Patenting Life
A Historical Overview of Law, Interests, and Ethics

by

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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 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,

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[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.

[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

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[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.] White, A Century of Service, p. 129.

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 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

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[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.

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 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

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[6.] Terry, The Stark Story, pp. 48-51; Hermitte, "Histoires Juridiques Extravagantes: La Reproduction Vegetale," in J.-C. Fritz and Ph. Kahn, eds., La Gestion des Ressources Naturelles d'Origine Agricole, 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

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 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

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Market Indicated by Survey," The National Nurseryman, 36(July 1928), 201.

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; Dreyer, A Gardener Touched with Genius, p. 218.

upon the Congress from horticulturalists, nurserymen, farmers, agricultural experiment stations, and their organized representatives, including the American Farm Bureau Federation, the National 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

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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.

[11] U.S. Congress, Senate, Congressional Record, 71st Cong. 2d Sess., April 9, 1930; April 17, 1930; May

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]

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

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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.

13. Congressional Record, 71st Cong., 2d Sess., 5, 12, and 13, May 1930, pp. 8391, 8751, 8866; and Doyle,

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." 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,

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Altered Harvest (cit. n. 15), p. 55. Identical bills for plant patents were introduced in the House and the Senate on 11 February 1930. Allyn, First Plant Patents (cit. n.1), p. 60.

[14.] Plant Patents, House Report 1129 (cit. n. 22), pp. 16-17.

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 "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.

[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,

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 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

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Trademarks and Copyrights of the Committee on the Judiciary, Hearings: Plant Patents, 86th Congress, 1st Sess., 9 July 1959.

16. Ibid., pp. 862-63.

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 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

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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.

19. Kloppenburg, First the Seed, p. 133.

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 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

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

[21.] Allyn, The First Plant Patents, pp. 18-38; 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

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

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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.

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.

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 discover 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]

Patents on Micro-organisms

There was no other extension of patent law to vital entities for forty years, but in

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[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

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 for patents; 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 bioengineered a bacterium to consume oil slicks, filed for a patent on the living, altered bacterium. The U.S. Patent Office denied him a patent arguing that no patent could be issued on a living organism, not least because it was a product of nature. Chakrabarty appealed his case through the courts, and at the end of 1979 it reached the United States Supreme Court under the rubric of *Diamond v. Chakrabarty*, in recognition of the fact that the position of the patent office was formally defended by Sidney Diamond, the current patent commissioner.

By the time the case arrived at the court, it had become charged with the social and economic stakes that surrounded the swiftly accelerating commercialization of molecular biology. In the 1970s the new techniques of recombinant DNA were beginning to be exploited by adventurous startups such as Genentech. Companies were being founded at a rapid pace, while major pharmaceutical firms as well as several oil and chemical giants were

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applications, see Ex Parte Kluis & Kluis , (PO BdApp) 70 USPQ 165.

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

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. Biotechnology firms and firms eager to get into biotechnology sought connections with university campuses. 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.

Chakrabarty had not used the technique of recombinant DNA to engineer his oil-eating bacterium, but the issue that his case raised -- the patentability of living organisms -- spoke directly to the rapidly increasing stake in biotechnology patents. Ten amicus briefs were filed in the case. Most supported Chakrabarty and came from economically interested organizations including Genentech, the Pharmaceutical Manufacturers Association, the American Patent Law Association, the New York Patent Law Association, and the American Society for Microbiology. The University of California also submitted a friend-of-the-court brief. It was not more alive than other universities to the hopes of revenues from biotechnology; only more immediately interested, by virtue of the fact that Herbert Boyer, one of the inventors of recombinant DNA and a cofounder of Genentech, was a member of the faculty on its San Francisco campus.

