

Who Owns Human Genes? Is DNA Patentable?

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Angelina Jolie's recent disclosure that she had undergone a prophylactic double mastectomy following a positive test for a *BRCA1* mutation (which increases lifetime breast cancer risk by 60%-87%) prompted a national conversation about genetic testing and preventive surgery.¹ Tests for *BRCA1* and *BRCA2* cost more than \$3000, placing them beyond the reach of many women. The high cost is partly a consequence of intellectual property protection afforded to Myriad Genetics Inc, which sequenced the genes and developed the testing capability.

The Patent Act permits exclusive control for a limited time (currently 20 years) of any "process, machine, manufacture, or composition of matter." Following a US Supreme Court ruling upholding the patentability of a microbe that dissolves oil,² the US Patent and Trademark Office (USPTO) began routinely granting gene patents. On June 13, 2013, the US Supreme Court unanimously held that extracted and isolated DNA is a product of nature and not eligible for patent, but that complementary DNA (cDNA), which is synthetic DNA created in the laboratory, is patentable because it is not naturally occurring.³

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The compromise ruling acknowledged difficult issues in a simmering controversy. Granting commercial rights over naturally occurring biological products seemed unethical because industry should not be able to control access to unaltered materials found in nature. However, failure to afford intellectual property protection could stifle innovation, robbing entrepreneurs of financial incentives for discovery. Myriad lost the exclusive right to isolate the *BRCA1* and *BRCA2* genes of individuals, but maintained the right to its unique method of synthetically creating *BRCA* cDNA to produce and market its tests.

Association for Molecular Pathology v Myriad Genetics

In 1997 and 1998, the USPTO granted Myriad patents for the precise location and sequence of *BRCA1* and *BRCA2* genes, which substantially increase breast and ovarian cancer risks. Sequencing the genes on chromosomes 17 and 13, which is an indispensable step in developing a reliable test, proved arduous and expensive. The Court,

however, in a 9 to 0 decision rejected Myriad's patents on isolated DNA because the company "did not create or alter any of the genetic information"; the location and order of the nucleotides exist in nature and Myriad did not alter the DNA structure. Justice Thomas stressed that "groundbreaking, innovative, or even brilliant discovery does not by itself satisfy" the criteria for a patent because "laws of nature, natural phenomena, and abstract ideas are not patentable."⁴

The method by which DNA is isolated, however, may be patentable. Had Myriad created an innovative process for manipulating genes while searching for *BRCA*, it could have sought a method patent. However, Myriad's techniques were well understood at the time the sequencing took place. At the same time, patents on new applications of knowledge may be allowed. For example, competitors have not challenged Myriad's patents on applications of *BRCA* genes.

The Court upheld Myriad's patents on synthetic DNA, reasoning that the creation of a cDNA sequence results in an exons-only molecule that does not exist in nature. This allows Myriad to maintain ownership of its testing technology, which relies on cDNA. However, it also opens the door for competitor companies to develop and deploy different formulations of cDNA that could lead to alternative testing capabilities, potentially lowering the costs.

Dueling Incentives

The US Constitution grants Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." The founders balanced competing values by providing incentives to innovate while ensuring affordability of patented products for the public good. In *Myriad*, physicians and scientists challenged the company's patents, claiming they encumbered research and the ability to diagnose patients. As the Court explained, granting patents to natural phenomena would "tie up" the basic tools of science and technology.

Intellectual property law provides biotechnology companies with incentives to innovate, but hinders wider scientific research. As long as the USPTO granted patents on genes, competitor companies could not use these genes, stifling their ability to develop lower-priced tests and pharmaceuticals. Immediately after the ruling, several competitor laboratories announced they would soon offer tests for assessing breast cancer risks. This should give women with a family history of breast or ovarian cancer, and their physicians, more options and clinical information to make life-changing decisions.

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How Broad or Narrow Is the Court's Ruling?

The majority of the more than 3000 patents issued by the USPTO on isolated human DNA are thought to also include claims of cDNA. However, the extent of the effect on the biotechnology industry is unknown because there are no studies on the economic benefit of isolated DNA patents compared with cDNA patents. Synthetic DNA undoubtedly has commercial value because it is often used to genetically engineer cells, plants, or animals. Moreover, the Court's decision does not entirely foreclose the exclusive use of isolated DNA if companies can show that their methods or applications are novel. Therefore, the decision leaves ample room for entrepreneurs to profit from their inventions.

The Global Dimensions

The United States often lobbies the international community to develop rigorous intellectual property protection. However, it also values international harmonization to promote trade and commerce. Therefore, the Obama Administration is likely to negotiate Free Trade Agreements and influence the World Trade Organization to conform to the US Supreme Court's position. The *Myriad* ruling brings the United States closer to Brazil and India, which stress the importance of access to essential medicines. However, it places the United States at odds with key trade partners such as Australia, Japan, and the European Union, which permit patenting of biological material isolated from the natural environment. After taking into consideration both strict intellectual property protection and international conformity, the Obama Administration may well press for an expansive interpretation of cDNA patentability.

Owning Nature

Controversy remains after the Supreme Court's ruling. There is still societal unease with the idea that for-profit companies can claim ex-

clusivity over cDNA. If novel products to combat life-threatening diseases continue to be priced out of reach, the public will resist. Patient advocates also bristle at companies profiteering from technologies spurred by massive public funding, such as the human genome project. However, if competitors can successfully patent their own cDNA formulations and prices decrease, this will certainly relieve the anxieties of the public.

Shaping the Course of Research

The Court's decision will influence the future of human genome research. The rapidly evolving capacity to sequence the genome will usher in an era of relatively inexpensive screening for multiple risks. Myriad plans to phase out *BRCA* gene tests by mid-2015, marketing instead a more comprehensive test panel for 25 genes. Competitor laboratories will also introduce panels, ultimately enabling detection of hundreds of genes.⁵

Research will be affected beyond human genetics; for example, researchers will likely challenge existing patents on bacterial genes. The Court's decision may also affect intellectual property protection afforded to a wide variety of naturally occurring substances, such as innovations derived from microorganisms or plants.

Ideally, the law ought to facilitate science as well as make life-saving technologies more affordable and accessible. The future should be filled with excitement as scientists and innovator companies expand the horizon of medical technologies to prevent, detect, and treat human diseases. Achieving this vision will require massive public investment, private innovation, and the useful application of new diagnostics and pharmaceuticals through the health care system.

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REFERENCES

1. Jolie A. My medical choice. *New York Times*. May 14, 2013; A25.
2. *Diamond v Chakrabarty*, 447 US 303 (1980).
3. *Association for Molecular Pathology v Myriad Genetics*, 569 US __ (2013).
4. *Mayo Collaborative Services v Prometheus Laboratories, Inc*, 132 S Ct 1289 (2012).
5. Pollack A. After DNA patent ruling, availability of genetic tests could broaden. *New York Times*. June 14, 2013; A16.