

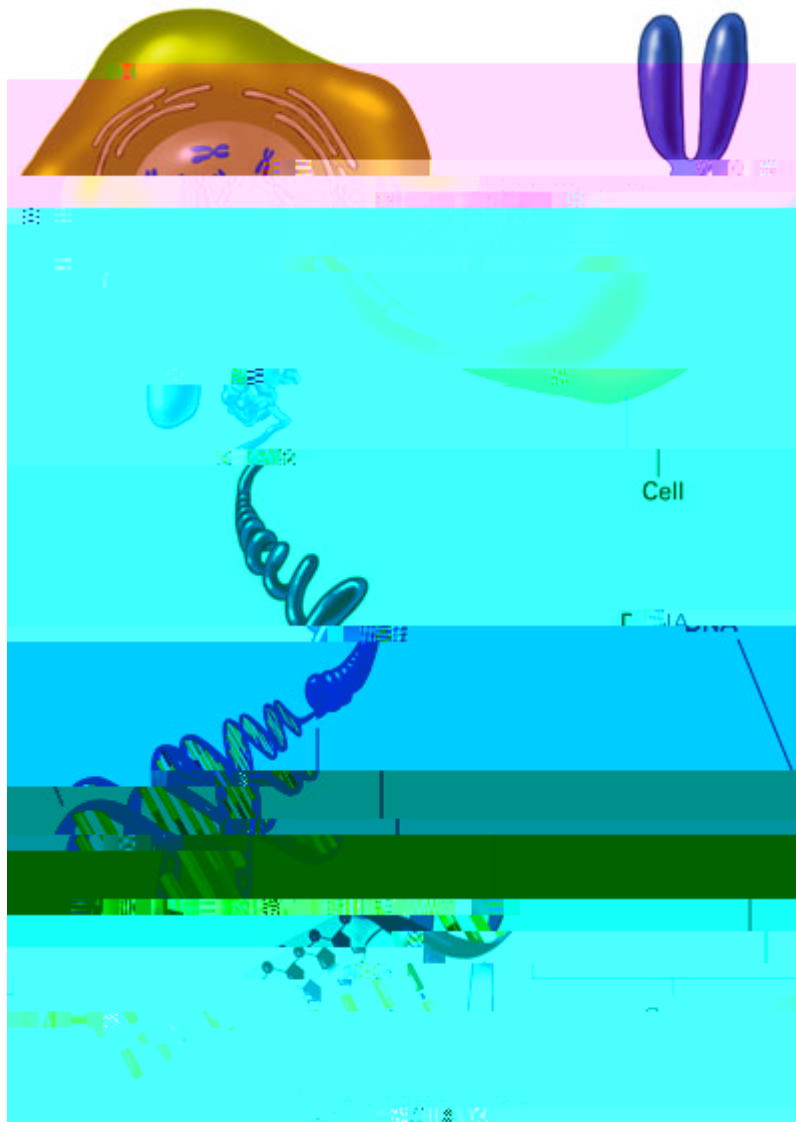
Legal Challenge to Human Gene Patents

The U.S. Patent and Trademark Office (PTO) has granted thousands of patents on human genes; in fact, about 20 percent of our genes are patented. The PTO gives patent holders the exclusive rights to genetic sequences, their usage, a

BRCA Genes and Patents – Frequently Asked Questions

What is a gene?

Genes are the basic units of heredity in all living organisms. A gene is a segment of DNA, the molecules that contain instructions for the development and functioning of living organisms. It is estimated that humans have approximately 30,000 genes that make up our genome. DNA is found inside each cell's nucleus, and is organized into structures called chromosomes. Humans have 46 chromosomes – two sets of 23, with one set coming from each parent. The human genome can be thought of as a set of encyclopedias with 23 volumes, where each chromosome represents one volume. The DNA code is like the letters that are used to build the words, paragraphs, and pages of text in those volumes. Because genes vary in size, they can be thought of as a single paragraph or an entire chapter inside each volume.



What are the BRCA genes?

The BRCA genes – BRCA1 and BRCA2 – are two genes that have been associated with hereditary forms of breast and ovarian cancer. Everyone has these genes. BRCA1 and BRCA2 are believed to be tumor suppressor genes, which means that when they are functioning normally, they suppress the growth of cancerous cells. Women who have certain mutations along these genes have an elevated lifetime risk of developing breast and ovarian can

How can someone patent part of the human body?

