Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents

By Douglas Robinson and Nina Medlock

A person who eats cornflakes at breakfast, puts on a cotton shirt, or takes a vitamin C supplement to ward off a cold almost certainly benefits from the US Supreme Court's 1980 decision in Diamond v. Chakrabarty.[1] It has been 25 years since this landmark decision, in which the Supreme Court held that a live, man-made microorganism is patentable subject matter under Section 101 of the US Patent Act.[2]

Chakrabarty is not well known outside the intellectual property community--the average person probably has never even heard the name. Yet Chakrabarty has affected the lives of virtually everyone in the United States, having contributed to a revolution in biotechnology that has resulted in the issuance of thousands of patents, the formation of hundreds of new companies, and the development of thousands of bioengineered plants and food products.

In Chakrabarty, the US Patent and Trademark Office (PTO) rejected claims to a genetically engineered bacterium on the ground that living organisms are not patentable. The Supreme Court disagreed, deciding by a five-to-four majority that a patent may be obtained on "anything under the sun that is made by man."[3] The Supreme Court decision opened the floodgates for protection of biotechnology-related inventions and helped spark the growth of an industry that no one, regardless of his or her moral or philosophical views, can deny is capable of modern-day miracles.

The Proceedings before the PTO and the Lower Court

Chakrabarty began with a patent application filed in 1972 by microbiologist Ananda Chakrabarty on an invention for treating oil spills. Scientists in the petrochemical industry had long been aware of the potential of certain strains of bacteria to metabolize and degrade hydrocarbon compounds into simpler, harmless substances that could serve as a food source for aquatic life. Because no single strain of bacteria was capable of metabolizing all the different hydrocarbon compounds present in crude oil, however, prior methods had to rely on a mixture of bacterial strains, each of which acted on a different set of hydrocarbon components. Unfortunately, not all the bacterial strains in the mixture could thrive in the various environmental conditions existing in the area of an oil spill, so that when a mixture of bacterial strains was used, only some of the bacteria survived long enough to attack the spill.

The key discovery in Chakrabarty's research was that "plasmids" control the oil degradation abilities of certain bacteria. Plasmids are transmittable, non-nuclear segments of DNA. Chakrabarty developed a process by which multiple plasmids capable of degrading different hydrocarbon components could be incorporated within a particularly "hardy" single bacterium. This genetically engineered bacterium was capable of breaking down oil spills at a much faster rate than naturally occurring bacteria. As importantly, it was not affected by varying environmental conditions.

Chakrabarty's 1972 patent application contained three groups of claims directed to

1. The method of producing the bacterium

2. An inoculum composed of a carrier material and the bacterium

3. The genetically engineered bacterium itself

The patent examiner allowed the first two groups but rejected the claims directed to the bacterium as unpatentable under 35 U.S.C. § 101. On appeal at the PTO, the Board of Patent Appeals and Interferences affirmed the examiner's rejection. The Court of Customs and Patent Appeals reversed the Board's decision, however, ruling that living organisms are patentable subject matter.[4] The PTO then filed a petition for writ of certiorari to the Supreme Court.

The Supreme Court Decision

The Supreme Court heard the Chakrabarty case in March 1980. Deputy Solicitor General Lawrence Wallace argued on behalf of the PTO. Edward McKie, William Schuyler, and Dale Hoscheit of Schuyler,

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Birch, McKie & Beckett represented Chakrabarty.[5]

The question before the Court was whether the claimed microorganism constituted a "manufacture" or "composition of matter" within the meaning of the US Patent Act. Reviewing the broad congressional mandate regarding patentable subject matter, the Supreme Court concluded that it did and asserted the principle for which Chakrabarty is best known: that "anything under the sun that is made by man" is eligible for patenting.

The Immediate Aftermath

The Chakrabarty patent was not the first US patent to issue on a living organism. The PTO had granted patents on single-cell organisms on several occasions dating back to 1873, when Louis Pasteur obtained a patent (US Patent No. 141,072) on a purified yeast cell. It was only after Chakrabarty, however, that the PTO clarified what had been an inconsistent approach to patenting living organisms. This clarification came in Ex Parte Allen,[6] when the Board of Patent Appeals and Interferences reversed the examiner's rejection of claims for genetically engineered oysters as unpatentable because it found "no evidence that the claimed polyploid oysters occur naturally without the intervention of man."[7]

Shortly after Ex Parte Allen was decided, the PTO issued a statement on April 7, 1988, announcing that "[t]he Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101."[8] Almost exactly one year later, on April 12, 1988, the PTO issued the first patent for a transgenic animal, commonly known as the "Harvard Mouse" (US Patent No. 4,736,866).

