked that few lawyers knew anything about patent law. “Everyone knows it is not part of the bar exam, so to hell with it.”[1] But while patent law is arcane, like many other branches of law in the United States – for example, business, regulation, and civil rights – it is also a branch of the more familiar political economy. And in recent years, the part of it that concerns the patenting of life, especially animals and genes, has also become, for the first time, a branch of ethics.

What is patentable in the United States according to statute dates back to the patent law of 1793, which declared, in language written by Thomas Jefferson, that patents could be obtained for "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof." Jefferson's phrasing remained -- and remains -- at the core of the U.S. patent code, except for the eighteenth-century word "art," which was replaced in a 1952 Congressional overhaul of patent law by the word "process."[2]

The code said nothing about patenting life, but a key precedent discouraging it was established in 1889, when, in a landmark ruling, the U.S. Commissioner of Patents rejected an application for a patent to cover a fiber identified in the needles of a pine tree. He noted that ascertaining the composition of the trees in the forest was "not a patentable invention,

---

[1] U.S. Congress, House, Hearings before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Committee on the Judiciary. Patents and the Constitution: Transgenic Animals. 100th Cong., 1st Sess., June 11, July 22, Aug. 21, and Nov. 5, 1987, p. 27 (hereafter, HJSH, 1987).

[2] Fritz Machlup, "Patents," International Encyclopedia of the Social Sciences, ed., David L. Sills (New York: Macmillan, 1968), XI, 461-64; Bruce W. Bugbee, Genesis of American Patent and Copyright Law (Washington, D.C.: Public Affairs Press, 1967), p. 152.

recognized by statute, any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found." The commissioner added that it would be "unreasonable and impossible" to allow patents upon the trees of the forest and the plants of the earth.[3] The commissioner's ruling formed the basis for what came to be known as the "product-of -nature" doctrine -- that while processes devised to extract what is found in nature can be patented, objects discovered there can not. They are not inventions, nor can they as a class be made anyone's exclusive property.

In 1891, in a report to the American Association of Nurserymen, the respected plant scientist Liberty Hyde Bailey, of Cornell University, added technical weight to the legal discouragement. Two years earlier Bailey had told the nurserymen that an obstacle to any type of intellectual property protection for plants was that new types of plants were difficult to define or specify. Now he pointed out that most new varieties were accidents that the nurseryman found rather than the product of systematic breeding, adding, however, that "when the time comes that men breed plants upon definite laws and produce new and valuable kinds, then plant patents may possibly become practicable."[4]

The rediscovery of Mendel's laws at the turn of the century encouraged breeders to think that the era of controlled plant innovation had arrived. Nurserymen first asked Congress for protection in the form of plant patents in 1906. Indeed, the power of Mendel's laws was

---

[3] *Ex Parte Latimer*, March 12, 1889, C.D., 46 O.G. 1638, U.S. Patent Office, Decisions of the Commissioner of Patents and of the United States Courts in Patent Cases. . . 1889 (Washington, D.C.: Government Printing Office, 1890), pp. 123-27. See also H. Thorne, "Relation of Patent Law to Natural Products," Journal of Patent Office Society, 6 (1923), pp. 23-28.

[4] Richard P. White, A Century of Service: A History of the Nursery Industry Associations of the United States (Madison, Wis.: American Association of Nurserymen, 1975), p. 129.

invoked by one Hyland C. Kirk, a horticultural spokesman, when he testified before the House Committee on Patents when it considered the 1906 bill to establish intellectual property protection for plants. The measure, originally aimed at strengthening plant trademarks against infringement, had been revised to allow patents for horticultural plants, trees, and vines. Kirk advanced a claim that would be repeated frequently in the debates over plant patenting and that had a certain degree of ethical content: the originator of a "new variety of plant, tree, or vine . . . is as truly an inventor and, as such, as justly entitled to protection as the originator of a new motor, a new chemical compound, or any other valuable combination of materials requiring experiment, deliberation, and design."[5]

Nevertheless, the bill died in committee. Evidently, few Congressmen considered breeding distinct enough from the practice of farming to warrant special protection. Farmers and horticulturalists often found plant sports or mutations in the field and routinely exploited them. Both breeders and farmers continued to benefit from the importation of new plant varieties from abroad and from the expanding activities of public breeders in the agriculture department and state universities, colleges, and experiment stations. Then, too, by practice and tradition, farmers assumed that they should enjoy free and unencumbered access to new seed varieties. And urban Americans probably tended, like Europeans, to think of food as a

---

[5.] The bill had originally been designed to authorize the Commissioner of Patents to register, and allow the exclusive use of, new plants for twenty years under the Trade Mark Law. It was amended into a plant patent bill. Hyland C. Kirk, "Brief on House Bill 18851 . . . , " and discussion, U.S. Congress, House, Committee on Patents, Arguments on H.R. 18851, May 17, 1906, pp. 5-7, 12-13; Jack Doyle, Altered Harvest: Agriculture, Genetics, and the Fate of the World's Food Supply (New York: Penguin Books, 1986), p.50.

scarce resource and to be reluctant to grant anyone a monopoly right over food products, even for a limited period.[6]

II. The Plant Patent Act

Although an immediate failure, the 1906 venture did lead to the formation of a lobbying group, the National Committee on Plant Patents, which was organized and kept alive by Archibald Augustine of Augustine Nurseries in Bloomington, Illinois. By the late 1920s, nurserymen were especially interested in patents, not least because the potential American market for their stocks was estimated -- according to a report delivered to the 1928 convention of the American Association of Nurserymen -- at one billion dollars, mostly for ornamental plants.[7] When Augustine was elected president of the American Association of Nurserymen in 1929, he was succeeded in the chairmanship of the National Committee by Paul Stark.

Stark was a principal in the Stark Brothers Nursery, which was now a century-old and, capitalized at one million dollars, was the largest breeder in the country. Stark brothers continued to derive some of its stock by running competitions for prize fruit specimens; bonanzas came in the mail, notably the yellow apple that arrived at the nursery in a box one day in the spring of 1914 and that they soon marketed as the Stark Golden Delicious. But the firm

---

6. Dickson Terry, The Stark Story: Stark Nurseries' 150th Anniversary (Columbus, Mo: Missouri Historical Society, 1966), pp. 48-51; Marie-Angèle Hermitte, "Histoires juridiques extravagantes: La reproduction végétale," in La Gestion des Ressources Naturelles d'Origine Agricole, eds. J.-C. Fritz and Ph. Kahn (Paris: Librairies Techniques, 1983), pp. 272-3.

7. Some 10,000,000 homes were said to need the services of nurserymen: Only 22% of front yards were planted; of rear yards, only 7%. "American Association of Nurseryman's Convention, Billion Dollar Market Indicated by Survey," The National Nurseryman, 36(July 1928), 201.

also relied on more consistent sources, notably the famed plant breeder Luther Burbank.[8] Paul Stark had met Burbank in 1893, when Burbank was worried about making enough money to continue his research. A friendship and business arrangement blossomed. Stark Brothers came to own exclusive licenses to many of Burbank's cultivars. When Burbank died, in 1926, his will stipulated that his farm, in Santa Rosa, California, be converted into the Stark-Burbank Research Laboratories and Experimental Grounds. Stark thus inherited hundreds of varieties of plums, peaches, apples, cherries, pears, roses and gladiolas that had never been marketed -- and that might be patented if only patent protection were available. It was Stark, who became the prime mover behind the 1930 Plant Patent Act.[9]

Stark himself drafted the measure. It was introduced in the Senate by John G. Townsend, Jr., of Delaware, who probably knew Stark and certainly had reason to sympathize with his purpose, since he owned 130,000 acres of apple orchards, which made him the second largest orchardist in the country.[10] Endorsements of the bill rained down upon the Congress from horticulturalists, nurserymen, farmers, agricultural experiment stations, and their organized representatives, including the American Farm Bureau Federation, the National

---

8. Terry, The Stark Story , pp. 48-51, 66.

9. Ibid., pp. 84-86; Doyle, Altered Harvest, pp. 51-53.

10. Richard B.Carter, Clearing New Ground: The Life of John G. Townsend, Jr. (privately printed, n.d.), pp. 349-52, 401-403; Doyle, Altered Harvest, pp. 51-53; Peter Dreyer, A Gardener Touched with Genius: The Life of Luther Burbank, rev.ed. (Berkeley: Univ. of California Press, 1985), p. 218. The largest orchardist in the country was reputedly Harry Flood Byrd, a Senator from Virginia and Townsend's good friend. Carter, Clearing New Ground, p. 352. Townsed celebrated the brains among the one third of the American poplation who worked on the land, noting: "Today we are, and for a century we have been, wasting this dormant talent that needs ony to be awakened by the hope of ultimate reward to bring into being marvels of plant life comparable in value to anything that the industrial genius has given to our civilization." "The Importance of Plant Patents to Agriculture: A Statement by Hon. John G. Townsend, Jr. . . . ," The National Nurseryman, 38(April 1, 1930), p. 5.

Grange, the International Appleship Association, and the Peony and Iris Association. Thomas Edison wired that Congress could do nothing better for American agriculture than "to give the plant breeder the same status as the mechanical and chemical inventors now have through the patent law." Luther Burbank's widow sent a telegram of her own declaring that her late husband would have been "unable to do what he did with plants had it not been for royalties from his writings and from other by-product lines of activity" and declared that most other plant developers were unlikely to derive such ancillary revenues from their work.[11]

In brief hearings, perfunctory floor debate, and the reports on the bill, its Congressional promoters noted the considerable dependency of plant breeding and research on governmental money, emphasizing that the establishment of a breeder's legal right in his innovations might stimulate private investment in these activities and make it possible for the breeder to reduce his prices. They pointed to the incentives that patent protection would give plant breeders to develop varieties resistant to blight and disease and rich in food or medicinal qualities; varieties that would strengthen public health, prosperity, and national defense -- and all without the expenditure of federal money. With sentimental nods to Luther Burbank, who was said to have made no money from his plants, the bill's enthusiasts invoked the ethical premise in a right to intellectual property, saying that it would rescue plant breeders from vulnerability to piracy and the fate of an impoverished death.[12]

[11.] U.S. Congress, Senate, Congressional Record, 71st Cong. 2d Sess., April 9, 1930; April 17, 1930; May 12, 1930, 6765, 7200-7201, 8750.

[12.] U.S. Congress, House Committee on Patents, Plant Patents, 10 April 1930, House Report 1129, pp. 11-12; and idem, Hearing on H.R. 11372: A Bill to Provide for Plant Patents, 71st Cong., 2d Sess., 9 April, 1930, p. 3.

In these first few months of the 1930s Depression, the measure appealed as a farmer's and plant breeder's relief bill, Hoover-Republican style. With Republicans still in control of the Congress, the prevailing wisdom around Washington about how to respond to the worsening economic slide was: encourage private enterprise, reduce government costs and activities. There was only scattered opposition to the bill, including some biting harassment from Congressman Fiorello Laguardia, who was hazy in his understanding of heredity in plants but who understood well that the measure did nothing for direct farm relief. The Plant Patent Act passed easily on a voice vote some three months after it had first been introduced. Edison cheered in The New York Times, "Luther Burbank would have been a rich man if he had been protected by such a patent bill."[13]

In a report on the bill, the House Committee on Patents, mindful of the product-of-nature doctrine, had addressed the constitutionality of the measure, asking: Would a new variety of plant be a discovery, and could its originator be considered an inventor or a discoverer? The report's answer: Yes, on both counts. In the reasoning of the document, while a new variety of plant found in the field was a product of nature and, hence, not patentable under the meaning of the word "discoveries" in Article I, Section 8, a new variety arising from cultivation was such a discovery -- and its cultivator a discoverer -- since it was created by human agency. The report saw no difference between "the part played by the plant originator in the development of new plants and the part played by the chemist in the development of new compositions of matter."

[13.] Congressional Record, 71st Cong., 2d Sess., 5, 12, and 13, May 1930, pp. 8391, 8751, 8866; and Doyle, Altered Harvest (cit. n. 15), p. 55. Identical bills for plant patents were introduced in the House and the Senate on 11 February 1930. Robert Starr Allyn, The First Plant Patents: A Discussion of the New Law and Patent Office Practice (Brooklyn, N.Y.: Educational Foundations, 1934), p. 60.

Both took the materials of nature, exploited its laws, and, by applying a variety of techniques, devised a new and useful product.[14]

However, in the 1930s chemical products and plants differed from each other in ways that affected the type of patent protection that plants could obtain. Patent law insisted that an invention be disclosed specifically enough to be identically reproducible. Chemical products, as dead matter, were highly specifiable as to composition and methods of production and reproduction. Plants, as living matter, were difficult to specify in either regard. These differences were reflected in the Plant Patent Act, which accommodated the basic tenets of patent law to the fundamental problem of biological specificity. The act limited patent protection to those plants that could be reproduced asexually. Often termed cloning, asexual reproduction was accomplished by budding, grafting, rooting of clippings, or dividing bulbs; it yielded progeny genetically identical to the parent plant or tree.

The act also explicitly excluded from patentability tuber-propagated plants -- a provision that would substantially affect only Irish potatoes, which was a major cash crop, and Jerusalem artichokes, a type of sunflower that was widely used as a vegetable and a livestock feed. Resistance to allowing monopoly control over major food stocks may have figured in the exclusion. However, to advocates of plant patenting, authorizing patents on tuber-propagated plants like the Irish potato threatened the enforceability of plant patents in general, mainly because the part of them that is involved in reproduction is also widely sold as food. Paul Stark later explained the reasoning behind the exclusion: Because potatoes were available everywhere

---

[14.] Plant Patents, House Report 1129, pp. 16-17.

"for use as food or for growing the plants," infringement of a potato-plant patent would be "easy" and "widespread," making enforcement "a farce." He added, "This would reflect unfavorably on enforcement with the other types of asexually reproduced plants -- so for that reason potatoes were excluded from the original Plant Patent Act in 1930."[15]

Stark and his allies had perceived an equally vexing enforcement problem for patents on sexually reproduced plants -- that is, plants reproducing by pollination and seeds. Such plants could not generally be relied upon to breed identically true to type from one generation to the next. (Sexual reproduction joins half the genes from one plant with half from another; over several generations, the progeny can easily drift genetically far from the original parental type.) Patents on sexually reproduced plants could not be enforced because the progeny would be different from the patented parent. The likely unenforceability prompted a special committee of the American Society for Horticultural Science to oppose flatly the provision of patent protection for seed-propagated plants, and it convinced key members of the Patent Office and the Department of Agriculture that no plant patent bill with such a provision could pass.[16] The Congressional stewards of the bill, although they may not have understood the genetics, were

---

[15.] Paul Stark, "Report," attached to Stark to Tom Brennan, 8 March 1968, U. S. Congress, Patent Law Revision: Hearings , Subcommittee on Patents, Trademarks, and Copyrights of the Senate Committee on the Judiciary, 90th Cong., 2d Sess., 30 and 31 Jan., and 1 Feb. 1968, Part 2, p. 865. [The report was filed after the hearings were held but before they were printed.] In 1930 there was no processed potato industry to object to the exemption on tuber-propagated plants as there was in 1959, when a potato chip company tried to overturn it. Congress reaffirmed the exemption, however, after seed certifying agencies argued that if farmers could simply buy their buds in bags in grocery stores, potato breeders could circumvent regulations on seed trade. U.S. Congress, Senate, Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, Hearings: Plant Patents, 86th Congress, 1st Sess., 9 July 1959.

[16.] U. S. Congress, Patent Law Revision: Hearings , Subcommittee on Patents, Trademarks, and Copyrights of the Senate Committee on the Judiciary, 90th Cong., 2d Sess., 30 and 31 Jan., and 1 Feb. 1968, Part 2,,, pp. 862-63.

evidently sufficiently aware that like did not necessarily breed like to omit from the final measure protection for plants that were reproduced sexually.

Despite the restricted coverage provided by the act, it was a boon to nurserymen like Paul Stark. While narrow, the category of asexually reproducible plants was capacious enough to include much of such breeders' stock in trade -- that is, virtually all fruit and nut trees; most small vinous fruits such as grapes, strawberries, and blueberries; and numerous ornamental shrubs, vines, and perennials, among them lilacs, wisterias, and peonies as well as roses.[17]

According to The First Plant Patents, a survey published in 1934 by a New York patent lawyer named Robert Starr Allyn, the government had granted eighty-four plant patents by the beginning of that year, including one to Secretary of the Interior Harold L. Ickes, for a red dahlia. Nine of the patents went to Burbank's estate for certain of his fruits and flowers. His widow assigned the patents to Stark Nurseries, which acquired rights to an additional five from other breeders.[18]

Since the wares of seedmen comprised sexually reproducing plants, the act disappointed the American Seed Trade Association, which had allied itself with Stark in the plant-patent legislative drive. Stark defended the omission of sexually reproduced plants from the coverage of the act, telling the association that "it seemed to be the wise thing to get established the principle that Congress recognized the rights of the plant breeder and originator," predicting that

---

17. "Patents on Plants," Science -- Supplement, 71(April 25, 1930), xiv.