The University of California's particular stake in the patenting of living products was echoed and generalized in a single amicus brief filed on behalf of the American Society of

Biological Chemists, the Association of American Medical Colleges, the California Institute of Technology, and the American Council on Education as well as several faculty in biochemistry and molecular biology from Caltech and the University of California at Los Angeles. The brief was unabashedly frank in declaring the fundamental interest of each of these friends of the court in the outcome of the case: "Some of the Amici receive contract funds from commercial corporations whose future funding of research in this field is certain to be influenced by this Court's decision. All of the individual Amici receive or plan to receive indirect funding from royalties on patents which are held by their respective universities. . . . They fear that adoption of a per se rule excluding all living things from patentability will inhibit commercial development of the advances they are making in recombinant DNA research."[27]

On June 16, 1980, the Court held, by the slim margin of 5 to 4, that whether the invention was alive or dead was irrelevant, that the bacterium was not a product of nature, that it was a product of Chakrabarty and hence deserved a patent. Chief Justice Warren Burger delivered the majority opinion, enthusing over the broad language that Thomas Jefferson had written into the patent law of 1793 -- which remained at the core of the patent code -- calling it expressive of its author's "philosophy that `ingenuity should receive a liberal encouragement'" and noting that all succeeding Congresses had left Jefferson's language

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[27] Brief Amicus Curiae of the Regents of the University of California, Jan. 1980; Brief of Dr. Leroy Hood, Dr. Thomas Maniatis, Dr. David S. Eisenberg, the American Society of Biological Chemists, the Association of American Medical Colleges, the California Institute of Technology, the American

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. 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.[28]

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 -- plants, animals, and possibly human beings -- or, by implication, to the genetic engineering of such life forms.[29] The legal opening ultimately came to the attention of 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. In September 1984, they 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

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Council on Education as Amicus Curiae, Jan. 28, 1980. The *amicus* briefs are with *Diamond v. Chakrabarty*, U.S. Supreme Court, Docket No. 79-136, 447 U.S. 303, January, 1980.

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

[29]. "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.

the improved oyster as such, which challenged precedent.[30]

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 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

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[30]. 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]

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."[31]

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 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.[32] The Board held that human beings fell outside the scope of patentability by reason of the13th 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.

Ex parte Allen meant a good deal to Harvard University and Philip Leder. A distinguished biomedical scientist, Leder was appointed, in 1981, to the faculty of the Harvard University Medical School. In conjunction with his recruitment, the DuPont Corporation had that year given Harvard $6 million for support of Leder's research. A Harvard spokesman stressed that the grant was "sympathetic with academic freedom and

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

the pursuit of knowledge," declaring that it imposed no restraints on the recipients' freedom to talk or publish. The principal *quid pro quo* was simple: While Harvard would own any patents that might arise from Leder's research, DuPont would be entitled to an exclusive license on any and all such properties.

During the next two years, Leder and his collaborator Tim Stewart developed a so-called oncomouse -- a mouse genetically engineered to be supersusceptible to cancer. They accomplished the feat by exploiting the then-recently developed transgenic technology to insert the *myc* oncogene tied to a mammary- specific promoter into the new embryo of a normal mouse. The work had not been done for 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, Leder 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.

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,

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[32]. *Ex Parte Allen*, United States Patent Quarterly, (1987), 1425.

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."

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. 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.

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The grant of patents on animals provoked a flood of ethical objections to the patenting of life, but such dissents had already been cropping up at the time of the *Chakrabarty* case. During arguments in the case, vigorous objection to Chakrabarty's claim had come from the People's Business Commission (PBC), an activist group headed by Jeremy Rifkin. Rifkin was a social agitator and sleepless critic of biotechnology. The PBC's dissent was partly economic – patents on living organisms would foster monopoly in vital areas such as the food industry. It was quasi-religious, too, holding that "the essence of the matter" 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.'"[33] In its ruling on the case, the Supreme Court majority took note of these and other apprehensions, observing that they "present a gruesome parade of horribles" and "that, at times, human ingenuity seems unable to control fully the forces it creates." The majority

[33] Brief on Behalf of the People's Business Commission, Amicus Curiae, 1979.

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."

What the patenting of animals did was to make the debate over the patenting of life more charged and to bring into it new groups -- notably animal rights activists, environmentalists, clerics, and farmer's representatives. Their objections were well aired in hearings held in 1987 and 1989 before the House Judiciary Subcommittee that dealt with patents and was chaired by Congressman Robert Kastenmeier.[34] The objections raised to the patenting of animals tended to be specific to the groups raising them: animal rights activists contending that such patents would exacerbate the degradation of animals; environmentalists arguing that genetically engineered animals would escape and threaten the integrity of wildlife; clerics claiming that patenting reduced God's creatures to mere material objects; and farm spokespersons worrying about the economic effects of patented animals on small farmers.

