

Judge Invalidates Human Gene Patent

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A federal judge on Monday struck down patents on two genes linked to breast and [ovarian cancer](#). The decision, if upheld, could throw into doubt the patents covering thousands of human genes and reshape the law of intellectual property



Ben Sklar for The New York Times

Genae Girard, one plaintiff, applauded the decision as “a big turning point for all women in the country that may have breast cancer that runs in their family.”

United States District Court Judge [Robert W. Sweet](#) issued the [152-page decision](#), which invalidated seven patents related to the genes BRCA1 and BRCA2, whose mutations have been associated with [cancer](#).

The [American Civil Liberties Union](#) and the Public Patent Foundation at the Benjamin N. Cardozo School of Law in New York joined with individual patients and medical organizations to challenge the patents last May: they argued that genes, products of nature, fall outside of the realm of things that can be patented. The patents, they argued, stifle research and innovation and limit testing options.

[Myriad Genetics](#), the company that holds the patents with the [University of Utah](#) Research Foundation, asked the court to dismiss the case, claiming that the work of isolating the DNA from the body transforms it and makes it patentable. Such patents, it said, have been granted for decades; the [Supreme Court upheld patents on living organisms](#) in 1980. In fact, many in the patent field had predicted the courts would throw out the suit.

Judge Sweet, however, ruled that the patents were “improperly granted” because they involved a “law of nature.” He said that many critics of gene patents considered the idea that isolating a gene made it patentable “a ‘lawyer’s trick’ that circumvents the prohibition on the direct patenting of the DNA in our bodies but which, in practice, reaches the same result.”

The case could have far-reaching implications. About 20 percent of human genes have been patented, and multibillion-dollar industries have been built atop the intellectual property rights that the patents grant.

“If a decision like this were upheld, it would have a pretty significant impact on the future of medicine,” said Kenneth Chahine, a visiting law professor at the University of Utah who filed an amicus brief on the side of Myriad. He said that medicine was becoming more personalized, with genetic tests used not only to diagnose diseases but to determine which medicine was best for which patient.

Mr. Chahine, who once ran a biotechnology company, said the decision could also make it harder for young companies to raise money from investors. “The industry is going to have to get more creative about how to retain exclusivity and attract capital in the face of potentially weaker patent protection,” he said.

Edward Reines, a patent lawyer who represents biotechnology firms but was not involved in the case, said loss of patent protection could diminish the incentives for genetic research.

“The genetic tools to solve the major health problems of our time have not been found yet,” said Mr. Reines, who is with the Silicon Valley office of the firm Weil, Gotshal & Manges. “These are the discoveries we want to motivate by providing incentives to all the researchers out there.”

The lawsuit also challenged the patents on First Amendment grounds, but Judge Sweet ruled that because the issues in the case could be decided within patent law, the constitutional question need not be decided.

The decision is likely to be appealed. Representatives of Myriad did not return calls seeking comment. But this month, the company’s chief executive, Peter Meldrum, [told investors that](#) “regardless of the outcome of this particular lawsuit, it will not have a material adverse effect on the company,” or its future revenues, according to the Pharmacogenomics Reporter, “or on the future revenues of our products.”

Myriad sells a test costing more than \$3,000 that looks for mutations in the two genes to determine if a woman is at a high risk of getting [breast cancer](#) and ovarian cancer. Plaintiffs in the case had said Myriad’s monopoly on the test, conferred by the gene patents, kept prices high and prevented women from getting a confirmatory test from another laboratory.

Janice Oh, a spokeswoman for the United States attorney's office in Manhattan, which represented the Patent and Trademark Office in the case, had no comment.

One of the individual plaintiffs in the suit, Genae Girard, who has breast cancer and has been tested for ovarian cancer, applauded the decision as "a big turning point for all women in the country that may have breast cancer that runs in their family." Chris Hansen, an A.C.L.U. staff lawyer, said: "The human genome, like the structure of blood, air or water, was discovered, not created. There is an endless amount of information on genes that begs for further discovery, and gene patents put up unacceptable barriers to the free exchange of ideas."

Bryan Roberts, a prominent Silicon Valley venture capitalist, said the decision could push more work aimed at discovering genes and diagnostic tests to universities. "The government is going to become the funder for content discovery because it's going to be very hard to justify it outside of academia."

John Ball, executive vice president of the American Society for Clinical Pathology, one of the plaintiffs in the case, called the decision "a big deal."

"It's good for patients and patient care, it's good for science and scientists," he said. "It really opens up things."