18. Allyn, The First Plant Patents, pp. 52, 55, 86, 90, 92, 97. Burbank's estate obtained a total of 15 plant patents through 1944. As of 1966, Stark Nurseries had acquired exclusive rights to 89 plant patents. Allyn, Plant Patents, 1934-1944 (Brooklyn, NY: Corsi Press, 1944), p. 9; Terry, The Stark Story, p. 87.

once the principle was in place, it would be "much easier" to get protection for plants propagated by seed.[19]

However, while the act installed the principle, the intellectual property protection it provided was no better than the degree of biological specificity -- which was to say the least limited -- with which plants could then be identified. The act was extremely permissive in inventive definition, allowing patents on plants, even naturally occurring ones, that might be no more than minimally distinguishable from others, so long as human intervention had been required to reproduce the plant asexually. Its disclosure requirements, adapted to the elusiveness of biological definition, were also, of necessity, loose. The act called for the submission of a color painting or photograph as well as a written description of the plant that was as "complete as is reasonably possible." It called for an historical preamble describing how the plant was bred or where the sports from which it was asexually reproduced had been found, and how it differed from the plants that comprised its pedigree. It asked for data concerning when the plant bloomed and which soils and climates best suited it. It expected a technical description outlining the color and shape of the bush, leaves, and flower.[20] The early applications included a few objective descriptions -- for example, lengths and the tones listed on Ridgway's Color Chart, a commercially manufactured set of cards, much like paint-sample cards, that breeders held against a plant to identify and match a name to its colors. it. Fruit, which was mostly described

---

[19.] Jack R. Kloppenburg, Jr., First the Seed: The Political Economy of Plant Biotechnology, 1492-2000 (New York: Cambridge Univ. Press, 1988), p. 133.

[20.] Allyn, The First Plant Patents, pp. 18-38; Robert C. Cook, "Other Plant Patents," Journal of Heredity, 24(February 1933), 49-54.

by external appearance, might be more objectively specified by such intrinsic characteristics as acidity and sugar levels.[21]

Given the relaxed nature of the disclosure requirements, critics questioned whether the Patent Office would be able to administer the act so as to distinguish genuine from counterfeit intellectual property. Their doubts were perhaps accentuated when the first examiner assigned to plant patents proved to be not a botanist but a mechanical engineer who was also charged with oversight for "Closure Operators, Fences, Gates, Tillage and Handling Implements." After a year, Herbert Hoover ordered the Department of Agriculture to assist the Patent Office. The first plant patent -- on a rose called the 'New Dawn' -- confirmed the critics' fears. An amateur gardener had found a bud mutation on the 'Van Fleet' rose, which had been painstakingly developed by an established breeder, that supposedly extended the life of the flower. Save for this "everblooming" quality, the New Dawn was identical to the Van Fleet. Most patents were issued to amateur gardeners who, finding sports and mutations on well established cultivars, assigned them to large nurseries.[22]

Robert C. Cook, the editor of the Journal of Heredity, feared that plant patents would become the conceits of amateur gardeners rather than real protection for professional breeders. In the hope of making plant patents more like industrial patents, he proposed "type plants" as in situ deposits, much as the patent office in the 1800s had demanded patent models when written

---

[21] Allyn, First Plant Patents, pp. 18-38; 35 USCA [U.S. Code, Annotated] Appendix, rule 162-3; and 37 CFR [Code of Federal Regulations, Section] 1.163. The reasonability exception to the general patent law was upheld in Kim Bros. v. Hagler, 120 USPQ 210 (21 November 1958); on the need to prove active and willful infringement, see Armstrong Nurseries, Inc. v. Smith, 120 USPQ 220.

[22.] "Patenting of Plants Promises Big Profits--and Big Problems, Business Week, Aug. 26, 1931, p.26.

descriptions were inadequate.[23] However, the imprecise disclosure of the plant patent application limited the protection that the federal government could offer to patent holders.

In practice, the Plant Patent Act only prevented unauthorized advertising by the patented name. It functioned more as a registration system than as the kind of rigorous examination and screening system characteristic for industrial inventions. Because the descriptions of patented plants were so poor, the cornerstone of most case law surrounding the act was not whether an alleged infringer's plant looked like a patented one but whether it could be proved to have been cloned from it. The definition of the inventive act was that a plant, even one found in the wild, had been asexually reproduced, in a sense reduced to practice. Many applications jointly listed the discoverer and the reproducer. The written descriptions advertised the commercial identity of the plant because breeders had to supply a name for the new cultivar -- usually it was a fancy one, like Delmass Peach or Peace Rose.[24] All that the breeders really got from the act was the ability to use a tradename and a legal basis for infringement suits. The weakness of the protection provided by the Plant Patent Act was perhaps revealingly expressed by the small number of patents issued under it -- 911 in the twenty years following its passage.[25]

[23.] Botanical gardens increasingly allied themselves with variety associations to maintain type plants. For instance, in 1946 the Huntington Gardens in Pasadena, California became the repository of all known varieties of camellias, a project sponsored by the Southern California Camellia Society. Botanical Gardens/Henry E. Huntington Library Institutional Archives, Henry E. Hungtington Library, San Marino, CA, file 50.1.1.1.

[24.] Allyn, The First Plant Patents, especially pp. 14, 18.

[25.] U.S. Patent Gazette, 635(January 1950). On the principle of asexual reproduction as reduction to practice, see Dunn v. Ragin v. Carlile, (PO Bd Inter Exam) 50 USPQ 472; on the allowance of joint applications, see Ex Parte Kluis & Kluis, (PO BdApp) 70 USPQ 165.

III. The *Chakrabarty* Case

There was no other extension of patent law to vital entities for forty years, but in 1970 Congress established a system -- through the Plant Variety Protection Act (PVPA) – for granting intellectual property rights in sexually reproducing plants.[26] The protection was weaker than what patents provided; it was nevertheless a step forward for plant breeders. More important, during that period it became possible to identify living organisms with a high degree of specificity through such markers as blood types and, in the 1970s, their DNA. Then, in the early seventies, Ananda Chakrabarty, a biochemist at the General Electric Company, having genetically modified the bacterium *Pseudomonas* to consume oil slicks, filed for a patent on the living, altered bacterium.

Chakrabarty judges that companies long accustomed to the product-of-nature barrier to patents -- say, companies such as the major drug firms, which deal in biological products -- would not have filed a patent application on his new bugs. They would have limited the application to the process of constructing them. However, General Electric, not being a biological company, operated in a different patent culture. The General Electric patent lawyer assigned to the case was Leo I. MaLossi, who had been with the firm since 1963, was used to filing patent applications on items like refrigerators, plastics, jet engines, and nuclear power plants, and thought that if you invented something new and useful, you deserved a patent covering whatever claims about it you could legally make. Chakrabarty recalls telling

---

[26] Glenn Bugos and Daniel J. Kevles, "Plants as Intellectual Property: American Law, Policy, and Practice in World Context," *Osiris*, 2nd Series, Vll (1992), 119-48.

MaLossi, during numerous consultations, that living creatures could not be patented. MaLossi would say, Why not? [27]

MaLossi remembers, "When I first proposed to introduce the claims to the organism per se, I had occasion to speak to various patent attorneys who had worked in that type of technology. . . . What intrigued me was that all of them said that such claims were unpatentable, but they all gave me different reasons why. Now that got me to thinking that there's something funny here. So I read all the case law I could lay my hand on that had any pertinence to the subject and then I became convinced that I was right. What had happened is that [the inadmissability of claims to live matter] had become a canon of patent law and nobody questioned it."[28]

To MaLossi, aware that by now scientists understood living matter, including bacteria, to be chemicals, Chakrabarty's bugs were manufactures, new compositions of matter -- and, hence, patentable. On June 7, 1972, Chakrabarty filed for a patent to cover not only the process by which he had constructed his oil-eating bacteria but also the product -- the living, genetically modified bacteria.[29]

In September 1973, Alvin E. Tanenholtz, the patent examiner supervising the review of Chakrabarty's application, rejected the product claims for the bacteria per se, though not for the

---

[27] Author's telephone interview with Ananda Chakrabarty, August 8, 1988; author's telephone interview with Leo I. Malossi, August 18, 1988.

[28] Author's telephone interview with MaLossi, Aug. 23, 1988.

[29] "Application of Ananda M. Chakrabarty, Filed June 7, 1972, Serial Number 260,563, for Microorganisms Having Multiple, Compatible Degradative Energy-Generating Plasmids and Preparation Thereof," in U.S. Court of Customs and Patent Appeals, Transcript of Record, Patent Appeal Docket No. 77-535. In the Matter of the Application of Ananda M. Chakrabarty, Applicant (Hereafter, Transcript of Record . . . Chakrabarty), pp. 6-7.

process of producing them; in April 1974, after several legal counters from MaLossi, he rejected the product claims finally.[30] Throughout the legal jockeying, Tanenholtz's principal ground for rejection was that the bugs were products of nature; their four plasmids had made them different in degree from naturally occurring Pseudomonas but not in kind. He also implied that living creatures were not patentable, if only because neither legislative nor case law had made them so. Leo MaLossi, in a protest brief filed in June 1974 to the Patent Office's internal Board of Appeals, insisted that the bugs were not products of nature because Chakrabarty's manipulations of their plasmids had altered them fundamentally. He also argued that nothing in case law disallowed a patent purely on grounds that the product was alive and he contended that the bugs were patentable because Chakrabarty's alterations had turned them into new compositions of matter.[31]

The three-man Board, ruling almost two years later, on May 20, 1976, conceded that Chakrabarty's bacteria did not occur naturally and, hence, were not products of nature, but it upheld Tanenholtz's rejection of the claims on a new explicit ground -- that the bacteria were not patentable because they were living organisms. Partly behind the Board's reasoning was a presumptive apothegm: In so many words, what the law did not prohibit, it did not necessarily allow. Although statutory patent code did not proscribe patents on plants, Congress had felt the

---

[30] Ray Penland was the patent examiner working on the case, but, according to Tanenholtz, Penland did not then have signatory authority and he, Tanenholtz, was responsible for the main arguments advanced against the grant of a patent for the bacteria up through the decision of the Board of Appeals. Author's telephone interview with Alvin E. Tanenholtz, August 29, 1988.

[31] "Letter of Examiner," Sept. 19, 1973; Chakrabarty,"Amendment," Dec. 6, 1973; "Letter of Examiner," Jan. 11, 1974; Chakrabarty, "Amendment," April 5, 1974; Malossi, "Brief," June 24, 1974; "Examiner's Answer," Sept. 23, 1974; Malossi, "Reply Brief," Oct. 10, 1974; "Opinion and Decision of Board of Appeals," May 20, 1976, all in Transcript of Record . . . Chakrabarty, pp. 59-61, 65-66, 68-73, 78-80, 82-84, 86-97.

need to enact a special Plant Patent Act to reward plant breeders. Yet the Board was also gripped by a specter of implications that Tanenholtz had raised in a reply to Malossi's brief: To adopt a broad interpretation of phrases such as "new composition of matter" would "open the flood gates to patentability for all newly produced microorganisms as well as for all newly developed multi-cellular animals such as . . . chickens and cattle." The Board's ruling reiterated Tanenholtz's warning and added that if patents could be granted to single-cell organisms with additional plasmids, so might they be given for "multicellular organisms (including human beings)" with transplanted livers or hearts. Chakrabarty's bugs might not occur naturally, but the Board chose to emphasize "that a human being with a transplanted liver or heart is also not naturally occurring."[32]

The Board's ruling had changed the complexion of the case for MaLossi and his boss, Charles Watts, the General Electric Patent Counsel for Materials Science and Engineering. For MaLossi, prior to the Board's ruling, Chakrabarty's had just been another workaday patent application. Now that the Board had shifted the issue to the patentability of living matter, MaLossi recognized with Watts that the G.E. patent department had been presented with an opportunity to participate in the making of new case law -- an opportunity, Watts later reflected, that "you don't often get in a career as a lawyer, especially in a large corporation."[33] General

---

[32] "Examiner's Answer," Sept. 23, 1974; "Opinion and Decision of Board of Appeals," May 20, 1976, in Transcript of Record . . . Chakrabarty, pp. 86-89, 92-97.

[33] Author's telephone interviews with Leo I. MaLossi, August 18, 1988, and with Charles Watts, August 18, 1988.

Electric decided to take Chakrabarty's case to the United States Court of Custom and Patent Appeals, which was seated in Washington, D.C.

By this point, late 1976, Chakrabarty's claim had become entwined with a complementary case advanced by Malcolm E. Bergy and fellow scientists at the Upjohn Company. They had developed a process for obtaining a purified strain of the newly discovered fungus Streptomyces vellosus, whose metabolic chemistry generated the antibiotic lyncomycin. In June 1974, Upjohn had applied for a patent on the method, but an Upjohn patent lawyer named Roman Saliwanchik thought the claim incomplete. Saliwanchik had been trained as an undergraduate in microbiology and biochemistry. From the time he had begun to study cases in law school, he had been puzzled why a living organism should not be patentable simply because it was living. He saw an opportunity to test that doctrine with Bergy's fungus: since it did not exist in nature as a biologically pure culture, it seemed to qualify for a patent as a manufacture. In January 1975, Salwanchik enlarged Bergy's claim to include the product -- the purified strain of the organism itself.[34]

The product application was initially rejected by a patent examiner on grounds that the fungus was a work of nature. In a brief addressed to the Board of Patent Appeals, on March 18, 1975, Saliwanchik insisted that the fungus was "not a product of nature" but "the product of a microbiologist." The Board sidestepped that issue to reject the claim, on June 22, 1976, for the deeper reason that the fungus was alive -- employing much the same arguments that it had used

---

[34] "Application of Malcolm E. Bergy . . .," June 10, 1974, in United States Court of Customs and Patent Appeals, Transcript of Record, Patent Appeal Docket No. 76-712, In Re Application of Malcolm E. Bergy, et al, Filed August 16, 1976, p. 6; telephone conversation with Roman Saliwanchik, Oct. 14, 1988.

to deny Chakrabarty's product claim the previous month and warning, similarly, that a liberal interpretation of the code would lead to the patenting of "new types of insects, such as honeybees, or new varieties of animals produced by selective breeding and crossbreeding." The Upjohn lawyers promptly brought their case to the Court of Customs and Patent Appeals -- promptly enough, as it happened, to arrive ahead of Chakrabarty's, which had been delayed in a further skirmish with the Patent Office Board. However, having been framed in almost the same terms, the Bergy case became a proxy for the issue that Chakrabarty's had initially raised.[35] Indeed, in arguments before the Court, on March 3, 1977, the battle line was drawn precisely across the question of whether living organisms qualified for patent protection under the Jeffersonian core of the patent code.[36]

On October 6, 1977, the Court ruled three to two in favor of Bergy. The majority opinion was delivered by Judge Giles S. Rich, who, before his appointment to the federal bench, in 1956, had distinguished himself as a patent attorney during some thirty years of practice in New York City and who manifestly recognized that, to a considerable extent, life was chemistry. Rich viewed it as "illogical" to allow patents for processes that relied upon the functions of living organisms but to deny patents to a living manufacture or new composition of matter as such. He contended that in their nature and commercial uses biologically pure cultures

---

[35] "Letter of Examiner, Feb. 6, 1975"; Roman Saliwanchik, "Brief," March 18, 1975; "Opinion and Decision of Board of Appeals, June 22, 1976," in United States Court of Customs and Patent Appeals, Transcript of Record, Patent Appeal Docket No. 76-712, In Re Application of Malcolm E. Bergy, et al, Filed August 16, 1976, pp. 34, 54, 62-63; In the Matter of the Application of Malcolm E. Bergy et al, Patent Appeal No. 76-712, U.S. Court of Customs and Patent Appeals, 563 F. 2d, 1032-1035 (1977); Application of Ananda M. Chakrabarty, Patent Appeal No. 77-535, U.S. Court of Customs and Patent Appeals, 571 F. 2d, 42 (1978).

[36] In the Matter of the Application of Malcolm E. Bergy et al, 563 F. 2d, 1034-1035 (1977).

of microroganisms were "much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses." He found nothing in the language of the patent laws that excluded such tools from patent protection solely on grounds of their being alive; it was being alive that made them useful. He held, "In short, we think the fact that microorganisms, as distinguished from chemical compounds, are alive is a distinction without legal significance." Rich took note of the fear that allowing patents for microorganisms would make patentable "all new, useful, and unobvious species of plants, animals, and insects created by man." He called the fear "far-fetched," while observing that, in any case, "that question is not before us."[37]

MaLossi argued Chakrabarty's case on December 5, 1977, and on March 2, 1978 the Court ruled three-to-two in Chakrabarty's favor. Judge Rich, speaking for the majority, saw only one issue --- the patentability of living organisms. The Court had dealt with the identical issue in the Bergy case and found its reasoning there sufficient and controlling. In a concurring opinion, Judge Howard T. Markey declared, "The [patent] statute is not ambiguous. No Congressional intent to limit patents to dead inventions lurks in the lacuna of the statute, and there is no grave or compelling circumstance requiring us to find it there." And he added, "As with Fulton's steamboat 'folly' and Bell's telephone 'toy,' new technologies have historically encountered resistance. But, if our patent laws are to achieve their objective, extra-legal efforts to restrict wholly new technologies to the technological parameters of the past must be eschewed."[38]

---

[37] Ibid., pp. 1037-1038.