The Post-Chakrabarty World

At the time Chakrabarty was decided, biotechnology was a newly developing field. No one could have foreseen in 1980 the phenomenal pace at which new biotechnology advances would develop. Neither could anyone have predicted the exponential growth in the number of patent applications and issued patents on biotechnology-related inventions that would occur over the next 25 years.

By virtually every measurable factor, the biotechnology industry has literally exploded in the 25 years since Chakrabarty. According to data compiled by Ernst & Young:[9]

- As of December 31, 2003, there were 1,473 biotechnology companies in the United States; the US biotechnology industry employed 198,300 people; and the US revenues for the biotechnology industry had increased from $8 billion in 1992 to $39.2 billion.

- In 2003 alone, the US biotechnology industry spent $17.9 billion on research and development.

- As of mid-March 2004, the total value, or market capitalization, of the 314 publicly held biotechnology companies had risen to $311 billion as compared to $45 billion in 1994.

The number of patent applications and issued patents on biotechnology-related inventions also has risen dramatically since Chakrabarty. Data complied by the Biotechnology Industry Organization, based in Washington, DC, shows that the number of biotechnology patents granted by the PTO rose from 2,160 in 1989 to 7,763 in 2002. Since 1998, that total has averaged over 7,000 patents each year.[10]

The biotechnology patents issued over the last 25 years have covered a wide range of technologies and products from medicine and diagnostics for treating diseases to agriculture and environmental products for feeding the world's growing population and safeguarding the environment. Some of the significant biotechnology patents to issue since the Chakrabarty decision are discussed below.

The Harvard Mouse

Among the most fascinating developments in the post-Chakrabarty world is the "Harvard Mouse," developed by Harvard University researchers Phillip Leder and Timothy Stewart. US Patent No. 4,736,866 received a great deal of attention when it was issued in April 1988, because it was the first US patent to issue for a transgenic animal (i.e., an animal created by injecting genes from another species into a fertilized animal egg and then surgically implanting the egg into the mother). The injected genes were oncogenes that triggered cancer growth, making the "oncomouse" a particularly valuable tool for testing the effects of cancer-fighting drugs and suspected carcinogens.[11]

Since the Harvard Mouse patent was issued in 1988, hundreds of other patents pertaining to transgenic animals have been issued in the United States, including patents to chickens (US Patent No. 5,656,479), cows (US Patent No. 5,750,176), dogs (US Patent No. 6,498,791), mice (US Patent No. 6,552,246), monkeys (US Patent No. 5,489,524), pigs (US Patent No. 6,498,285), rabbits (US Patent No. 5,675,063), rats (US Patent No. 5,489,742), and sheep (US Patent No. 5,763,739).

The Harvard Mouse is also patented in Europe and Japan. However, not all countries have been willing to join the United States in allowing patents on higher life forms. Canada, for example, has refused to patent transgenic animals. The Supreme Court of Canada ruled in December 2002 that the Harvard Mouse is not patentable subject matter within the scope of the Canadian Patent Act.[12]

The Polymerase Chain Reaction

The polymerase chain reaction (PCR)--the subject of US Patent Nos. 4,683,195, 4,683,202, and 4,965,188, issued in 1987 and 1990--has been hailed as one of the most important scientific technologies to be developed in the last hundred years. Euphemistically referred to as a copying machine for DNA, PCR is a technique for amplifying, detecting, and cloning DNA sequences. Using this process, scientists can take a tiny fragment of DNA and generate an unlimited number of copies in just a few hours.

In the short time since its invention, PCR has revolutionized drug research and medical diagnostics, aiding scientists in detecting hereditary diseases, identifying viruses, and mapping the human genome. The process has become critical in the forensic science of genetic fingerprinting, where initial samples often are too small to test. PCR has even been used successfully to analyze ancient DNA from sources ranging from Egyptian mummies to a 40,000-year-old mammoth.