Strong defenses of animal patenting came from other witnesses, notably representatives of the biotechnology industry and of major universities. Their arguments, echoing those advanced in the large majority of the amicus briefs submitted in the

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[34] 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; U.S. Congress, House,

Chakrabarty case, emphasized the role of patents in stimulating biotechnological innovation, fostering American competitiveness, and advancing medical research, including diagnostics, therapies, and cures. No significant objection was raised against animal patenting by university representatives or scientists on grounds that such patenting would impede access to or use of transgenic research materials.

Kastenmaier and his subcommittee responded to the debate pragmatically -- ignoring most of the objections raised by Rifkin and his allies but paying attention to those that touched directly on issues of public policy concerning the key interest groups involved, particularly agriculture. In 1988, Kastenmeier 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 cannot be patented. The bill passed the House, but it was not taken up in the Senate before the end of Congress. Since then, no bill addressing animal patents has reached the floor of the House or Senate.

Moreover, advocates of biotechnology insisted on distinguishing between issues of political economy and issues of ethics. 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.

Subcommittee on Courts, Intellectual Property, and the Administration of Justice, Committee on the

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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 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,

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Judiciary. Transgenic Animal Patent Reform Act of 1989. 101st Cong., 1st Sess., Sept. 13 and 14, 1989.

oncomouse was a new variety of animal, the product of a natural biological process, and, hence, ineligible for a patent under the convention.[35]

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 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.

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

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.[36]

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 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.[37]

Mouse."

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

[37] "European Patent Application No. 86 304490.7, President and Fellows of Harvard College, Response

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.[38] 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.

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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

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to the Official Letter of 11th December 1990. . . ."

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

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.[39] Such a fragment was called an "expressed sequence tag," or EST.[40] Although just 150 to 400 base pairs long, each was unique and served to identify the gene of which it was a part.[41] In June 1991, Venter and NIH filed for patents on 315 ESTs and the human genes from which they came.[42]

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

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[39]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.

[40]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.

[41]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.

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

all.[43] 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, the successor to the PBC, 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."[44] He held that Congress should "intercede to decide where this ethical and legal free-fall ends."[45]

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.[46] Moreover, advocates of biotechnology insisted on distinguishing between issues of political economy and issues of ethics.[47] 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

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

[44] 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).

[45] *Ibid*.

[46] 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).

[47] Testimony of William D. Noonan, *ibid*.

were the legislative and regulatory arenas of government, not the Patent Office.[48]

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.[49] Richard Land, President of the Christian Life Commission of the Southern Baptist Convention, 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."[50]

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."[51] 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

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[48] Ibid.

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

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

countries, including Betty Friedan, Gloria Steinem, and Bella Abzug, the former member of Congress and herself a breast-cancer survivor.[52] 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." [53]

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.[54] 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-being, good policy or good morals of society."[55] 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.[56] 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,

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

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

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

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

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

called Celera that would be located next door, in Rockville, Maryland.[57] 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.[58] 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.[59] 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.[60] It was also unclear how the company could publish and profit from its 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.[61]

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

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[56] *Ibid*.

[57] Eliot Marshall and Elizabeth Pennisi, "Hubris and the human genome," *Science, 280* (15 May 98), 994-995; J. Craig Venter et al., "Shotgun sequencing of the human genome," *Science, 280* (5 Jun 98), 1540-1542.

[58] Eliot Marshall and Elizabeth Pennisi, "Hubris and the human genome," *Science, 280* (15 May 98), 994-995; J. Craig Venter et al., "Shotgun sequencing of the human genome," *Science, 280* (5 Jun 98), 1540-1542.

[59]; J. Craig Venter et al., "Shotgun sequencing of the human genome," *Science, 280* (5 Jun 98), 1540-1542.

[60] Eliot Marshall and Elizabeth Pennisi, "Hubris and the human genome," *Science, 280* (15 May 98), 994-995.

patents covering these new genes, arguing that their functions were likely the same as those of the genes with similar structure.[62] 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.[63] They called guessing at gene function by computerized searches of genomic data bases "a trivial matter."[64] 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."[65]

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.

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

[62] Author's conversation with Rebecca Eisenberg.

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

[64] *Ibid*.

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 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.

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[65] *Ibid*.