[38] Application of Ananda M. Chakrabarty, 571 F 2d, 43-44 (1978).

Ranking lawyers in the U.S. Patent Office now had to decide whether to appeal the decision to the Supreme Court, and it was at this point that considerations of the political economy of biotechnology began to figure in the case. The scientific key to the commercialization of molecular biology was the technique of recombinant DNA that had been co-invented, in 1973, by Herbert Boyer and Stanley Cohen, biologists at, respectively, the University of California San Francisco Medical School and Stanford University. The advent of the technology provoked controversy, as scientists warned that its use might lead to the release of dangerous new organisms into the environment or throw evolution off course. The apprehensions spread rapidly through the lay community, stimulating moves in state legislatures and the United States Congress to impose severe restrictions on research with recombinant DNA. By 1978, most molecular biologists were convinced that the dangers had been exaggerated. The National Institutes of Health had established regulations for the confinement to safe facilities of whatever recombinant research. And the trend to acceptance of recombinant techniques was being reinforced by the growing commercial interest in them.

Herbert Boyer had helped lead the way. In 1976, Boyer and a venture capitalist named Robert A. Swanson formed the biotechnology firm Genentech -- short for "genetic engineering technology." In 1977, the company used recombinant techniques to engineer a bacterium so that it generated the mammalian hormone somatostatin, which is produced at the base of the brain and is involved in the regulation of growth. In 1978, it announced in a press conference that its scientists had succeeded in producing human insulin by similar means. The achievement with insulin was heralded in every major newspaper and magazine in the United States except The New York Times, which was on strike. Newsweek typically

proclaimed that "recombinant DNA technology can undoubtedly be used to make scores of other vital proteins, such as growth and thyroid hormones, as well as antibodies against specific diseases."[39]

By now, new biotechnology companies were being founded at a high pace, while major pharmaceutical firms as well as several oil and chemical giants were plunging into recombinant DNA, initiating research programs of their own, letting research contracts to the startups, and even obtaining an equity interest in some of them.[40] Biotechnology firms and firms eager to get into biotechnology sought connections with campuses.[41] In return, the campuses could expect dividends from the biotechnology industry in the form of gifts, research grants, and license fees for the use of patents covering the valuable research products of their laboratories.

However, the dissent from recombinant DNA had not disappeared entirely, either among scientists or the lay community. The critics kept warning that genetically engineered microorganisms threatened the environment and could pose hazards to human health. Some also predicted that genetic engineering would eventually be applied to human beings, ushering in a new era of eugenics, and that essential features of the organic world would fall under the control of profit-making corporations. An increasingly prominent critic was the social activist Jeremy Rifkin, a graduate of the Wharton Business School who had turned left and who headed a

---

[39]Steven S. Hall, Invisible Frontiers: The Race to Synthesize a Human Gene (New York, NY: The Atlantic Monthly Pres, 1987), pp. 87-88, 199-203, 213-22, 231-35, 241-48, 266, 269-83; Matt with Joseph Contreras, "Making Insulin," Newsweek, 92(September 18, 1978), p. 93.

[40]Martin Kenney, Biotechnology: The University-Industrial Complex (New Haven: Yale University Press, 1986), pp.44-45, 56, 61-67, 73, 78-80, 140, 191; Nicholas Wade, "Recombinant DNA: Warming Up for the Big Payoff," Science 206(Nov. 9, 1979), 663,665; The Wall Street Journal, May 10, 1979.

[41]Susan Wright, "Recombinant DNA Technology and Its Social Transformation, 1972-1982," Osiris, 2nd Series, 2(1986), 303-60.

public-interest group called the People's Business Commission. A newcomer to the issues of genetic engineering, he predicted eugenic and corporate capture of recombinant DNA and was resolutely opposed to the patenting of life.

The Patent Office lawyers, well aware of the controversy over genetic engineering and of its commercial prospects, recognized that the stakes in patenting life now reached far beyond purely legal questions. Gerald Bjorge, the Associate Solicitor in the Patent Office, remembered a key point in the discussions about whether to appeal the Bergy and Chakrabarty cases to the U.S. Supreme Court: The belief that living products could be patented would call forth considerable investment in biotechnological enterprises. However, while the Court of Customs and Patent Appeals might today decide in favor of the patentability of living microorganisms, federal appeals courts elsewhere might in the future decide against it, placing the issue in legal limbo. An adverse ruling by the Supreme Court at that point would throw the biotechnology industry into turmoil. Better to have the high court clarify the issue now rather than leave the matter to the uncertain future. If it ruled against Bergy and Chakrabarty, the issue could be referred to the Congress, where the Patent Office, of course, thought it belonged anyway.[42]

On April 20, 1978, on behalf of the Patent Office, the Solicitor General of the United States moved to appeal the Bergy decision to the United States Supreme Court, warning, in his petition, that "since the number of living things is vast, the decision opens an enormous range of subject matter to patentability," that policymaking concerning the extension of the patent laws to

---

[42] Telephone interview with Gerald Bjorge, March 12, 1989.

new fields was for Congress, not the courts, and that allowing the Bergy ruling to stand would further complicate the "policy problems" -- the brief noted the 1976 NIH guidelines -- "of genetic engineering, already highly controversial."[43] On June 26, on the last day of its term, the Court ordered that the Bergy decision be vacated and it sent the case back to the patent appeals court for reconsideration in light of a decision that it had rendered four days earlier, in another patent case, Parker v. Flook."[44] In August, over MaLossi's objections, the appeals court vacated its judgment in Chakrabarty's case, too, also compelling reconsideration of it in light of Flook. Though the two cases were not formally consolidated, the appeals court chose to deal with them together, receiving briefs from the parties in September and October and hearing arguments on both, on November 6, 1978.[45]

The Supreme Court had given no specific indication of the relevance of Flook to Bergy's claim, which left the matter somewhat shrouded in mystery, all the more so since the case concerned the patentability of a mathematical algorithm for the control of a production process. Under the circumstances, each of the principal parties in the proceeding found in Flook what suited its interest. The government's lawyers locked onto a point in one of the precedents that the high court had cited in the case -- that an expansion of patent rights "would require a clear and certain signal from Congress" -- and contended yet again that, since Congress had not provided for

---

[43] Solicitor General, Petition for a Writ of Certiorari . . ., In the Supreme Court of the United States, October Term 1977, Lutrelle F. Parker v. Malcolm E. Bergy et al, Docket No. 77-1503, filed April 20, 1978, pp. 6-7.

[44] Parker v. Flook, 437 U.S. 584, 98 Ct. 2522, at 2528; "Application of Malcolm E. Bergy . . ., Application of Ananda M. Chakrabarty," Appeal Nos. 76-712, 77-535, U.S. Court of Customs and Patent Appeals, March 29, 1979, 596 Federal Reporter, 2d Series, 952, at 957.

[45] "Supplemental Brief for Appellant," U.S. Court of Customs and Patent Appeals, Patent Appeal Docket No. 77-535, In Re Application of Ananda M. Chakrabarty, Appellant," [filed fall 1978], p. 4.

the patenting of living matter, neither Bergy's nor Chakrabarty's claim should be allowed. But while introducing the precedent, the Court had observed that "we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress."[46]

Leo MaLossi ingeniously turned that observation to Chakrabarty's advantage by pointing out, in his brief, that Chakrabarty's oil-eating bugs did not fall into an area of innovation that Congress had not foreseen. They had not been produced by recombinant DNA in the sense of contemporary genetic engineering but had been devised by a traditional method of recombining DNA -- by the interbreeding of different strains, hybridization. Congress had been familiar with plant and animal breeding since the founding of the republic -- George Washington himself had been instrumental in the promotion and improvement of mule breeding, MaLossi noted -- and yet it had never prohibited the patenting of living organisms. On the contrary, Congressional committee reports drawn up in connection with the last major overhaul of U.S. patent law, in 1952, had declared that an invention could be "anything under the sun." MaLossi concluded that Flook had no bearing on Chakrabarty's claim, and Saliwanchik concluded similarly about his client Bergy's claim, too, arguing that, since it concerned only the purification of a microrganism, it was irrelevant to disputes about either mathematical algorithms or genetic engineering.[47]

---

[46] Parker v. Flook, 437 U.S. 584, 98 Ct. 2522, at 2528; "Supplemental Brief for the Commissioner of Patents and Trademarks," filed Oct. 20, 1978, U.S. Court of Customs and Patent Appeals, Patent Appeal No. 77-535, In the matter of the Application of Ananda M. Chakrabarty, p. 4.

[47] "Supplemental Brief for Appellant," U.S. Court of Customs and Patent Appeals, Patent Appeal Docket No. 77-535, In Re Application of Ananda M. Chakrabarty, Appellant," [filed fall 1978], p. 4, 6-8, 15, 22; Saliwanchik, "Brief in Opposition to Petition for Writ of Certiorari . . .," In the Supreme Court of the United States, October Term 1977, No. 77-1503, Lutrelle F. Parker v. Malcolm E. Bergy, filed May 11, 1978, p.5; "Supplemental Brief for Appellants," U.S. Court of Customs and Patent Appeals, Patent Appeal Docket No. 76-712, In Re Application of Malcolm E. Bergy, et al, Appellants, pp. 2-4; telephone interview with Gerald Bjorge, March 12, 1989.

MaLossi and Saliwanchik hewed to narrow legal ground because each wanted to win for his respective client, yet Saliwanchik, alive to the longrange interests of Upjohn, permitted himself a word or two in praise of the genetic engineering of microorganisms and the allowance of patents for its living products. Indeed, both cases were taken to be weighted with sufficiently broad import for the future of biotechnology as to prompt Genentech and the University of California to file amicus briefs -- the former's within two weeks of the insulin press conference -- on the side of Bergy and Chakrabarty. Under the terms of Genentech's contracts for the somatostatin project, UC San Francisco and City of Hope could patent the results, giving Genentech an exclusive license to produce the hormone. Genentech itself would seek the patent on the recombinant insulin developed in its own laboratory. Now, the university and Genentech each declared that it had a vital stake in the outcome of the matter -- the university, because it expected to realize income on patents for genetically engineered products invented in its laboratories; the company, because the patent incentive would be "an important if not indispensable factor in attracting private capital support for life-giving research in the pharmaceutical field." Neither proposed to argue the particular merits of the Bergy or Chakrabarty claims, preferring to address the key principle at stake -- that is, the patentability of living organisms. The university stressed that at issue was only the patentability of "single-cell organisms which are mindless, soulless and brainless," not that of higher life forms. Along with Genentech but more expansively, it also contended that the line between dead chemicals and living microrganisms was "well-nigh imperceptible," adding that, in this respect, even skilled

scientists could only with difficulty draw "a bright line between life and its absence" and that recognition of that fact "destroys the argument that life itself . . . precludes patentability."[48]

Both amicus briefs conceded that recombinant genetic engineering was a new technology. In the view of the university, however, it was unimaginable that the Congress of 1793 had intended to disqualify from patent protection "the fruits of human creativity in then unknown technologies, whether airplanes, space craft, or, now, genetically engineered microorganisms. Genentech's counsel -- he was Thomas D. Kiley, of the Los Angeles firm of Lyon & Lyon -- acknowledged that the courts might be doubly cautious in permitting patents in areas of innovation that, like genetic engineering, were both unanticipated by Congress and somewhat controversial. He also shrewdly countered that, still, it was "not the job of the Patent System to regulate new technologies, but rather to bring them into being, and into public view," continuing, "Congress is quite capable of regulating the use of technology without judicial gerrymandering of the System that inspires its creation. A veritable alphabet soup of other Agencies attests to that." In Kiley's view, the government's concern with the controversialism of genetic engineering was "a red herring."[49]

---

[48] Kenney, Biotechnology, pp. 94-96; The Wall Street Journal, September 7, 1978, p. 17; Saliwanchik, "Brief in Opposition to Petition for Writ of Certiorari . . .," In the Supreme Court of the United States, October Term 1977, No. 77-1503, Lutrelle F. Parker v. Malcolm E. Bergy, filed May 11, 1978, pp. 6-7; "Brief Amicus Curiae of the Regents of the University of California," U.S. Court of Customs and Patent Appeals, Patent Appeal Dockets Nos. 76-712 and 77-535, In the Matter of . . . Bergy and In the Matter of . . . Chakrabarty, pp. 1, 2, 14-20; "Motion for Leave to Appear as Amicus Curiae and Brief Amicus Curiae of Genentech, Inc.," In the Matter of . . . Chakrabarty, Patent Appeal No. 77-535, United States Court of Custom and Patent Appeals, filed Sept. 20, 1978, pp. 1b-1d, 6, 8-9, 12-13.

[49] "Brief Amicus Curiae of the Regents of the University of California," U.S. Court of Customs and Patent Appeals, Patent Appeal Dockets Nos. 76-712 and 77-535, In the Matter of . . . Bergy and In the Matter of . . . Chakrabarty, pp. 1, 2, 14-20; "Motion for Leave to Appear as Amicus Curiae and Brief Amicus Curiae of Genentech, Inc.," In the Matter of . . . Chakrabarty, Patent Appeal No. 77-535, United States Court of Custom and Patent Appeals, filed Sept. 20, 1978, pp. 1b-1d, 6, 8-9, 12-13.

On March 29, 1979, the Court of Customs and Patent Appeals held by a three-to-two majority that it could find nothing in Flook that shed light on the Bergy and Chakrabarty cases. In a fifty-page opinion on behalf of the majority -- the length of the opinion was unusual and was perhaps prompted by the likelihood that the cases would return to the Supreme Court -- Judge Giles Rich noted that in oral argument the government's solicitor had admitted that the technologies at issue were not new, and Rich stressed that it was not necessary anyway for Congress to have foreseen a new field of technology to make inventions in it patentable. The majority scoffed at moral pitfalls, rejecting as "hyperbole" the solicitor's warning that if patents were allowed for microorganisms, they might have to be permitted for an enormous range of living matter. On the substantive merits, the majority' position was unchanged from what it had been in the first round. Indeed, if anything, the position had been reinforced by Genentech's triumphs with somatostatin and insulin, which Rich's opinion endorsed by quoting from an enthusiastic report of them in Kiley's brief. Rich reiterated that "life is largely chemistry," declaring that the court could see "no legally significant difference between active chemicals which are classified as 'dead' and organisms used for their chemical reactions which take place because they are 'alive.'" The court once again reversed the Patent Appeals Board, upholding Bergy and Chakrabarty's claims -- but this time by a majority of four to one, since another justice, although disagreeing with parts of Rich's opinion, concurred on the key issue of the patentability of living products.[50]

---

[50] "Application of Malcolm E. Bergy . . ., Application of Ananda M. Chakrabarty," Appeal Nos. 76-712, 77-535, U.S. Court of Customs and Patent Appeals, March 29, 1979, 596 Federal Reporter, 2d Series, 952, at 952-53, 955, 967, 973-75, 984-5, 986, 999.

Most high officials in the Patent Office agreed that the decision in the Bergy and Chakrabarty cases should once again be appealed to the Supreme Court, for much the same reasons as had moved them to do so the first time. According to the recollection of a staff member in the Patent Office, the principal exception in the Office was Donald Banner, the U.S. Commissioner of Patents, who had come to his post, in 1978, from the Borg-Warner Corporation, where he had been general patent counsel, and who liked the decision of the appeals court. Determined to keep it away from the uncertainties of judgment by the Supreme Court, he wanted to let it stand. However, a discreet telephone call from the Patent Office brought Banner's obstructionist attitude to the attention of the Office of the U.S. Solicitor General, who, after determining Banner's views directly, promptly reminded the Patent Commissioner that the Solicitor General controlled the legal proceedings of federal agencies and that this Solicitor General -- he was Wade McCree -- intended to appeal the Bergy and Chakrabarty cases. On July 27, 1979, McCree petitioned the Supreme Court for review of the two cases and, on October 29, review was granted.[51]

In December, the Upjohn lawyers amended their patent application to omit the product claim on Bergy's purified lyncomycin --a move that rendered the company's case moot and saved it the not inconsiderable cost of an appeal to the Supreme Court. Roman Saliwanchik later explained that the company thought its claim for the purified natural fungus was weak and might drag Chakrabarty's case, which was much stronger but which had become legally joined with Bergy's, down to defeat. However, Chakrabarty, though now unencumbered, did not have

---

[51] Interview with a staff member in the Patent Office who does not wish to be identified.

to fight on alone. By the end of January 1980, ten amicus briefs, most of them in support of his case, had been filed by various individuals and organizations, including, once again, Genentech and the University of California, but now also the Pharmaceutical Manufacturers Association, the American Patent Law Association, the New York Patent Law Association, and the American Society for Microbiology. The Supreme Court chambers were packed when, on March 17, 1980, the Justices heard oral arguments in the case, which was by then known as *Diamond v. Chakrabarty* -- Sidney Diamond was the new Commissioner of Patents -- and which had acquired a degree of economic and social interest far transcending the particulars of Ananda Chakrabarty's oil-eating bugs.[52]

The first amicus brief to be filed came from Rifkin's People's Business Commission and was the only one to take the government's position. It attacked genetic engineering as such, warning for example, that it might "irreversibly pollute the planetary gene pool in radical new ways" -- yet several of its arguments were embraced and given credibility in the brief of the U.S. Solicitor General, which otherwise repeated the objections it had advanced against patenting life before the appeals court.[53] As a result, the brief of the People's Business Commission -- the PBC, as it referred to itself in the document -- drew pointed attention, not only from MaLossi but also from several of the amici who filed on Chakrabarty's side.

