

# US court says human genes cannot be patented (Update 4)

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A technician loads patient samples into a machine for testing at Myriad Genetics Friday, May 31, 2002, in Salt Lake City. DNA samples are moved from one tray to another by the eight-needle apparatus at left. The Supreme Court ruled Thursday, June 13, 2013 that Myriad Genetics Inc. cannot patent the BRCA genes, which are tested to check a woman's risk for breast and ovarian cancer. Mutations in these genes are what led Angelina Jolie to have both her breasts removed because she had such a high cancer risk. Some experts think the court ruling may lead to lower cost testing because there could be more competition. (AP Photo/Douglas C. Pizac)

The U.S. Supreme Court on Thursday unanimously threw out attempts to

patent human genes, siding with advocates who say the multibillion-dollar biotechnology industry should not have exclusive control over genetic information found inside the human body.

But the high court also approved for the first time the patenting of synthetic DNA, handing a victory to researchers and companies looking to come up with ways to fight—and profit—from medical breakthroughs that could reverse life-threatening diseases such as breast or ovarian cancer.

The decision "sets a fair and level playing field for open and responsible use of genetic information," said Dr. Robert B. Darnell, president and scientific director of the New York Genome Center. "At the same time, it does not preclude the opportunity for innovation in the genetic world, and should be seen as an important clarifying moment for research and the healthcare industry."

The high court's judgment, written by Justice Clarence Thomas, reverses three decades of patent awards by government officials and throws out patents held by Myriad Genetics Inc. involving a breast cancer test brought into the public eye recently by actress Angelina Jolie's revelation that she had a double mastectomy.

Jolie said she carries a defective BRCA1 gene that puts her at high risk of developing breast and ovarian cancers, and her doctor said the test that turned up the faulty gene link led Jolie to have both of her healthy breasts removed. Jolie's mother died of ovarian cancer and her maternal grandmother also had the disease.

The high court's ruling immediately prompted one of Myriad's competitors to announce it would offer the same test at a far lower price.

Justice Clarence Thomas, who wrote the court's decision, said Myriad's

assertion—that the DNA it isolated from the body for its proprietary breast and ovarian cancer tests were patentable—had to be dismissed because it violates patent rules. The court has said that laws of nature, natural phenomena and abstract ideas are not patentable.

"We hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," Thomas said.

However, the court gave Myriad a partial victory, ruling that while naturally-occurring DNA was not patentable, synthetically-created DNA, known as cDNA, can be patented "because it is not naturally occurring," as Thomas wrote.

The split decision mitigates potential damage to the multibillion-dollar biomedical and biotechnological industries in the U.S., experts said. It will affect companies like Myriad and others doing similar work, said Courtenay Brinckerhoff, a lawyer at Foley & Lardner.

"The decision is likely to have the greatest impact on diagnostic/genetic screening patents similar to those at issue in Myriad, but the ruling will impact the patent-eligibility of other newly discovered compounds that are 'isolated' from nature, such as medicinal compounds isolated from plants, beneficial proteins isolated from human or animal sources, and beneficial microorganisms isolated from soil or the deep sea," she said.

For the most part, biotech companies already have moved on from trying to patent isolated DNA, instead looking at synthetic options and other ways of protecting their multimillion-dollar investments, said Matthew McFarlane of Robins, Kaplan, Miller & Ciresi L.L.P.

"On a day-in and day-out basis, I don't see this changing that part of the industry," McFarlane said. "Isolated DNA itself is not something that

companies seek to protect anymore."

Patents are the legal protection that gives inventors the right to prevent others from making, using or selling a novel device, process or application.

The U.S. Patent and Trademark Office has been awarding patents on human genes for almost 30 years, but opponents of Myriad Genetics Inc.'s patents on the two genes linked to increased risk of breast and ovarian cancer say such protection should not be given to something that can be found inside the human body.

The company used its patents to come up with its BRCAAnalysis test, which looks for mutations on the breast cancer predisposition gene, or BRCA. Women with a faulty gene have a three to seven times greater risk of developing breast cancer and also have a higher risk of ovarian cancer.

Myriad sells the only BRCA gene test, which costs around \$3,000. Opponents said the company has used its patents to keep other researchers from working with the BRCA gene to develop other tests. The challenged patents would have expired in 2015.

"Today, the court struck down a major barrier to patient care and medical innovation," said Sandra Park, a lawyer for the American Civil Liberties Union Women's Rights Project. "Myriad did not invent the BRCA genes and should not control them. Because of this ruling, patients will have greater access to genetic testing and scientists can engage in research on these genes without fear of being sued."

American Medical Association President Dr. Jeremy A. Lazarus agreed. "Removing the patents on the building blocks of life ensures that scientific discovery and medical care based on insights into human DNA

will remain freely accessible and widely disseminated, not hidden behind a vast thicket of exclusive rights," he said.

Not long after the ruling, DNATraits, part of Gene By Gene, Ltd., said it would offer BRCA gene testing in the United States for \$995—less than a third of the current price.

Thomas noted there are still ways for Myriad to make money off its discovery. "Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent," he said. And he noted that the case before the court did not include patents on the application of knowledge about the two genes.

For its part, Myriad focused on what the ruling left intact.

"We believe the court appropriately upheld our claims on cDNA and underscored the patent eligibility of our method claims, ensuring strong intellectual property protection for our BRACAnalysis test moving forward," said Peter D. Meldrum, Myriad's president and CEO. "More than 250,000 patients rely upon our BRACAnalysis test annually, and we remain focused on saving and improving peoples' lives and lowering overall healthcare costs."

Companies had billions of dollars of investment and years of research on the line in this case. Their advocates argue that without the ability to recoup their investment through the profits that patents bring, breakthrough scientific discoveries to combat all kinds of medical maladies wouldn't happen.

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