Genetically Engineered Crops

US Patent Nos. 4,940,835 and 5,188,642 are two key patents in the area of genetically engineered crops. Issued to Dilip Shah of the Monsanto Company on July 10, 1990, and February 23, 1993, these patents are directed to a technique for genetically altering plant seeds so that the plants are resistant to glyphosate-containing herbicides. These herbicides can then be safely applied in crop fields to selectively kill and control weeds without also killing the crops.

Other gene-altering techniques also are in use today to increase the nutritional content of some foods and the resistance of crops to particular insects.[13]

Thanks to biotechnology, the future has literally come to the dinner table. By some estimates, more than 70 percent of processed foods sold in the United States today contain some biotechnology products. In 2004, the US Department of Agriculture reported that genetically altered soybeans accounted for 85 percent of the soybeans grown in this country and that genetically altered corn accounted for 45 percent of the US corn crop.

Primate Embryonic Stem Cells

US Patent No. 6,200,806 was issued on March 13, 2001, to University of Wisconsin's James Thomson for his method of isolating and sustaining embryonic stem cells in culture so that the cell lines continue to proliferate in an undifferentiated state. Embryonic stem cells, unlike other cell types, are "pluripotent," meaning that they can develop into any organ or tissue type.

Thomson's invention electrified developmental biologists, who saw the potential for directing cell differentiation to generate any organ or tissue type desired. It also created considerable controversy, as debates raged regarding the harvesting of stem cells from aborted embryos. Swayed by the tremendous promise that stem cell research holds for the treatment of such tragic diseases as Parkinson's and Alzheimer's, the US House of Representatives passed HR 810 on May 24, 2005, expanding federal funding for embryonic stem cell research. The Bush Administration is opposed to the bill, but lawmakers are confident that there will be sufficient votes to overcome any Presidential veto.

Conclusion

It is impossible to know whether biotechnology research and development would have been stunted had the Supreme Court ruled against the inventor in Chakrabarty. Yet, the decision in Chakrabarty surely provided companies in the nascent biotechnology industry with the needed incentives to invest in the production of new medical treatments and drug therapies, new and better diagnostic tools, and stronger and more disease-resistant crops. It also emboldened the industry to seek patent protection on an ever-broadening range of technological advances. As biotechnology has progressed from the genetic manipulation of microorganisms to transgenic animals and human gene sequences, some religious and public interest groups who oppose the patenting of animal life forms on moral and ethical grounds have raised objections. Yet, these issues have less to do with patent law than with defining the appropriate ethical limits on scientific development. As stated by Chakrabarty's counsel, Dale Hoscheit:

The issue decided in Chakrabarty was a narrow one, but it led to the removal of barriers to patents for a wide variety of biotechnological innovations. The patents for these innovations are limited only by the skill of the individuals drafting the claims. Although there are moral and ethical issues involved in the manufacture of living things, patents themselves are not designed to address such issues. The role of the Patent Office is to determine novelty and nonobviousness; issues of morality and ethics are best left to other organizations specifically tasked to deal with those issues.

Notes

1. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
2. 35 U.S.C. § 101.
3. Chakrabarty, supra n.1, at 309.
4. Application of Chakrabarty, 571 F.2d 40 (CCPA 1978), aff'd on reh'g, 596 F.2d 952 (CCPA 1979).
5. Schuyler, Birch, McKie & Beckett is a predecessor firm to the authors' firm.
6. Ex Parte Allen, 2 U.S.P.Q.2d 1425, 1427 (Fed. Cir. 1987).
7. *Id*.
8. US Patent and Trademark Office Notice, "Animals-- Patentability," 1077 O.G. 24 (Apr. 21, 1987) (emphasis added).
9. Ernst & Young, LLP, Annual Biotechnology Industry Reports 1993–2004.
10. "Biotechnology Industry Facts." June 9, 2005, available at *www.bio.org/ speeches/pubs/er/statistics.asp.*
11. The patent is commonly referred to as the "oncomouse" patent, but the patent claims cover any "transgenic nonhuman mammal" whose germ and somatic cells contain a recombinant activated oncogene sequence introduced into the mammal, or an ancestor of the mammal, at an embryonic stage.
12. President & Fellows of Harvard College v. Canada (Commissioner of Patents) [2002] SCC 76.
13. Glenda D. Webber, "Insect-Resistant Crops through Genetic Engineering," University of Missouri-Columbia, June 9, 2005, available at *www.muextension.missouri.edu/explore/regpubs/ncr553*.