---

[52] In the Supreme Court of the United States, October Term, 1979, Docket No. 79-136, Motion to Discuss and Vacate as to Respondents Malcolm E. Bergy, et al, Dec. 20, 1979, pp. 1a-2a; The Wall Street Journal, Jan. 15, 1980, p.4; telephone interview with Roman Saliwanchik, Oct. 14, 1978; "Supreme Court Hears Argument on Patenting Life Forms," Science, 208(April 4, 1980), 31. The amicus briefs are with Diamond v. Chakrabarty, Docket No. 79-136, 447 U.S. 303.

[53] In the Supreme Court of the United States, October Term, 1979, Parker v. Bergy et al and Parker v. Chakrabarty, Brief on Behalf of the People's Business Commission, Amicus Curiae, Dec. 1979, pp. 17-18; Diamond v. Bergy et al and Diamond v. Chakrabarty, Brief for the Petitioner, pp. 10, 20-21.

What most exercised the other amici was the PBC's claim that patenting life was not in the public interest -- a claim that the PBC sought to support by alleging that the Plant Patent Act, of 1930, and the Plant Variety Protection Act, of 1970, were directly responsible for a dangerous trend in the world's agriculture. The trend was the steady reduction in the number of varieties cultivated in major food crops -- for example, the number of different strains of wheat -- and the resultant narrowing of each crop's genetic diversity. Many native strains of plants were being lost as farmers replaced them with a few superior varieties. And the less genetically diverse a crop, the more susceptible it was to one or another disease. Indeed, in 1970, a corn blight had wiped out nearly fifteen percent of that crop in the United States, which prompted a study by the National Academy of Sciences to note that "genetic uniformity is the basis of vulnerability to epidemics" and to add that "most crops are impressively uniform genetically and impressively vulnerable."[54]

According to the PBC, the reduction in crop varieties was the consequence of plant patents (the brief casually lumped together under the term "patents" both the genuine patents established by the 1930 act and the weaker protection certificates provided by the 1970 act). In the brief's analysis, seed and grain companies bred only those plants that could be patented -- a small number, it held -- and then (somehow) persuaded farmers to buy and substitute them for native strains. Furthermore, a few large corporations -- frequently the same drug and chemical

---

[54] In the Supreme Court of the United States, Parker v. Bergy et al and Parker v. Chakrabarty, Brief on Behalf of the People's Business Commission, Amicus Curiae, Dec. 1979, p.pp. 5-9; National Research Council, Committee on Genetic Vulnerability of Major Crops, Genetic Vulnerability of Major Crops (Washington, D.C.: National Academy of Sciences, 1972), p.1. See also U.S. Department of Agriculture, National Plant Genetics Resources Board, Plant Genetic Resources: Conservation and Use (Washington, D.C., 1979).

companies that were beginning to invest in biotechnology -- had been acquiring independent seed companies and their plant "patents" (protection certificates). For example, Upjohn, together with three other companies, now held 79% of such "patents" in beans. The overall result: "thanks to the patent laws, the bulk of the world's food supply is now owned and developed by a handful of corporations which alone, without any public input, determine which strains are used and how."[55]

The PBC also caught the attention of other amici by insisting that allowance of the patenting of microorganisms as new compositions of matter would leave no scientific or legal basis to preclude the patenting of higher life forms, including mammals and the human manufactures of some Brave New World. Its brief predicted that patenting animals would lead to consequences identical to those it alleged had occurred with plants -- a reduction in the world's domestic animal varieties and genotypes. Yet what most distressed the PBC -- what it saw as "the essence of the matter" in the Chakrabarty case -- was that to permit patents on life was to imply that "life has no 'vital' or sacred property," that it was only "an arrangement of chemicals, or mere 'compositions of matter.'"[56]

Solicitor General Wade H. McCree, Jr.'s brief did not endorse the PBC's on the merits but rather drew upon the Commission's claims to bolster its own principal legal argument -- that legislation was necessary to extend patent protection to living organisms. Genetic engineering

---

[55] In the Supreme Court of the United States, Parker v. Bergy et al and Parker v. Chakrabarty, Brief on Behalf of the People's Business Commission, Amicus Curiae, Dec. 1979, pp. 7-9, 12-13.

[56] In the Supreme Court of the United States, Parker v. Bergy et al and Parker v. Chakrabarty, Brief on Behalf of the People's Business Commission, Amicus Curiae, Dec. 1979, pp. 11-12, 21-22, 27, 29-30.

had raised issues of ethics (the creation of new life forms, including human ones); also of safety (recombinant organisms polluting the environment), continuing controversy over which, in the Solicitor's misinformed view, had led to a revision of the guidelines governing recombinant research. Both issues had stimulated high disputes of a type that should be resolved by the Congress, not the courts. MaLossi reiterated why no Congressional action was required for a patent to issue on Chakrabarty's bugs, stressing, in addition to the intricacies of the law, that the bugs had nothing to do with the kind of recombinant DNA that was controversial. However, he did feel compelled to point out to the Court the "distortion of the record" concerning recombinant DNA presented in the Solicitor's brief, particularly with respect to public health and safety. Contrary to the Solicitor's impression, the revisions in the NIH guidelines indicated a progressive reduction, not enlargement, in the estimate of environmental risk in recombinant research. Beyond that, MaLossi deemed it best to let the pro-recombinant amici represent their own interests to the Court. [57]

The amici obliged, especially the two -- Genentech and the Pharmaceutical Manufacturers Association -- with the greatest immediate economic interest in the outcome of the case. To both, the positions of the government and the PBC seemed to flout fact and logic. Their briefs sought to set matters straight and to provide what amounted to basic instruction in the fundamentals of the patent system, at least as they saw it. Patents did not foster but actually penetrated industrial secrecy to an extent, because they compelled publication of the means and

---

[57] Diamond v. Bergy et al and Diamond v. Chakrabarty, Brief for the Petitioner, [Jan. 1980], pp. 9-10, 17-21; Parker v. Bergy et al and Parker v. Chakrabarty, Chakrabarty's Brief in Opposition to Petition for Writ of Certiorari to the United States Court of Customs and Patent Appeals, Sept. 1979, p. 6, n.3; Diamond v. Chakrabarty, Brief for the Respondent, [Jan. 1980], pp. 27-28.

methods that led to a patentable product. Denying patents on life would throw corporate recombinant research deeper into the realm of trade secrets and away from public scrutiny of the degree to which the corporate world was actually abiding by the NIH guidelines. Patents encouraged technological innovation, and they should be allowed to encourage it in genetic engineering, since the field was recognized as a richly promising contributor to the nation's high-technology competitiveness. By offering the incentive of certificate protection, the Plant Variety Protection Act had not reduced but had increased the number of plant varieties available to the American public. For example, as many new varieties of wheat had been developed in the seven years after the passage of the act, in 1970, as in the seventeen years before it. (Genentech found it difficult to credit the argument that patents for life forms would diminish genetic diversity, "when any shovel full of backyard sod can yield micro-organic life in endless variety, and when genetic engineering itself permits the creation of new varieties.")[58]

Speaking from its own experience, Genentech called the patent system at its best "a pro-competitive system," one that could facilitate "the interposition of small but fruitful companies" in industries traditionally dominated by major firms. In fact, according to the Pharmaceutical Manufacturers, since 1970, as a result of the Plant Variety Protection Act, the number of seed companies had increased, especially in wheat, cereal grains, and soybeans (before that year, six companies had been engaged in the development of soybean varieties; now the number was twenty-five). Also since 1970, almost 1,000 applications had been submitted for plant variety

---

[58] Diamond v. Chakrabarty, Brief on Behalf of the Pharmaceutical Manufacturers Association, Amicus Curiae, Jan. 1980, pp. 13, 26-28, 48; Brief on Behalf of Genentech, Inc., Amicus Curiae, Jan. 1980, pp. 13, 17-18.

protection certificates on 57 distinct crops. About ten percent of these had come from agricultural experiment stations at colleges and universities; about twenty percent, from the six largest U.S. seed companies; and almost 70%, from private breeders of all sizes.[59]

The American Patent Lawyers Association took the trouble to point out what should have been obvious to anyone -- that living entities (innumerable varieties of domesticated plants and animals) had been treated as property since the advent of acquisitive man. Several of the amici conceded that allowing a patent property right in Chakrabarty's bugs might raise the question of the patentability of higher life forms. However, higher life forms were not at issue in the case, only microorganisms. The courts could only resolve the scope of the patentability of life if and when that question came concretely before them, not prospectively. (The Pharmaceutical Manufacturers opined that, should the matter arise, it would be easy to draw a line between higher life forms and "the mindless soulless microorganism involved in Chakrabarty"; Genentech scoffed at the idea that a grant of Chakrabarty's claim would permit patents on human beings, declaring that such argument "extends literalism beyond reason.")[60]

Genentech supplied a trenchant counter to what the Pharmaceutical Manufacturers termed the "sky-is-falling" issues that had been insinuated into the case. The company's brief contended that it would defeat the patent system to permit controversialism to be a criterion of patentability, that the best science and invention were revolutionary, and often controversial,

---

[59] Diamond v. Chakrabarty, Brief on Behalf of the Pharmaceutical Manufacturers Association, Amicus Curiae, Jan. 1980, pp. 28-29; Brief on Behalf of Genentech, Inc., Amicus Curiae, Jan. 1980, pp. 3.

[60] Diamond v. Chakrabarty, Brief on Behalf of the American Patent Law Association, Inc., Amicus Curiae, Jan. 1980, p. 22; Brief on Behalf of the Pharmaceutical Manufacturers Association, Amicus Curiae, Jan. 1980, pp. 20, 22-23; Brief on Behalf of Genentech, Inc., Amicus Curiae, Jan. 1980, pp. 12.

and that it was not the province of the Court "to attempt, like King Canute, to command the tide of technological development," adding, "The Patent System is, out of necessity, neutral. It cannot be too finely tuned to the kind (as distinguished from the quality) of creation involved.... Most particularly must it abjure prior restraints, because they chill expression in literature and science alike. The neutrality of the Patent and Trademark Office requires that it leave to other agencies the regulation of technology, after the fact of its creation."[61]

The pro-Chakrabarty amici briefs may have told on the government. Presenting its case in oral argument, Deputy Solicitor General Lawrence G. Wallace allowed to the Court that the case did not involve broad issues of public policy. It concerned only the narrow field of statutory interpretation and Congressional intent, to which he proceeded to confine his remarks. Chakrabarty was represented by Edward F. McKie, Jr., of Washington, D.C., who maintained that existing statutes were broad enough to allow his client's claim, that a living microorganism did not open a new area of patent protection. MaLossi remembered with pleasure that several of the justices wanted to know whether the bugs were the product of a new technology and that Wallace had to concede that they were not. Justice John Paul Stevens asked Wallace to explain why patents should be granted to new chemicals but not to newly fashioned bacteria. Wallace replied, lamely, that bacteria just did not "fit well within the statute," whereupon Justice William Rehnquist retorted, "Do you fear an invasion of the spores?"[62]

---

[61] Diamond v. Chakrabarty, Brief on Behalf of the Pharmaceutical Manufacturers Association, Amicus Curiae, Jan. 1980, pp. 15-16; Brief on Behalf of Genentech, Inc., Amicus Curiae, Jan. 1980, pp. 4-12.

[62] Arguments before the Court: Patents," The United States Law Week, 48(March 25, 1980), 3609-3610; telephone conversation with Leo MaLossi, Aug. 23, 1988.

On June 16, 1980, the United States Supreme Court held, by a vote of five to four, that Chakrabarty had a right, within existing statutes, to a patent on his microorganism. Chief Justice Warren Burger delivered the majority opinion, which echoed much of the reasoning in the appeals court opinion of Judge Giles Rich. Justice Burger enthused over the broad language that Jefferson had written into the patent law of 1793, calling it expressive of its author's "philosophy that 'ingenuity should receive a liberal encouragement'" and noted that all succeeding Congresses had left Jefferson's language virtually intact. Rejecting the contentions of the Patent Office, he found that the patent code as written was ample enough to accommodate inventions in areas unforeseen by Congress, including genetic technology, and to cover living microorganisms. Congress, in passing the plant acts of 1930 and 1970, had "recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." Chakrabarty's bugs were new compositions of matter, the product of his ingenuity, not of nature's. As such, they were patentable under existing law. The minority's opinion, delivered by Justice William Brennan, argued precisely the opposite -- that, in view of the legislative history of the two plant acts, the extension of patent protection to living microorganisms required new law.[63]

There was no particular ideological split between the majority (in addition to Burger, Justices Rehnquist, Stevens, Potter Stewart, and Harry Blackmun) and the minority (besides Brennan, Justices Byron White, Thurgood, Marshall, and Lewis Powell). Both the majority and the minority agreed that the question before the Court was the narrow one of statutory

---

[63] Diamond v. Chakrabarty, 447 U.S. 303, 100 S. Ct. 2204 (1980) at 2206-2212.

interpretation. However, Justice Lewis F. Powell, Jr. dissented in the case, as he wrote to Brennan, because of "the relative novelty of patenting a living organism, and by my conviction that the issue should be decided by Congress." At Powell's urging, Brennan's opinion included the observation -- Powell wrote the passage -- that the case concerned a composition that "uniquely implicates matters of public concern" and advanced that fact as a special reason for Congressional jurisdiction.[64]

Chief Justice Burger also took the trouble to address the apprehensions of the Patent Office and the People's Business Commission concerning the "grave risks" in genetic engineering, writing in his opinion that their briefs "present a gruesome parade of horribles" and reminded the Court "that, at times, human ingenuity seems unable to control fully the forces it creates." Burger observed, however, that genetic research with its attendant risks would likely proceed with or without patent protection for its products and that neither legislative nor judicial fiat as to patentability would "deter the scientific mind from probing into the unknown any more than Canute could command the tides." More important, the Court was "without competence" either to brush aside the horribles "as fantasies generated by fear of the unknown, or to act on them." Matters of high policy, embodying competing interests and values, were best handled by Congress and the Executive -- the political rather than the judicial branches of the government. The Court's task was the "narrow one of determining what Congress meant by the words it used

---

[64] *Ibid.*; Lewis F. Powell to Mr. Justice Brennan, May 29, 1980, William J. Brennan MSS, Library of Congress, Container 535.

in the statute" -- which the Court had done -- and once that was accomplished, its powers were "exhausted."[65]

IV. Plant and Animal Patents

After the *Chakrabarty* ruling, several critics insisted that the decision appeared to leave no legal obstacle to the patenting of higher forms of life, including animals and, possibly, human beings.[66] In fact, a number of biologists began genetically engineering animals primarily for research purposes -- for example, to study how cells differentiate as an animal develops from a newly fertilized egg or to explore the genetic dynamics of cancer. But their efforts produced animals that were new compositions of matter and that in some cases had commercial -- and, hence, patentable -- possibilities.

The genetic engineering was accomplished by inserting foreign genetic material into an animal's genome using a method that had been recently devised independently in several laboratories. The fundamental step in the process was to introduce foreign DNA obtained with recombinant techniques into a newly fertilized mammalian egg. The immigrant DNA could integrate into and then proliferate with the creature's native genome, eventually finding its way into every cell of the grown animal, including its sex cells. When the animal reproduced, the DNA would be transmitted to some fraction of its progeny, automatically supplying a large

---

[65] Diamond v. Chakrabarty, 447 U.S. 303, 100 S. Ct. 2204 (1980) at 2211-12.

[66]. "Blue Chips for a Biochemist." Time, March 9, 1981, p. 57; Peter Gwynne, "Court Decision Spurs Genetics Research," Industrial Research and Development 22(August, 1980) 45-46; Debra Whitfield, "Patent Decision Could Spur Genetic Research Industry," Los Angeles Times, June 17, 1980, p.11; C. Larry O'Rourke, "The Chakrabarty Decision," Environment 22(July/Aug. 1980), 5.

number of such genetically transformed animals. The efficacy of the method was demonstrated in 1980 at Yale University by Jon W. Gordon and Frank H. Ruddle, who declared their results to mean that "genetic transformation can be extended to whole mammalian organisms at a very early stage in their development."[67]

By then, engineering animals with foreign genes -- "transgenic" animals," to use the term that Gordon and Ruddle soon coined -- had begun to shape the collaborative research of Ralph Brinster, a veterinary biologist at the University of Pennsylvania, and Richard Palmiter, a molecular biologist at the University of Washington. They first introduced a test construct of foreign DNA that comprised a gene attached to a sequence of DNA taken from mice that would promote and regulate the gene's expression. The promoter/regulator gene did its job, and they obtained expression of the gene in the recipient mouse.[68]

Brinster and Palmiter then decided to try their method of gene injection to correct dwarfism in a strain of mice that resulted from a lack of growth hormone. The strategy was to introduce into the mice the gene for rat growth hormone (rGH) attached to the gene for the protein metallotheinin (MT), the same one that had worked in the test construct. MT regulates the level of heavy metals in the body; its gene is abundantly expressed in many organs, especially the liver. The ingestion of, say, too much zinc would stimulate the production of MT, which would then tie up the zinc. Palmiter proposed to exploit that process to control the

---

[67] Jon W. Gordon et al, "Genetic Transformation of Mouse Embryos by Microinjection of Purified DNA," Proc. National Academy of Sciences, 77(Dec. 1980), 7380-84; Ralph L. Brinster and Richard D. Palmiter, "Introduction of Genes into the Germ Line of Animals," The Harvey Lecture, Series 80 (1986), 1-4.