Good question! The patent system was designed to grant certain rights to inventors for their inventions in order to reward and encourage human ingenuity. But genes are naturally-occurring parts of our bodies, not inventions. Researchers identify genes, they don't invent them. U.S. law recognizes this differentiation; there is long-standing legal precedent that "products of nature" are not patentable. You can't patent gold or other basic elements, for example.

Nevertheless, the USPTO has ignored this obvious discrepancy for roughly 20 years and has proceeded to issue gene patents on the basis that genetic sequences are "isolated and purified." But all this means is that the gene has been removed from the human body and the non-coding regions of the gene stripped away. These steps – simple enough for any graduate student in genetics or a related field to perform – do not make a gene patentable, any more than removing gold from a mountain makes gold patentable. This is why we are suing the USPTO, to get them to stop issuing such patents which are contrary to the law.

Didn't the Supreme Court resolve this issue in 1980 in *Diamond v. Chakrabarty*?

No. In *Diamond v. Chakrabarty*

Genetics filed for a patent on the BRCA1 gene in 1994.⁹ Myriad either bought out or fought off any other company that was providing tests or performing research on the BRCA1 gene. By 1999 Myriad was the only company offering a test for and performing research on the BRCA1 gene.¹⁰ Myriad filed for a patent on the BRCA2 gene in 1995.¹¹ The USPTO then granted Myriad exclusive rights over this gene.

What does Myriad have patents for exactly?

Myriad has patents on both the BRCA1 and BRCA2 genetic sequences, as well as any mutations along those genes. That means, if you were to take the gene you have in your body right now and remove it

- *The USPTO has allowed Myriad alone to determine which mutations on the BRCA genes to look for. For a period of time, Myriad's method of testing had a false negative rate that was estimated to be as high as 12%.¹² When Myriad decided to extend its testing to look for the mutations its standard test was missing, it chose to offer the new testing as a separate test, at an additional cost.*
- *The USPTO has given Myriad the sole power to determine what to do with the data it collects from people who are tested. Women who receive test results indicating that they have a "variant of uncertain significance" have no way to access further testing to find out if they are at elevated risk for cancer or to force Myriad to share their data with other researchers. African-Americans, Hispanics, and Asian-Americans are disproportionately likely to receive these ambiguous test results.*

The American public's

invention so that others can “invent around” it – that is, improve upon the original invention and design alternatives. This is best illustrated by an example:

When the first cell phone was invented in 1973, the inventor, Martin Cooper of Motorola, was able to patent his particular device. He was required to publish information about the device so that other inventors could learn from it and invent their own alternative devices. Hence the plethora of cell phone companies and options we have today.

But genes are different from cell phones and other things that are patented because they are not inventions, and other researchers cannot invent alternative genes. Even if patent-holders publish information about the genes they have identified, there is nothing to invent around – the genetic material contained in the gene *is* the information. Because this information is the foundation for future diagnostic tests and potential treatments, tying it up as intellectual property can inhibit, rather than stimulate, advances in biomedical research.

What about the argument that patents are a necessary incentive for research?

People who support gene patents often argue that genetic investigation is like drug development and will not take place without the incentive of the patent system. But studies sponsored by the federal government have established that gene patents, unlike other patents, are not required to incentivize research.¹⁵ The Human Genome Project sequenced the *entire human genetic sequence* and did not patent any of the genes it identified. More than five million dollars of federal tax money funded the pursuit of the BRCA1 gene specifically.¹⁶ Overall, much of the world of science has progressed without any expectation of patents: Einstein’s equation, $E=MC^2$, and his theory of general relativity were developed without any patent incentives.

Who are the ACLU and PUBPAT suing?

The first defendant is the U.S. Patent and Trademark Office (USPTO). That office has granted thousands of patents covering human genes – an estimated 20 percent of human genes are patented. We believe the USPTO should never have granted these patents in the first place, because patenting human genes is unconstitutional and unlawful. In order to invalidate gene patents, we have to challenge at least one specific gene patent. Since the patents on the genes that correlate with an increased risk of breast and/or ovarian cancer are among the most offensive, we are also suing Myriad Genetics because it controls the BRCA patents and aggressively enforces them. Myriad does not allow anyone else to conduct clinical full sequencing testing. In addition, these patents have particularly broad claims on the BRCA genes, covering mutations that had not yet even been identified.

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¹⁵ Secretary’s Advisory Committee on Patent Reform, Report of the Secretary’s Advisory Committee on Patent Reform, 115 F.3d 1211 (CA-11, 2004).