[68] Brinster and. Palmiter, "Introduction of Genes into the Germ Line of Animals," pp. 4-6

expression of the growth hormone gene in the transgenic mice. By regulating the amount of metals such as zinc in their diet, he expected to control the action of the MT gene and, thus, of the growth-hormone gene. [69]

However, before introducing the rGH-MT combination into dwarf mice, Brinster and Palmiter thought to inject it first into the newly fertilized eggs of normal mice to check that it was properly constructed, that it would integrate into the genomes of the mice, and that it would express itself in their livers after they were born. Palmiter recalled that a couple of months after the mice were made, Brinster telephoned to report, "They're growing larger than normal!" A number were 20 to 40 percent larger. Some were almost twice as big.[70] In December 1982, Brinster and Palmiter reported their results in *Nature,* which gave their findings prominent coverage, including a cover picture of a mouse made huge by the growth hormone gene crouched next to one of normal size. They then achieved even better results using human growth hormone instead of the rat variety and, in November 1982 published their findings in *Science*, which heralded their article with a dramatic cover illustration comparable to *Nature*'s.[71]

The graphic demonstration of what might be achieved with transgenic animals excited many biologists, but perhaps none more than Brinster and Palmiter themselves. Brinster, the product of a farming family, had long been concerned with the improvement of agricultural animals. Early in 1982, he had established a collaborative effort to produce transgenic

---

[69] *Ibid*, pp. 6-9; author's interview with Richard Palmiter, October 25, 1990 (hereafter, Palmiter interview).

[70]Palmiter interview.

[71] Palmiter et al, "Dramatic growth of mice . . . ," Nature, 300(16 Dec. 1982), 611-615; Palmiter et al, "Metallothionein-Human GH Fusion Genes Stimulate Growth of Mice," Science, 222(18 Nov. 1983);

animals with scientists at the United States Agricultural Research Service Center in Beltsville, Maryland. The group experimented with transgenic sheep for about a year but failed in most of them to obtain integration of the transgene into their genomes. Then Brinster began working with pigs. By that time, he and Palmiter had achieved their spectacular success with mice. Palmiter remembered that because the mouse grew after the insertion of a growth-hormone gene, "we now expected everything to grow." He and Brinster reasoned that pigs, made transgenic by injection of such a gene, might grow to twice current market size or grow to market size in half the time.[72]

Working with a Beltsville scientist named Vernon Pursel, Brinster and Palmiter used a transgenic construct for the pigs that coupled the MT promoter gene to the gene for human growth hormone. Some of the resulting transgenic pigs grew bigger than normal ones; they also were less fatty and converted feed into meat more efficiently. But they suffered from various afflictions, including gastric ulcers, kidney disease, arthritis, lameness, lethargy, and a tendency to injury when they moved. They also lacked libidinal energy, a condition that dampened expectations that, once created, they would happily reproduce themselves.[73]

The Beltsville experiments indicated that transgenic transformation that worked well in one species, the mouse, would not necessarily work well in another, pigs. Nevertheless, Brinster, Palmiter, and Pursel continued their experiments with pigs, trying to find a promoter that would

---

[72] Author's interview with Ralph Brinster, Feb. 14, 1991; Brinster and. Palmiter, "Introduction of Genes into the Germ Line of Animals," pp. 26-28. Brinster and Palmiter also introduced growth-hormone gene into rabbits.

[73] V.G. Pursel et al, "Insertion of Growth Hormone into Pig Embryos," in R.B. Heap, C.g. Prosser, and G.E. Lamming, eds., Biotechnology in Growth Regulation. . . (London: Butterworth, 1989), pp. 1818-86; Vernon G. Pursel et al, "Genetic Engineering of Livestock," Science 244(16 June 1989), 1281-1288.

work. Scientists in universities and biotechnology firms embarked on transgenic research programs with other farm animals. They hoped to engineer chickens with higher resistance to disease, for example, or sheep that produced more wool, or cows that provided more meat.[74]

Some also pursued what came to be called "molecular farming" -- genetically modifying animals so that they manufactured valuable proteins. Genentech had obtained its first commercially significant product, human insulin, by inserting the gene for human insulin into bacteria, which then manufactured its constituent elements. But animals were far more efficient producers of mammalian proteins. The gene for, say, Factor 9, a blood-clotting agent that hemophiliacs lack, could not be produced in bacteria; but it might be inserted into a cow's genome and harvested from its blood.[75] In all, molecular farming appeared to offer a means of turning common animals into factories for the production of valuable human proteins that were otherwise difficult and expensive to obtain, if they could be obtained at all.

While Brinster and Palmiter were pursuing the line of research that led them to Beltsville, still other scientists were creating transgenic laboratory animals that would serve as models for the study of genetically-based diseases. At Harvard University, Philip Leder and his postdoctoral collaborator Tim Stewart developed a transgenic mouse that was supersusceptible to breast cancer because it contained an oncogene -- that is, a tumor-causing gene -- tied to a promoter that would activate the gene in the mammary glands. The work had not been done for

---

[74] Robert A. Jones, "Biotechnology, In Search of a More Perfect Pig," Los Angeles Times, July 12, 1987, p. 1; "Genetic Tests Open Scary World of Super Species," Toronto Star, March 29, 1988, p. A27; Richard Saltus, "Era of 'Designer Animals' Looms," Boston Globe, Dec. 26, 1988, p. 63.

[75] Palmiter interview; . Jones, "Biotechnology, In Search of a More Perfect Pig"; Saltus, "Era of 'Designer Animals' Looms."

the sake of devising a patentable product, but once it was accomplished, Leder recognized that it might have commercial possibilities. About the end of 1983, he brought his mice to the attention of the Office of Technology Licensing and Industry Sponsored Research, the recently established patents arm of the Harvard Medical School.[76]

To explore the issue, the Office of Technology Licensing assembled a small group, including, along with Leder and several DuPont intellectual property lawyers, a patent attorney named Paul Clark, from the downtown Boston law firm of Fish and Richardson, Harvard's principal outside patent counsel. Clark later recalled that "the work's most apparent and compelling manifestation was the animal itself," continuing, "it became clear immediately that it was important to claim the mice, to give Harvard and its licensee, DuPont, all the legal rights to which they were entitled. Claims on methods of using the mice, or on plasmids, although of some importance, would not have adequately protected the invention." Clark's reasoning was standard among patent lawyers: better to protect the product as well as the processes used to produce it; otherwise, competitors, using different processes, could develop similar products.

Clark also saw that Leder's transgenic animals were, like the bacteria in Chakrabarty, new compositions of matter made by man, and he knew that the Supreme Court had admonished in the Chakrabarty case that a court cannot properly consider the state of being alive when deciding whether something falls within the protection of patent law. Thus, Clark explains, "it was hard for me to see any legal basis for excluding claims on animals."

---

[76] Author's interviews with Philip Leder, June 21, 1988, June 6, 1991.

On June 22, 1984, on behalf of Harvard University, Clark filed an application for a patent on Leder and Stewart's invention. The main utilities that he claimed were straightforward, including the use of such animals as sources of malignant or proto-malignant tissue for cell culture and as living systems on which to test compounds for carcinogenicity or -- in the case of substances like Vitamin E -- power to prevent cancers. However, Clark had not been at all conservative in what he claimed as the actual invention. It was not simply a transgenic mouse with an activated *myc* gene, which would have been extraordinary enough. It was any transgenic mammal, excluding human beings, containing in all its cells an activated oncogene that had been introduced into it -- or an ancestor -- at an embryonic stage.

The same year that Harvard filed the patent application on Leder and Stewart'smouse, three marine biologists in Washington state -- Standish K. Allen, Jr. and Sandra L. Downing, of the University of Washington, and Jonathan A. Chaiton, of the Coast Oyster Company -- applied for a patent on an improved version of Crassostrea gigas, a variety of the Pacific oyster. The claim was partly for a process that made the oyster more edible. However, it also covered the improved oyster as such, which challenged precedent.[77]

The examiners in the U.S. Patent Office denied the claim, holding that neither *Diamond v. Chakrabarty* nor any other patent ruling authorized the grant of a patent on a higher animal, even if only an invertebrate. The examiners also found that the triploid oyster was not patentable on the technical ground that the innovation was obvious to anyone schooled in the art of oyster

---

[77]. Copy of Original Patent Application, Sept. 6, 1984, in the U.S. Court of Appeals for the Federal Circuit, Appeal No. 87-1393, In re Standish K. Allen, Jonathan A. Chaiton, and Sandra L. Downing, Joint Appendix, filed Nov. 24, 1987, pp. 12-23. [Hereafter, Joint Appendix]

breeding. Allen and his colleagues appealed the examiners' decision to the Board of Patent Appeals and Interferences, of the U.S. Patent and Trademark Office.

The Board could have pointed to the limited scope of *Diamond v. Chakrabarty* and found that Congressional action was necessary to extend patent protection further to living organisms. However, it had already cast a vote against Congress and for biotechnology in 1985, when it reviewed the patent application of Kenneth Hibberd, a scientist at a subsidiary of Molecular Genetics Research, Inc., in Minnetonka, Minnesota. Hibberd had applied for a patent under the industrial patent laws for a type of genetically engineered corn -- "a maize seed having an endogenous free tryptophan content of at least one-tenth milligram per gram dry seed weight and capable of germinating into a plant capable of producing seed" with the same level of free tryptophan. Although the examiners acknowledged that the innovation fell within the scope of *Chakrabarty,* they had denied Hibberd's application, claiming that Congress had intended plants to be protected exclusively under the Plant Patent Act and the PVPA. However, the Patent and Trademark Appeals Board awarded Hibberd his patent, holding, in *Ex parte Hibberd*, that the utility patent law (35 USC 101) "has not been narrowed or restricted" by the passage of the Plant Patent Act or PVPA, that it predated both acts, and that -- with genuflection to *Diamond v. Chakrabarty* -- these plant-specific acts did not "represent exclusive forms of protection for plant life."[78]

In 1987, in the oyster case, the Board cast another vote for legal logic and, in consequence, for biotechnology, issuing the decision known since as *Ex Parte Allen*. It upheld

---

[78] *Ex Parte Hibberd, et al.*, (1985) 227 United States Patent Quarterly, 443.

the examiners on the point that obviousness of art disqualified the oyster for a patent, but it also declared that that patents could in principle be granted on living animals -- but not on human beings.[79] The Board held that human beings fell outside the scope of patentability by reason of the 13th Amendment to the U.S. Constitution. Since the amendment outlawed slavery, it in effect prohibits one human being from holding a property right in another.

Following *Ex parte Allen*, the patent examiners had no problem granting Leder and Stewart's claim. And in April 1988, a U.S. patent was awarded to Harvard University on any non-human mammal transgenically engineered to incorporate in its genome an oncogene tied to a specific promoter.

V. Ethics and Economics

The grant of patents on animals provoked a flood of ethical and economic objections to the patenting of life, expanding on those that Jeremy Rifkin and the People's Business Commission (which had by now turned into the Foundation on Economic Trends) had raised during the *Chakrabarty* case. In 1984, still determined to defend the integrity of living creatures, Rifkin filed suit in federal district court to halt the experiments with pigs under way at Beltsville. Declaring them "morally reprehensible," Rifkin said it was "shocking that the U.S. government would condone the introduction of human genes into an animal.[80] The suit failed, but the *Ex Parte Allen* ruling in 1987 induced further outcries from Rifkin. And opposition to

---

[79] *Ex Parte Allen*, USPQ, (1987), 1425.

[80] Christine Russell, "USDA Using Human Gene in Effort to Grow Super Livestock," Washington Post, Oct. 1, 1984, p. 1; Boyce Rensberger, "Scientists Hail Gene Transfers as Promising," *ibid.*, Nov. 20, 1984, p. 1

transgenic research with higher animals gained leverage when about the same time reports were published in the American and Canadian press about the Beltsville experiments, including the health problems of the pigs.[81]

In mid-May 1987, Senator Mark Hatfield of Oregon, who sympathized with the animal rights movement, urged the commissioner of patents and trademarks to impose a moratorium on the processing of animal patent claims until congress could develop a policy on the issue. He also got the Senate to pass a two-month moratorium as an amendment to an appropriations bill.[82] In the House, Congressman Robert Kastenmeier, of Wisconsin, chairman of the House Judiciary Subcommittee that dealt with patents, attempted to come to grips with the issue by holding hearings on animal patents in mid-1987 and again in September 1989.[83]

Kastenmeier, a left-of-center Democrat, was thoughtful and forthright, his judgments well considered, his approach to issues "cerebral," as one of his staff put it. He had been wondering since the advent of recombinant DNA in the early 1970s whether genetic engineering comprised a wonderful advance or raised a terrible specter. He believed that Americans were divided about the issue; the closeness of the Supreme Court's ruling in the Chakrabarty case was indicative of the division. He appreciated the social activists' worries about animal patenting, taking the reports of "new varieties of pig, rust colored and large" as

---

[81] Jones, "Biotechnology, In Search of a More Perfect Pig"; "Genetic Tests Open Scary World of Super Species"; Saltus, "Era of 'Designer Animals' Looms."

[82] New York Times, May 15, 1987, p.9; HJSH, 1987, p.2.

[83] HJSH, 1987; U.S. Congress, House, Hearings before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Committee on the Judiciary, Transgenic Animal Patent Reform Act of 1989, 100th Cong., 1st Sess., Sept. 13 and 14, 1989 (hereafter, HJSH, 1989).

reason enough to concern "those who do not wish to see animals mistreated or monster forms created." He was also sensitive to the economic implications of animal patenting.[84] His congressional district included farming communities, the University of Wisconsin, and the agricultural biotechnology firms that were growing up around it.

Kastenmeier doubted the adequacy of *Ex Parte Allen*'s prohibition against patents on human beings: Did it extend to human organs, genes, or other parts? He doubted, too, that the answers to such questions should be left entirely to the commissioner of patents. He thought that the extension of patent protection to higher organisms constituted a "quantum leap," one that the patent office had been high-handed in making. In his view, the Constitution gives power in determining the scope of patents to the Congress, and Congress ought to exercise it. Amid the controversy *Ex Parte* Allen had aroused, he considered it imperative to probe the merits of animal patents before the issuance of such patents turned into a policy that was both broad and irreversible.[85]

The proposed moratorium on the issuance of animal patents drew support from animal rights activists, clerics, and environmental-minded critics of animal patents. At the hearings, John Hoyt, the president of the Humane Society of the United States, attacked animal patents on both pragmatic and principled grounds. Such patents provided incentives for the kind of genetic engineering that produced the suffering of the pigs at Beltsville. They reflected "a human

---

[84]Author's interviews with Robert Kastenmeier, July 22, 1987, October 10, 1991 (hereafter, Kastenmeier interviews); Kastenmeier's observation appeared in the transcript of HJSH, June 11, 1987, pp. 3-4, subcomittee files, though not in the published version of the proceeding.

[85] Kastenmeier interviews.

arrogance towards other living creatures" that denied "the inherent sanctity of every unique being and the . . . ecological and spiritual inter-connectedness of all life." They also suggested "that animals have no inherent value other than that which serves the end of human beings." [86] In the view of a Lutheran bishop, genetic engineering as such was morally dubious and so was the reduction of life to mere material objects. John Barnes, a veterinarian representing the Alliance for Animals and the Federated Humane Society of Wisconsin, wondered whether the genetic engineering of animals might produce "a Frankenstein effect," unleashing a dangerous creature that might "inadvertently escape from laboratory isolation . . . and threaten life on earth." Barnes claimed that animal patenting would "compromise the integrity of animal species and ultimately lead to the control of life forms by a few multinational corporations."[87]

Congressman Charles Rose, of North Carolina, whose wife was an enthusiast of animal rights, appeared as a witness to warn that scientists were "playing God" by putting human genes into animals. "What would happen to the rodent community in America if [rats with human growth genes] got loose in our society?" Rose was unwilling "to let the market place determine the future of the animal kingdom." Neither was Congressman Benjamin Cardin, of Maryland, a member of the subcommittee. He wondered whether the patent office would have any trouble dealing with a two-headed animal -- part dog, part cat -- that was claimed "as a useful invention . . . for a sideshow and circus. There might be great demand for such a creature because of

---

[86]HJSH, 1987, transcript, pp. 55-56; HJSH, 1989, pp. 108-9, 115.

[87] Bishop Schumacher, HJSH, 1987, pp. 345-46, 351-52.

"a lack of good freaks today," he noted. Cardin figured, with obvious disapproval, that in light of *Ex Parte Allen* the patent office would have no problem granting a patent on it.[88]

Some farm spokespeople chimed in with ethical and environmental objections to animal patenting. Gervase Heffner, of the National Farmers Organization in Wisconsin, said he was "real concerned" about how in, say, fifteen years, would farmers "market that hog using human growth hormones? Where is that going to fit in the showcase in a store?" He declared that if one of those experimental pigs was "put out into the market, I would stop eating pork."[89] But for all the grandiloquent and homely posturing that the ethical issues stimulated, far greater attention in the hearings went to the potential economic consequences of animal patents on farming.

Spokespersons for small farmers warned that the consequences would be disadvantageous to family farmers. Among them was Stewart Huber, representing the Wisconsin Farmers' Union, who leveled multiple complaints against animal patenting. Much of the research that undergirded the creation of potentially patentable animals had been paid for by the public; yet private corporations would, for the period of the patent, be gaining a monopoly property right in the genetically engineered animal, forcing consumers to pay twice for the same product. Allowing patents on genetically engineered animals would "shift the profit motive for livestock improvement from the family farmers, who have used the classical breeding practices over the years, to the giant corporations which have the resources to use . . . DNA research for

---

[88] HJSH, 1987, pp. 110-111, 31-32.

[89] Ibid., p. 313. See also the testimony of Debra Shwarze, of the Wisconsin Family Farm Defense Fund, Inc, who emphasized the broad range of environmental, ethical, food safety, and animal health issues raised by biotechnology, ibid., pp. 329-33.

their own benefit." The process would have "a chilling effect on traditional family lifestyle farms," speed vertical integration in farming, and make "individual farmers . . . wards of Wall Street in the biotechnology establishments." And dealing with the progeny of patented animals would pose legal and financial burdens that would be both impractical and unjust. "Farmer-to-farmer livestock sales . . . could be construed to infringe on corporate patent rights, making the farmer subject to civil prosecution every time an animal was sold."[90]

What bothered small farmers did not, however, worry agribusiness. James Terrell, of the American Farm Bureau Federation (AFBF), told Kastenmeier's subcommittee that the Federation did not consider the ethical concerns important and that they should not be allowed to interfere with the incentives that patents provided for the engineering of better farm animals. He added that the AFBF did recognize that the disposition of rights in the progeny of the animals might pose problems but that they were not insuperable. The Federation, he stressed, did not fear monopoly pricing of prize animals. If producers regarded the patented animal as sufficiently valuable, they would pay for it; if not, not.[91]

Strong defenses of animal patenting came from other agribusiness witnesses as well as from academic scientists, and the biotechnology industry. They stressed that new farm technologies were essential to feed the world's growing population and were indispensable to

---

[90] HJSH, 1987, pp. 307-9. See also the testimony of Tom Saunders, Wisconsin Farm Unity Alliance, who declared, "Thousands of Wisconsin registered breeders, who have invested decades in building the genetic base of their cattle, will find the value of their registered herd eroded by the development of new super-registered patented livestock. For many farmers, the extra income from the sale of breeding stock is the difference between keeping and losing our farm." Ibid., pp. 321-24.

[91] HJSH, 1987, pp. 124-27.

American farmers in competing in the international market. Noting that the Japanese were taking steps to encourage their biotechnology industry, they warned that the United States had to guard against losing its biotechnological edge to Japan as it had done in microelectronics. Practicing scientists pointed out that patents were preferable to trade secrets because they compelled the patent holder to disclose the details of the protected innovation, thus giving others the opportunity to improve upon it. Philip Leder explained the significance of Harvard's oncomouse for understanding breast cancer, suggesting that animal patents were necessary to attract industrial investment to advanced medical research that relied on animal models for developing diagnostics, therapies, and cures for human disease.[92]

The key witnesses for academic and industrial biotechnology were Tom Wagner, Winston Brill, and Richard D. Godown. Wagner, a descendant of five generations of Ohio farmers, was the director of the Edison Animal Biotechnology Center, a state-supported consortium at Ohio University, his home institution in Athens. Brill, a biologist, was vice president for research and development of the Agracetus Corporation, a biotechnology firm concerned with agriculture. Godown was president of the Industrial Biotechnology Association. They all adamantly opposed a moratorium on animal patenting and, to that end, vigorously contested the chief ethical and economic objections that had been raised against the practice.

Brill insisted that "monster animals . . . will not result from this technology." Any organism's genes comprised a finely tuned ensemble. One could not "take genes from a chicken and add them to a cow's chromosome and get a cow that lays eggs."

---

[92] HJSH, 1987 pp. 114-35, 208-58, 320, 350; HJSH, 1989, pp. 1193-202.

Godown dismissed as "ridiculous" the Frankenstein scenarios that had been appearing in parts of the press -- for example, the myth that "genetic engineers are trying to develop some sort of humanoid slave containing the genes of humans and chimpanzees." Wagner contended that genetically engineered animals posed no threat to the environment. Farmers were likely to keep them penned up and to retrieve any that did escape. Besides, animals, he explained, don't "infect other animals [genetically] or humans except in sexual reproduction within their own species. A lot of us eat pork chops, a very few of us oink. [Pigs] cannot impart their genetic material to anything other than pigs."[93]

All three argued that genetic engineering, rather than increase animal suffering, would in fact reduce it. The outcomes of conventional breeding were unpredictable because they joined in one animal half of each parent's genes. The process, Brill pointed out, could yield progeny that were "healthy or unhealthy, large or small, commercially interesting or not." Genetic engineering, in contrast, involved adding just one or at the most several genes to an animal's native complement. It was thus "more specific, more predictable and faster than breeding" Brill said, implying that it was on the whole more humane, too. Wagner noted that agricultural animals had been modified from the wild type by breeding over 10,000 years. "Anyone who believes [that] the chickens in Frank Perdue's chicken houses are living in a natural ecosystem is simply unrealistic, " he said, adding that genetic engineering could make farm animals resistant to the diseases that afflicted them in their synthetic environments.[94]

---

[93]HJSH, 1987, pp. 218, 38, 259.

[94]Ibid., pp. 218-19, 38.

Wagner claimed that patented animals would help rather than hurt the small family farmer. The prime breeding stock of the chicken industry were hybrids whose characteristics were trade secrets held by just a handful of breeding firms that operated in closed arrangements with an equally small number of producers. Wagner warned that if genetically engineered animals were not patented, similar secrecy would prevail among their developers; they would make "exclusive arrangement with vertical integrators," and "we will see a concentration of agriculture in the way chickens have been concentrated." Godown added that genetically engineered animals would "enable farmers to produce leaner beef . . . at lower cost . . . an advantage in anybody's language."[95]

Kastenmeier was convinced by much of the defense of animal patents. He expected that genetic engineering of animals would proceed with or without the encouragement of the patent system. A moratorium would only set a bad precedent and irritate the patent community without achieving any good purpose. Besides, he was convinced that patents were superior to trade secrets, and he thought that even opponents of animal patents would prefer openness to secrecy in agricultural research and development.[96]

He also felt that while many of the ethical issues raised by the witnesses were legitimate, they did not fall within the realm of patent policy. In the United States, patent policy was literally amoral; it dealt only with the establishment and scope of property rights in innovations. It excluded others from making, using, or selling the property, but it did not by fundamental statute

---

[95]Ibid., 1987, pp. 39, 259. See also Glenn E. Bugos, "Intellectual Property Protection in the American Chicken-Breeding Industry," *Business History Review*, 66(Spring 1992), 127-168.

[96]Kastenmeier interviews.

categorically exclude any invention from patentability.[97] Kastenmeier believed that issues such as whether the genetic engineering of animals might unduly foster animal suffering were within the regulatory powers of congress but not within the jurisdiction of his subcommittee.[98]

He was certain that the issue of patents on human beings did fall within it and he remained convinced that Congress needed to address it now rather than later. In keeping with his concern for both agriculture and the nascent biotechnology industry, he hoped to strike a balance between the creators and the users of animal patents. He repeatedly pressed witnesses for their views on a "farmer's exemption" -- whereby farmers could do what they wished with the offspring of patented animals, including selling them without paying a fee to the patent owner. Michael Ostrach, a senior official with the Cetus Corporation, a biotechnology company that had formed Agracetus, strongly objected. A farmer's exemption, he predicted, would only lead patent holders to charge farmers a higher price for the animal, thus making it very expensive.[99] In 1988, Kastenmeier nevertheless produced a bill that would exempt farmers from any restraint, including the restraint of royalty payments, on what they did with the progeny of their patented animals. It declared explicitly that human beings could not be patented. The bill passed the House, but it was not taken up in the Senate before the end of Congress.[100]

---

[97] In contrast, Article 53 (a) of the European Patent Convention -- which was established in 1962 and governs the national patent systems of its adhering nations -- prohibits patents on any invention that is contrary to public order or morality. When Harvard University applied for a patent on its oncomouse, it had to demonstrate that the creation of Leder and Stewart did not violate the article. See Daniel J. Kevles, "Of Mice and Money: The Story of the World's First Animal Patent," Daedalus, forthcoming, 2002

[98] Kastenmeier interviews.

[99] HJSH, 1987, p. 296.

[100] The bill was H.R. 4970. U.S. Congress, House, Congressional Record, Sept. 13, 1988, pp. H7436-H7438.

Kastenmeier attempted to advance another bill on the subject in 1990 but failed; and defeated in the 1990 primary election, he was thereafter unable to push the issue. Since then, Congress has generally ignored the issue of animal patents. One reason is the force of the biotechnology complex in the political economy of intellectual property, but another is that the genetic engineering of animals has not fulfilled expectations, either in improving agricultural animals or in turning them into factories for molecular farming.[101] Only about 25 animal patents have been granted in the United States, most of them on laboratory mice and rats. [need to check this] However, if and when the genetic engineering of animals becomes scientifically achievable enough to figure in the political economy of agriculture, animal patenting may once again find a place on the public agenda.

VI. Ethics and Europe

In contrast, the European Patent Convention -- which was established in 1962 and governs the national patent systems of its adhering nations -- specifically excludes two types of inventions from eligibility for patents. Article 53(a) prohibits patents on any invention that is contrary to public order or morality. And Article 53(b) prohibits them on plant or animal varieties, or anything produced by a natural biological process, except for microbiological products. Article 53(a) seems to have its roots in Roman law. Article 53(b) was adopted to prevent interference with the international system for the protection of breeder's rights -- it is known acronymically as UPOV and was created in 1961 -- in new varieties of plants. At the

---

[101]"Biotechnology Venture Hits Unexpected Snags," New York Times, Nov. 23, 2001, p. C5.

time of the creation of UPOV, the extension of the exclusion to animal varieties was undoubtedly an afterthought.

However, both articles were brought into play when the European Patent Office (EPO), which administers the convention and which is headquartered in Munich, came to take up Harvard University's application, filed in 1984, for a European patent on its oncomouse. Ruling in June 1989, the EPO found that oncomouse did not violate the public-order-and-morality clause of the convention, but it rejected Harvard's application on grounds that the mouse did violate Article 53(b). In the view of the EPO examiners, oncomouse was a new variety of animal, the product of a natural biological process, and, hence, ineligible for a patent under the convention.[102]

Harvard quickly appealed the rejection, insisting that its mouse was not a new variety but a new type of animal that transcended varietal classification, and that it was not a natural biological product but -- echoing Chakrabarty's claim -- a biological entity made by man. The appeal provoked an unprecedented degree of third-party filings. (Under the European Patent Convention, interested third parties can file comments for or against pending applications and appeals, an option that is unavailable in the American patent process.) Many of the filings were identical, the products of organized opposition to animal patenting in Europe from public-interest organizations concerned with animal rights, Third World agriculture, and environmental issues. The dissent mobilized by these public-interest groups appears to have been centered in England, where animal welfare groups are powerful, and in Germany, where opposition to

---

[102] European Patent Office, Press Release No. 10/89, "EPO Refuses Patent Application for Oncogenic Mouse."

genetic engineering and Greenish concern with environmental protection are vigorous. The arguments raised by these groups closely resembled those advanced in the United States against animal patenting. However, the European agricultural community appears to have been more profoundly split on patents for plants and animals than its American counterpart, with considerable opposition coming from countries where small-scale agriculture (as distinct from agribusiness) continues to flourish -- for example, Denmark.

The third-party filings evidently contributed significantly to the decision of the appeals board, which in 1990 returned the Harvard application to the original examiners for reconsideration. The appeals board, agreeing with Harvard, declared that the rejection on grounds of Article 53(b) was without merit, but it held that the examiners had to review the application against Article 53(a), the morality clause. Part of what the examiners were compelled to reconsider were issues raised by the third-party filings, particularly whether a patent on oncomouse would lead to animal suffering (mice with cancer) and environmental danger (their spreading of oncogenes into the natural mouse population if they were to escape). However, the appeals board also instructed the examiners to weigh those matters against the likely benefit to human beings that might arise from research with oncomice.[103]

Harvard's lawyers in Europe contended that the mice would, of course, contribute to the battle against cancer, making them distinctly beneficial to human beings. They also argued that, since the mice were super-susceptible to the contraction of cancer, fewer of them would be required to test for carcinogens and, thus, fewer mice would suffer in such testing. Finally, they

---

[103] European Patent Office, "Decision of the Technical Board of Appeal 3.3.2 of 3 October 1990."

pointed out that the mice posed only a minute environmental risk, because they were to be confined to the laboratory rather than released into the wild; and while unintended release might occur, the danger was surely not a matter for the patent system but for the agencies concerned with the control of hazardous materials.[104]

The Harvard lawyers' arguments persuaded the European Patent Office, which incorporated them in a ruling, issued in October 1991, indicating that a patent on the mouse could and would likely be granted.[105] Under the terms of the convention, the ruling was liable to still further third-party objections; the comment period closed in February 1993, having drawn many more inches of dissent, most of it advancing the same arguments and coming from roughly the same sources as in the first round.

The third-party dissidents did not prevail, just as the opponents to animal patenting have not prevailed in the United States. However, even though American patent law continues to be literally amoral, anyone seeking a patent on a living organism in Europe will have to satisfy the requirements of Article 53(a). In the globalizing political economy of biotechnology, American innovators were on notice that in Europe they had to attend to the ethical features of their innovations.

---

[104] "European Patent Application No. 86 304490.7, President and Fellows of Harvard College, Response to the Official Letter of 11th December 1990. . . ."

[105] European Patent Office, Press Release 3/92, "European Patent for Harvard's Transgenic Mouse."

VII. Echoes in Canada[106]

What they had to do in Canada was much less clear. Living micro-organisms first became an issue in the Canadian patent system about the same time as in the United States. But while they were held to be patentable shortly after the *Chakrabarty* decision, in sharp contrast to the course of events in the United States, neither the Canadian Patent Office nor Courts proceeded rapidly to extend patentability to higher organisms.

Patents for Micro-organisms

In 1976, the Abitibi Company of Toronto applied for a patent on a new mixed fungal yeast culture system. Scientists at the University of Ontario, in Western Ontario, had developed the culture for the company to absorb foaming spent-sulfite liquor generated by its papermaking business. They had isolated fungi and subjected them to increasing concentrations of foaming sulfites (among other nutrients) in water. The organisms that survived the sulfite were then subjected to increasing concentrations of foaming sulfite liquor in their culture media. Eventually they obtained five mutated fungi that could consume the foaming effluent, thus clearing the waste stream of the contaminant. Abitibi's patent application covered both the process of creating the mixed fungal yeast culture system and the product of the system -- that is, the yeast culture itself. The patent examiner allowed Abitibi's process claims but rejected the claims on the microbial culture system on the grounds that living matter was not patentable subject matter under section 2 of the Canadian Patent Act. The Abitibi Company appealed the

---

[106] I am grateful to Kari Theobald for research assistance on patenting life in Canada.

rejection of its product claims to the Commissioner of Patents, who had it considered by a Patent Appeal Board.[107]

Section 2 of Canadian patent law authorized the grant of a patent on a new manufacture and "composition of matter." Similar to American patent law in its explicit content, it further resembled the United States patent code in that it said nothing about patents on living organisms. The Abitibi case thus posed challenges to Canadian patent law like that raised by Chakrabarty, whose application was then making its way through the U.S. Patent Office. By the time the Abitibi case reached the Appeal Board, the Chakrabarty case had been decided and was being widely publicized. The Board noted that the Canadian prohibition on patenting living matter had been based on various precedents in the United Kingdom but that "the Chakrabarty decision casts doubt upon the correctness of that practice."[108]

In 1982, two years after *Chakrabarty*, the Board recommended to the Commissioner that the terms "manufacture" and "composition of matter" included, the subject matter of Abitibi's application, declaring:

> All new life forms which are produced *en masse* as chemical compounds and are prepared and formed in such large numbers that any measurable quantity will possess uniform properties and characteristics are patentable. Patentable subject matter includes micro-organisms, yeasts, molds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa.[109]

---

[107] *Re Application of Abitibi Co.* (1982), Canadian Patent Reporter (CPR), Vol.62, 2nd, p.81.

[108] Ibid., p.87.

[109] Ibid., p.82.

The Board also proposed criteria for the patentability of living organisms:

> The conditions of patentability of such subject matter are that the organism to be claimed, must not of course have existed previously in nature, for in that event the "inventor" did not create it, and his invention is old. It must be useful, in the sense that it carries out some useful known objective. . . . It must be sufficiently different from known species that it can be said that its creation involved the necessary element of inventive ingenuity.[110]

The Board's recommendation was evidently influenced not only by legal logic but by considerations of political economy, particularly international competition in biotechnology. It noted that cases in Australia, Germany and Japan seemed to point to the patentability of living matter, observing, "Throughout the world various judicial bodies, without changes in legislation, have gradually altered their interpretation of statutory subject-matter to adapt it to new developments on technologies, and current concepts of industrial activity."[111] The Commissioner of Patents accepted the Board's recommendations. Thus, responding to the changing legal and competitive environment in the world, Canada granted patent no. 1,131,371: *Foam Activated Sludge Process* to the Abitibi Company, the nation's first patent on living matter.

---

[110]Ibid.

[111] Ibid., p.88.

Patents on Plants

While the Abitibi decision dealt only with micro-organisms, the Board was well aware that its decision raised implications for the patentability of higher life forms. Acknowledging that the issue was debatable, the Board nevertheless suggested that such life forms were patentable by reason of legal logic:

> 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 tool of man as a micro-organism. 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.[112]

So far as the CPO was concerned, multicellular organisms *were* be treated differently. It did not subscribe to the doctrine set forth by the U.S. Congress in 1952 that "anything under the sun" qualifies as patentable subject matter. Apparently after the Abitibi decision, the CPO modified its *Manual of Patent Office Practice* (MOPOP) chapter on “Utility and Non-Statutory Subject Matter" to state: “Plants and animals are not patentable subject matter. Seeds are also non-patentable, however, a coated seed may be patentable if the invention resides in the coating

---

[112]Ibid. pp. 89-90.

given to the seed provided that the life process of the seed has not been altered and there is no new living matter."[113]

A key test of the CPO's position on plants came in 1983, when Pioneer Hi-Bred, a Canadian subsidiary of Pioneer Hi-Bred International, in Des Moines, Iowa, applied for a patent on a new soybean variety, designated "Soybean Variety 0877."[114] A product of the research branch of the parent company, the new variety, had been devised using traditional cross-breeding techniques among three known varieties. The inventors claimed that it was the result of human intervention, did not occur in nature, and that it incorporated utilities such as high oil content, early maturity, stable high yields, resistance to seed shattering, and resistance to root rot caused by a fungus. At the time, Canada provided no intellectual property protection for new varieties of plants. Pioneer Hi-Bred believed its invention merited such protection in part because of the implications of the Abitibi case and *Diamond v. Chakrabarty* for patent coverage of higher organisms.[115]

The examiner at the Canadian Patent Office (CPO) rejected Pioneer's claims on grounds that its policy manual held unpatentable both the processes for creating new varieties of plants

---

[113] Canadian Intellectual Property Office, "Chapter 16: Utility and Non-Statutory Subject Matter, section 16.04 Examples of Non-Statutory Subject Matter," Manual of Patent Office Practice[only available online at http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/mopop/mopop_dnld-e.html, 1996].

[114] Pioneer Hi-Bred International, Inc., founded in 1926, is now the world's leading agricultural genetics company operating in more than 120 countries worldwide. See the company's website at http://www.pioneer.com/canada/

[115] *Re Application for Patent of Pioneer Hi-Bred Ltd.* (1986), 11.CPR (3d) 311 (Patent.App.Bd.), p.313. For further features of the soybean, see p.314; Ken MacQueen, "Soybean patent case goes to top court," The Vancouver Sun, May 9, 1988, p.C2; Danyl M. Stotland, "Is Biotechnology Patentable in Canada," Canadian Intellectual Property Review ,9(1991), p.1-24.

and animals as well as the new varieties themselves.[116] Pioneer Hi-Bred appealed the ruling through the CPO, contending that the policy should be changed "in the light of the wording of the *Patent Act* and developments in the law."[117]

A Patent Appeal Board appointed by the Commissioner of Patents reviewed the matter and, on March 4, 1986, the Commissioner, accepting the Board's recommendations, upheld the examiner's decision. He rested the ruling on the tenor of precedent in the Canadian courts rather than on the implications of the Abitibi case as the Appeal Board had earlier spelled them out. According to the Commissioner: The Canadian courts, differing from their counterparts in the United States, had tended to circumscribe rather than broaden the wording of section 2 "by holdings that have excluded some subject-matter areas and human activities from patentability." Furthermore, the Canadian court decisions overpowered the Abitibi ruling, which strictly speaking covered only microorganisms, not higher life forms. The Commissioner also held that the processes used by Pioneer Hi-Bred in creating its soybean were traditional, commonly used breeding methods; and that as such, they were not patentable under Canadian law.[118]

Pioneer appealed its case to the Federal Court of Appeal, thus bringing the issue of the patenting of higher life forms to the Canadian courts for the first time. Ruling on March 11, 1987, the Court upheld the Commissioner of Patents decision to reject Pioneer Hi-Bred's claims. The Court was unconvinced that the terms "manufacture" and "composition of matter" applied to a plant variety produced by cross-breeding: "Such a plant cannot really be said, other than on

---

[116] Re Application for Patent of Pioneer Hi-Bred Ltd. (1986), p.313.

[117] Ibid.

[118] Ibid., p.313, 315, 318-20.

the most metaphorical level, to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means." [119]

The Court also found that Pioneer Hi-Bred's application failed to satisfy the disclosure and reproducibility requirements of Canadian patent law. According to those requirements, the method of producing a patentable product had to be described in sufficient detail so that a person skilled in the art could reproduce it.[120] In the view of the Court, the processes employed by Pioneer Hi-Bred in breeding its new soybean variety "involved a 'degree of luck', 'an element of good fortune.' It follows that even a complete and accurate disclosure by the appellant of everything that the alleged inventor did to develop the new plant would not enable others to obtain the same results unless they, by chance, would benefit from the same good fortune.[121]

Pioneer Hi-Bred then took its case to the Supreme Court of Canada, which on June 22, 1989, unanimously upheld the decision of the Federal Court of Appeal. The justices agreed with the Appeal Court that the company had failed to meet the disclosure and reproducibility requirements of the law. Calling that inadequacy sufficient to reject Pioneer Hi-Bred's claim, they declined to rule on whether a plant was patentable under Section 2.[122]

The Federal Appeal Court had questioned the Patent Commissioner's implicit claim of authority -- contrary to that of his counterparts in the United States and England -- "to establish limits to patentability other than those expressly or impliedly defined by Parliament." Here the

---

[119] Ibid., p.495-96.

[120] Canadian Patent Act, s.36 (1)

[121] Pioneer Hi-Bred Ltd. v. Commissioner of Patents (1987), p.492-493.

[122] Ibid., p.265.

Court evidently alluded to the fact that the CPO's longstanding policy of holding living matter unpatentable because the Canadian Parliament had not explicitly made it patentable.[123] The Appeal Court's observation had clearly left open the possibility that higher life forms might be patentable. The Supreme Court's sidestepping of the issue reinforced the fact that the issue remained outstanding. However, the decision of both courts to uphold the Patent Commissioner on his reasons for denying Pioneer Hi-Bred its patent left the patentability of higher life forms in a murky state, with ammunition for disputants on both sides of the issue.

The Harvard Mouse

On June 21, 1985, Harvard University filed for a Canadian patent on the oncomouse that Leder and Stewart had engineered. On March 24th, 1993, the patent examiner granted patent protection to the oncogenetic construct that had been introduced into the mouse and to the processes used to create the mouse, but he refused it for the mouse itself. The examiner cited the CPO's policy manual and the decision of the Federal Court of Appeals in the Pioneer Hi-Bred case.[124] Harvard soon requested a review of the examiner's decision by the Commissioner of Patents. The Commissioner consulted with the Patent Appeal Board, which heard oral arguments on the case. On August 4, 1995, the Commissioner reaffirmed the examiner's decision and dismissed Harvard's application for a patent on Leder and Stewart's mouse. The Commissioner argued that the transgenic mouse was not an "invention" because, once the

---

[123]Ibid., p.495-96.

[124]In the Canadian Patent Office—The Decision of the Commissioner of Patents, Harvard Oncomouse case, August 4, 1995, p.2.

oncogene was inserted into the newly fertilized mouse egg, nature rather than the inventors controlled the creation of the whole animal. The inventors only ensured the reproduction of the oncogene. Unlike the Commissioner at the time of the Abitibi case, this Commissioner asserted that Canada need not take its cue on patent policy from the United States.[125]

Harvard thereupon appealed the matter to the Federal Court of Canada, Trial Division. Contesting the substantive argument of the Patent Commissioner, Harvard's lawyers argued that the inventors had complete control over the oncogene, the animal's innovative characteristic. Moreover, they contended that the oncomouse could be seen as both a "manufacture" (because the mouse is produced from hand labor and results in a new form) and as a "composition of matter" (because the mouse is produced by combining a gene with a fertilized mammalian egg).[126]

On April 21, 1998, the trial court ruled against Harvard. The presiding judge held that being able to demonstrate the presence of the oncogene in the mouse did not constitute control of the mouse and that the insertion of the oncogene into the mouse zygote did not constitute invention of it. The mouse possessed numerous other characteristics independently of Leder and Stewart's manipulations. The judge also found that the reproduction of the oncogene from one generation to the next was attributable to the laws of nature, not the inventors. The mouse was not reproducible within the requirements of the law because it married human intervention with the laws of nature. "If someone skilled in the art wanted to

---

[125] *Ibid*., p.6-7.

[126] "Designer Mouse is not a Patentable Invention," Canadian Patent Trademark Newsletter, June 1998 http://www.patentable.com/newsletters/jun98news.html

produce an oncomouse with the gene in a particular organ, he or she would only be able to do so if lucky," he contended.[127]

Yet the judge was concerned not only with law but with the process for making it in an arena of patents that was ethically charged. He declared that “a complex life form does not fit within the current parameters of the Patent Act without stretching the meaning of the words to the breaking point, which I am not prepared to do.” He added that he was "not persuaded by the majority decision in Chakrabarty" and was "in complete agreement with the minority.” He further noted that the ethical considerations involved in determining the patentability of higher life forms should be left to the legislators to decide: “[I]f Parliament so wishes, it clearly can alter the legislation so that mammals can be patented."[128]

Harvard then brought its case to the Federal Court of Appeal (FCA). The Canadian Environmental Law Association (CELA) requested and was granted status in the FCA proceedings as an intervener against Harvard's claims. The CELA raised various arguments that the Commissioner of Patents had not. One arose from the passage in 1991 of the Plant Breeders' Rights Act, a system of intellectual property protection for plants akin to that established in the United States by the Plant Variety Protection Act in 1970. [129] The CELA argued that the passage of the Act demonstrated that the products of plant breeding were not meant to be covered under the Patent Act, and by implication, that all other life forms that are the products

---

[127] President and Fellows of Harvard College (appellant) v. Commissioner of Patents (respondent), 1998, pp.289-291.

[128] *Ibid.*, pp.291-2.

[129] Plant Breeders’ Rights Legislation For Canada”, Canadian Intellectual Property Review, 1992, p.38-43.

of genetic engineering are similarly unpatentable. It contended in addition that since the Canadian Patent Act did not explicitly authorize the patenting of living matter, such matter was therefore not patentable under the Act. Finally, the CELA also advanced a number of arguments like those raised in the Kastenmeier hearings, pointing to adverse public-interest effects that might arise from patenting the products of biotechnology -- for example, hazards to the environment, to human health, and to animal welfare-- and to the sacrilege of commodifying life.[130]

On August 3, 2000, the Appeal Court, overturning the Commissioner of Patents and the trial division court, decided by a majority of two to one that the Harvard oncomouse was indeed a patentable invention. The dissenting justice held that the patentability of inventions falls within the expertise of the Commissioner of Patents, that in denying Harvard a patent on a living mouse he had exercised his authority reasonably and in accord with law and precedent. Morevoer, given "the serious moral and ethical implications of this subject-matter, it seems that the Parliament is the most appropriate forum for the resolution of the dispute here.[131]

Justice Marshall Rothstein crisply iterated the majority's reasons. Since the Canadian Patent Act was modeled on the U.S. statute and used the same broad language, the Chakrabarty decision should be persuasive to Canadian courts. The Patent Act did not exclude living organisms from eligibility for patents. Neither therefore should the Court. The framers of the Patent Act could not have been expected to anticipate every future invention.

---

[130] President and Fellows of Harvard College (appellant) v. Commissioner of Patents (respondent), 2000, pp. 34-35.

[131] Ibid., pp.3,7.

As to the CELA's legal objections, in the United States, the majority in *Chakrabarty* "found that a rule that would deny patent protection because an invention was unknown when the Act was passed would conflict with the core concept of patent law, that anticipation undermines patentability, and that broad general language was employed because inventions are often unforeseeable." Furthermore, nothing in the Canadian Plant Breeders' Rights Act implied that living things are excluded from the definition of "invention" in the Patent Act provided they are the result of human ingenuity and are not solely a product of the laws of nature.[132]

Judge Rothstein went on: The Canadian Supreme Court's decision in the Pioneer Hi-Bred soybean case was based on the issue of disclosure; it did not rule out the patentability of higher life forms. Unlike the breeders of the new soybean variety, the Leder and Stewart had intervened in the mouse to change its genetic composition. The onocmouse could indeed be considered a new "composition of matter" comprising the combination of the oncogene (a physical substance) and the fertilized egg (a biological matter). Besides, if lower life forms were compositions of matter, so too were higher life forms. The Commissioner of Patents and the trial court had given too much weight to the question whether the oncomouse was a product of human intervention or of nature. "The use of the laws of nature by inventors does not disqualify a product from being an invention, provided inventiveness or ingenuity is also involved." And whether the inventors sufficiently controlled the production of their invention was not a "useful" criterion. "All that is important for the usefulness of the product (the use of

---

[132]Ibid., pp. 25-26, 31,.34.

the oncomouse in carcinogenecity studies) is that, using the methods described by the inventors, a mouse is produced with all of its cells affected by the oncogene."[133]

Judge Rothstein declined to address the CELA's public-interest concerns, maintaining that it was for Parliament, and not the Court, to deal with such issues. Like the majority in *Chakrabarty*, he held that the Court's sole task was to interpret the Patent Act. However, aware that the FCA's ruling might raise apprehensions that human beings might be next, Judge Rothstein added, in an echo of *ex Parte Allen*, that "the Patent Act cannot be extended to cover human beings," continuing, "Patenting is a form of ownership of property. Ownership concepts cannot be extended to human beings. There are undoubtedly other bases for so concluding, but one is surely section 7 of the *Charter of Rights and Freedoms* . . . which protects liberty. There is, therefore, no concern by including non-human mammals under the definition of 'invention' in the Patent Act, that there is any implication that a human being would be patentable in the way that the oncomouse is."[134]

The FCA decision delighted Harvard's Canadian lawyer, who reflected, "The trouble you get into is that in the spectrum of life on earth, there is no difference between a mouse and a bacterium -- it's a continuum. Where do you draw the line? Do you patent the squid, but you don't patent the shark? Or do you patent the shark but you don't patent the porpoise?"[135] The Canadian biotech industry was equally pleased. A legal specialist in biotechnology declared,

---

[133] Ibid., pp. 22-24, 29.

[134] Ibid, p.36.

[135] David Gambrill, "Court allows patent on Harvard Mouse: Decision paves the way for patenting all life forms except humans"" Law Times, 2001, www.canadalawbook.ca/headline52_arc.html, p.2.

"The decision . . . is a triumph of logic and reason over the evisceral fear of the new technologies."[136]

The decision failed to provoke a widespread national outcry, even though it received some attention in the Canadian national press, but it did irritate several agrarian, religious, environmental, and public-interest groups.[137] The Rural Advancement Foundation International (RAFI), Canadian division, a non-governmental organization dedicated to the conservation and sustainable improvement of agricultural biodiversity, was concerned with the impact of intellectual property on agriculture and world food security. One of its members deplored the FCA decision, saying, "For the first time in Canada, something that can look you in the eye is considered an invention. . . . The implications of this change in Canadian patent law are profound and the outcome will be viewed with dismay by many nations who have been following the Canadian case closely."[138]

The response of religious leaders resembled that of their counterparts in the United States. The Evangelical Fellowship of Canada (EFC) urged that the patenting of life forms ought to be completely prohibited. "The question of whether or not higher life forms should be patentable creates unease for Canadians because it raises social, philosophical, moral and religious questions about the nature of life and the ownership of life," said the Director of EFC's Centre for Faith and Public Life. He further noted that "We are stewards of God's creation, not

---

[136] Ibid., p.3

[137] L.J. Deftos, "Patenting Life: The Harvard Mouse that Has Not Roared," The Scientist, November 27, 2000.

[138] "Court rules that mammals can be patented", Natural Life, 2000, p.2.

owners, and our task is to care for that which has been entrusted to us. Theology, philosophy and law remind us that human ownership is not limitless."[139]

The CELA, its intervention in the case having proved fruitless, despaired that the social policy issues raised by animal patenting would ever be addressed.[140] One CELA member reiterated the position it had advanced to the FCA, declaring that the decision whether to patent higher life forms "should be made by legislative review, after a full public debate of all the implications. If Parliament did consider the issue, it could then decide whether there should be safeguards such as ethical and environmental reviews, other public protections for food security and the protection of animals, the appointment of a body of ethical advisors or involvement of the public in decisions made by the Patent Office. Only Parliament, not the Courts, could ensure that such safeguards are in place for the public interest.[141]

The CELA was joined in its call for legislative review of the issue by the Canadian Biotechnology Advisory Committee (CBAC), a group of experts in science, nutrition, business, law, environment, ethics, philosophy and public advocacy. Established to counsel government ministers, it was to suggest ways to make Canada internationally competitive in biotechnology, while incorporating social and ethical considerations into biotechnology policy.[142] In a memorandum to the Canadian Government, the CBAC faulted the FCA ruling on several grounds.

---

[139] "EFC Makes Submission on Patenting Higher Life Forms", EFC Press Releases, http://www.evangelicalfellowship.ca/ media/pr_viewer.asp?Press_Release_ID=78, May 24, 2001

[140] Gambrill, "Court allows patent on Harvard Mouse: Decision paves the way for patenting all life forms except humans"" Law Times, 2001, p.3.

[141] "Court rules that mammals can be patented", Natural Life, 2000, p.2.

[142] See official CBAC website at www.cbac-cccb.ca

It made no distinction between life forms; plants and primates were equally patentable. And it set no limits to what could be patented.[143] The CBAC argued that, because biotechnology patenting had become a major part of globalization, it was imperative that the Canadian Parliament, with full public participation, develop a domestic policy on the patenting of life as quickly as possible, taking into account the "full range of moral, ethical and social issues that are at stake in this case." [144]

The CBAC proposed specifically that Parliament consider amending the Patent Act explicitly to forbid, if required, particular classes of higher life forms such as primates, the human body and certain plant species. Parliament might also want to consider adding to Canadian patent law a policy provision such as the clause in the European Patent Convention prohibiting the grant of patents on inventions that were contrary to public order and morality.[145] As an alternative to Parliamentary action, the CBAC proposed that the government appeal the ruling of the FCA on the Harvard mouse to the Canadian Supreme Court, a course of action that several other groups also urged.[146]

The government showed no interest in having Parliament review the Patent Act. However, on October 2, 2000, it did file an appeal of the FCA ruling and stated that a public dialogue was needed on the issue of animal patents. It also filed a notice of motion to stay the

---

[143] Canadian Biotechnology Advisory Committee Advisory Memorandum: The Federal Court of Appeal's Decision Against the Commissioner of Patents on the Harvard Onco-mouse Case, http://www.cbac-cccb.ca/documents/oncomouse1.pdf, September 8, 2000, p.3

[144] Ibid.

[145] Canadian Biotechnology Advisory Committee Advisory Memorandum: The Federal Court of Appeal's Decision Against the Commissioner of Patents on the Harvard Onco-mouse Case , p.5.

[146] Ibid. One of the groups was the Council of Canadians, an independent, non-partisan citizens' interest group that provides a critical and progressive voice on key national and international issues, "Court Ruling Opens Door to Corporate ownership of Life Forms," The Council of Canadians (Media Releases), www.canadians.org/media/media-000929.html.

FCA's order.[147] A press release explained that "the government considers it necessary to refer the matter to the Supreme Court of Canada in order to obtain a definitive judgement on the scope of the current patent law.[148]

The Supreme Court agreed to hear the case.[149] The Canadian Patent Office resolved that it would continue to deny patents on higher life forms until the Court ruled definitively on their patentability.[150] As of the end of 2001, the Court had not yet delivered its decision.

VIII. Gene Patenting

In 1991, shortly before the Harvard mouse was granted its European patent, J. Craig Venter, a biologist at the National Institutes of Health (NIH), in Bethesda, Maryland, raised the both the economic and ethical stakes in the patenting of life or its parts by proposing the wholesale patenting of human gene fragments. Venter's lab, using automated machines, had sequenced not whole genes but random fragments of cDNA -- that is, DNA complementary to the coding regions in genomic DNA -- derived from part of the brain.[151] Such a fragment was

---

[147] "The Government Seeks Leave to Appeal the Federal Court of Appeal's decision on the Harvard Oncomouse case to the Supreme Court," Ottawa, October 4, 2000, http://www.strategis.ic.gc.ca/sc_mrksv/cipo/corp/corp_appeal-e.html

[148] "The Government Seeks Leave to Appeal the Harvard Oncomouse Case to the Supreme Court," CNN News Release, October 4, 2000.

[149] Bita Amani, "The Mouse Trap: Patenting Complex Life Forms in Canada, Mr. Morrow & the Harvard Mouse," from the website of the Canadian Centre for Innovation Law and Policy, http://128.100.167.70/lawforum/pages/2publications.htm

[150] Email, Peter Davies, of the Canadian Intellectual Property Office, to Kari Theobald, July 27, 2001.

[151]Mark D. Adams, Jenny M. Kelley, Jeannine D. Gocayne, Mark Dubnick, Mihael H. Polymeropoulos, Hong Xiao, Carl R. Merril, Andrew Wu, Bjorn Olde, Ruben F. Moreno, Anthony R. Kerlavage, W. Richard McCombie, and J. Craig Venter, "Complementary DNA sequencing: expressed sequence tags and Human Genome Project," Science, 252 (June 21, 1991), pp. 1651-1656; Christopher Anderson, "US patent application stirs up gene hunters," Nature, 353 (Oct. 10, 1991), pp. 485-486.

called an "expressed sequence tag," or EST.[152] Although just 150 to 400 base pairs long, each was unique and served to identify the gene of which it was a part.[153] In June 1991, Venter and NIH filed for patents on 315 ESTs and the human genes from which they came.[154]

Venter's initiative failed, largely because ESTs did not fully characterize genes, but once he put ESTs on the patent agenda, Rifkin and his allies contended that human genes, even those fully characterized as to composition and function, should not be patented at all.[155] At Senate hearings on ethical issues in gene patenting in 1992, Andrew Kimbrell, the policy director and attorney for Jeremy Rifkin's Foundation on Economic Trends argued in favor of a moratorium on gene patenting, saying, "We are right in the middle of an ethical struggle on the ownership of the gene pool."[156] He held that Congress should "intercede to decide where this ethical and legal free-fall ends."[157]

---

[152]Mark D. Adams, Jenny M. Kelley, Jeannine D. Gocayne, Mark Dubnick, Mihael H. Polymeropoulos, Hong Xiao, Carl R. Merril, Andrew Wu, Bjorn Olde, Ruben F. Moreno, Anthony R. Kerlavage, W. Richard McCombie, and J. Craig Venter, "Complementary DNA sequencing: expressed sequence tags and Human Genome Project," Science, 252 (June 21, 1991), pp. 1651-1656; Christopher Anderson, "US patent application stirs up gene hunters," Nature, 353 (Oct. 10, 1991), pp. 485-486.

[153]Mark D. Adams, Jenny M. Kelley, Jeannine D. Gocayne, Mark Dubnick, Mihael H. Polymeropoulos, Hong Xiao, Carl R. Merril, Andrew Wu, Bjorn Olde, Ruben F. Moreno, Anthony R. Kerlavage, W. Richard McCombie, and J. Craig Venter, "Complementary DNA sequencing: expressed sequence tags and Human Genome Project," Science, 252 (June 21, 1991), pp. 1651-1656; Christopher Anderson, "US patent application stirs up gene hunters," Nature, 353 (Oct. 10, 1991), pp. 485-486.

[154] Leslie Roberts, "Genome patent fight erupts," Science, 254 (Oct. 11, 1991), pp. 184-186.

[155] Ted Peters, "Patenting life: Yes," First things: a monthly journal of religion and public life, 63 (May 1996), pp. 18-20.

[156] Kimbrell testimony, The genome project:the ethical issues of gene patenting, Hearing before the Subcommittee on Patents, Copyrights and Trademarks of the Committee on the Judiciary, U.S. Senate, 2:S. Hrg. 102-1134, Sept. 22, 1992 (U.S. Govt. Printing Office, 1993).

[157]Ibid.

Congress, its eye on the economic and medical potential of biotechnology, was unwilling to do anything of the sort. Patent attorneys, biotech representatives, and several congressmen warned that restrictions or a moratorium on the patenting of life or its parts would put the U.S. at a competitive disadvantage internationally and impede research on cures and therapies for disease.[158] Moreover, advocates of biotechnology insisted on distinguishing between issues of political economy and issues of ethics.[159] The former had a place in disputes over patent policy; the latter, at least in the United States, did not, even though they might be legitimate in principle. The appropriate venues for considering them were the legislative and regulatory arenas of government, not the Patent Office.[160]

Rifkin nevertheless maintained an ethical enfilade against gene patenting, finding allies among clerics, feminists, and whoever else might feel threatened or offended by private ownership of the gene pool. In 1995, prompted by his Foundation on Economic Trends, several prominent clerics announced at a press conference in Washington, D. C. that a coalition of one hundred eighty religious leaders representing eighty denominations had joined Rifkin's group in signing a joint appeal opposing the patenting of human genes and genetically altered animals.[161] Richard Land, President of the Christian Life Commission of the Southern Baptist Convention,

---

[158] Testimony, The genome project:the ethical issues of gene patenting, Hearing before the Subcommittee on Patents, Copyrights and Trademarks of the Committee on the Judiciary, U.S. Senate, 2:S. Hrg. 102-1134, Sept. 22, 1992 (U.S. Govt. Printing Office, 1993).

[159] Testimony of William D. Noonan, ibid.

[160] Ibid.

[161] Ted Peters, "Patenting life: Yes," First things: a monthly journal of religion and public life, 63 (May 1996), pp. 18-20.

declared that "[T]he patenting of human genetic material attempts to wrest ownership from God and commodifies human biological materials and, potentially, human beings themselves."[162]

The next year, Rifkin mobilized women's rights leaders against attempts to patent genes implicated in breast cancer, claiming that such efforts represented an "assault on women" and "denies them control over the most intimate aspect of their being, their bodies' genetic blueprint."[163] He said that a coalition would petition the Patent Office to challenge claims that had been filed on the breast cancer genes BRCA1 and BRCA2. Rifkin's statements were endorsed by members of women's health organizations in sixty-nine countries, including Betty Friedan, Gloria Steinem, and Bella Abzug, the former member of Congress and herself a breast-cancer survivor.[164] Abzug averred, "Human genes are not for sale or profit. Any attempt to patent human genetic materials by individuals, scientific corporations, or other entities is unacceptable." [165]

In the United States in December 1997, Rifkin and a biologist announced that, as a provocation, they would seek a patent on methods to create a human/animal hybrid, a creature part animal and part person.[166] Bruce Lehman, the U.S. Commissioner of Patents, declared that the Patent and Trademark Office would in general reject patents that were "injurious to the well-

---

[162] Richard D. Land and C. Ben Mitchell, "Patenting life: No," First Things, 63 (May 1996), pp. 20-22.

[163] "US coalition counters breast gene patents," Nature, 381 (May 23, 1996), p. 265.

[164] Ibid.; Eliot Marshall, "Rifkin's latest target: genetic testing," Science, 272 (May 24, 1996), p. 1094.

[165] Eliot Marshall, "Rifkin's latest target: genetic testing," p. 1094.

[166] David Dickson, "Legal fight looms over patent bid on human/animal chimaeras," Nature, *392* (2 Apr 1998), 423.

being, good policy or good morals of society."[167] Patent lawyers roundly attacked Lehman, contending that he had no authority in U.S. patent law, because it is literally amoral, to back such a prohibition.[168] Yet even if ethics has no rightful presence in American patent policy, an ethical principle – that the human genome must not be locked up -- has been creeping into it through the issue of gene patenting. And nothing has done more to introduce it than the robust ambitions of Craig Venter.

In May 1998, Venter, who had left NIH several years before for a non-profit genome research institute, announced that he would move to a new, for-profit company, called Celera that would be located next door, in Rockville, Maryland.[169] Celera would aim to sequence all the DNA in the human genome by 2001, using rapid new automated machines supplied by its principal owner, the Perkin-Elmer Corporation.[170] Venter declared that Celera would make all its sequence data publicly available while at the same time earn money from selling access to the information.[171] Venter's rapid-fire approach to the sequencing prompted scientific critics to predict that his company's data would contain numerous serious gaps in the DNA, perhaps 100,000 of them.[172] It was also unclear how the company could publish and profit from its

---

[167] Meredith Wadman, "…as US office claims right to rule on morality," Nature, *393* (21 May 1998), 200.

[168]Ibid.

[169] Eliot Marshall and Elizabeth Pennisi, "Hubris and the human genome," Science, *280* (15 May 1998), 994-995; J. Craig Venter et al., "Shotgun sequencing of the human genome," Science, *280* (5 Jun 1998), 1540-1542.

[170] Marshall and Pennisi, "Hubris and the human genome," pp. 994-995;Venter et al., "Shotgun sequencing of the human genome."pp. 1540-1542.

[171]Venter et al., "Shotgun sequencing of the human genome,"pp. 1540-1542.

[172] Marshall and Pennisi, "Hubris and the human genome," pp. 994-995.

sequence data. Early in 2000, strategies that Celera said it would follow to profit from its work appeared to threaten broad access to the sequence information.[173]

But Venter has revived his original goal of wholesale gene patenting. Along with several other genomic companies, Celera has proposed to use ESTs to identify new genes and guess their function by finding genes of known function and similar structure through computerized searches of the genomic data base. The company would then seek utility patents covering these new genes, arguing that their functions were likely the same as those of the genes with similar structure.[174] That strategy stimulated a forceful statement in late March by Aaron Klug and Bruce Alberts, the presidents, respectively, of the Royal Society of London and the National Academy of Sciences in the United States.[175] They called guessing at gene function by computerized searches of genomic data bases "a trivial matter."[176] Its outcome might satisfy "current shareholders' interests," but it did "not serve society well." Holding that its results did not warrant patent protection, they stressed that "the human genome itself must be freely available to all humankind."[177]

The U.S. Patent and Trademark Office, however, flatly disagrees, judged by its current policy on the patenting of genes and DNA sequences. At the end of 1999, it invited public comments on that policy and subsequently received them from 35 individuals and 17

---

[173] Eliot Marshall, "Talks of public-private deal end in acrimony," *Science, 287* (10 Mar 00), 1723-1725.

[174] Author's conversation with Rebecca Eisenberg, March 2001.

[175] Bruce Alberts and Sir Aaron Klug, "The Human Genome Itself Must be Freely Available to All Humankind," Nature, Vol. 404 (3/23/00): 325.

[176] Ibid.

[177] Ibid.

organizations. Some of the comments were ethical, echoing those of Alberts and Krug; some were legal or practical, raising objections, for example, to granting patents on DNA sequences such as ESTs by arguing that they should not be patentable because they exist in nature. In January 2001, the Office found reasons to refuse to incorporate any of the comments in its policies. Indeed, its responses to the comments in effect promulgated a policy governing the patentabilty of genes and DNA sequences that is enormously broad.[178]

Gene patenting has exposed a conflict and, possibly, an incompatability in patent policy between the United States and the European community. Even though the former does not impose ethical constraints on the patentability of products, the latter does, with the consequence that what may be patentable in the U.S. may not be so in Europe. Paradoxically, while trade barriers have been steadily falling with globalization, at least in the commerce of living organisms and their parts, patent barriers may be arising to some degree.

The transatlantic mismatch aside, within both the United States and Europe, gene patenting has prompted important challenges to the scope of intellectual property rights in genes. The human genome is not only widely regarded as a common birthrate of people everywhere; it is also finite. Critics in biomedical research and health delivery have begun contending that monopoly control of its crucial parts -- the genes responsible for common diseases -- can be counterproductive to both science and health. Their arguments are economic and consequential rather than, like Rifkin's, quasi-theological and abstract. They point, for

---

[178] Department of Commerce, Patent and Trademark Office, "Revised Utility Examination Guidelines; Request for Comments," *Federal Register*, 64: no. 244, Dec. 21, 1999, 71440; Department of Commerce, Patent and Trademark Office, "Utility Examination Guidelines," *Federal Register*, 66: no. 4, Jan. 5, 2001, 1092. I am indebted to Professor Hal Edgar, Columbia University Law School, for calling my attention to these documents.

example, to the insistence of corporate gene-patent holders on charging license fees to scientists who want to pursue research on the covered genes; and to the high prices charged for diagnostic tests using them. They also point out that a good deal of the intellectual capital contained in these patents was provided at public expenses.

Biotechnologists counter, like Burbank's posthumous advocates, that they have an ethical claim on the products of their innovations and that the intellectual property rights in gene patents must be absolute if investment in that branch of biotechnology is to be sustained. In a sense, then, gene patenting has produced a conflict between the ethical and practical interests of innovators on the one side and the larger society on the other. If the conflict grows sharper, governments may choose to limit the property rights in human DNA sequences by regulating their use.

European Commission

A history of patenting life in the United States with comparative attention to Europe and Canada

Luxembourg: Office for Official Publications of the European Communities

2002 — iv, 84 pp. — 21 x 29.7 cm

ISBN 92-894-2063-4

15 6 KA-41-01-462-EN-C

OFFICE FOR OFFICIAL PUBLICATIONS
OF THE EUROPEAN COMMUNITIES

L-2985 Luxembourg

ISBN 92-894-2063-4