

US supreme court rules human genes cannot be patented



Medical groups challenged patents on two genes linked to breast and ovarian cancer owned by Myriad Genetics. Photograph: Mauricio Lima/AFP/Getty Images

The [US supreme court](#) has ruled unanimously that natural human genes cannot be patented, a decision that scientists and civil rights campaigners said removed a major barrier to patient care and medical innovation.

The court on Thursday held that human DNA was a "product of nature", a basic tool of scientific and technological work, thereby placing it beyond the domain of patent protection. It struck down patents held by Myriad [Genetics](#) Inc, a Utah company, on two genes linked to a higher risk of breast and [ovarian cancer](#).

But it also said that synthetic genetic material could be patented, in a mixed ruling for the biotechnology industry, which has argued that patents are necessary to recoup the billions of dollars it spends on research.

Myriad carries out tests for BRCA genes, recently brought into the public eye when actor Angelina Jolie revealed she had a double mastectomy after learning she tested positive for one of the genes.

The ruling represents a major shift in the law, overturning three decades of patent awards by the US government and could have a profound effect on the biotechnology and drug industry.

Justice Clarence Thomas ruled that Myriad's assertion that the DNA it isolated from

the human body for its tests were patentable had to be dismissed because it violated patent rules. The court said that laws of nature, natural phenomena and abstract ideas lay outside patent protection.

"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.

He said there would be "considerable danger" that without such an exception, the granting of patent would "tie up" the use of such tools and future innovation based on them.

In a statement made after the ruling, Myriad Genetics stressed that the court had upheld its patents on complementary DNA and said that it retained "strong intellectual protection" for its BRCA test.

Peter Meldrum, president and CEO of Myriad Genetics, said: "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 BRCA-Analysis test moving forward."

Myriad said it still had more than 500 valid and enforceable claims in 24 different patents conferring strong patent protection for its BRCA test.

Nabeela Rasheed, a lawyer with McAndrews Held and Malloy, who specialises in biotechnology, said that because the case did not involve method or application claims, Myriad could still be in a reasonable position to retain a monopoly on its BRCA test. "Myriad's history is that it defends its patents" said Rasheed. "I don't see why if they have method claims why they wouldn't continue to enforce them."

Opponents had argued that patent protection should not be granted to something within the human body.

"Today, the court struck down a major barrier to patient care and medical innovation," said Sandra Park, an attorney with the ACLU Women's Rights Project, which brought the case on behalf of scientists, [cancer](#) patients and medical associations. "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."

The patents allowed Myriad to control access to the genes, known as BRCA1 and BRCA2, and gave the company the right to limit others from doing research or diagnostic testing of the genes. 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.

Opponents of the patents argued that research and diagnostic testing from others is crucial for patients making important medical decisions. They also said that the patents allowed Myriad, which sells the only BRCA gene test, to set the cost and other parameters of tests, making it difficult for women to access alternate tests or get a comprehensive second opinion about their results.

"The court rightfully found that patents cannot be awarded for something so fundamental to nature as DNA," said Daniel B Ravicher, executive director of Public Patent Foundation and co-counsel in the lawsuit.

However, Dr Penny Gilbert, a partner at UK law firm PowellGilbert and expert in life sciences, said it was a "compromise decision".

"It's not as bad as had been anticipated by the biotech industry, because it is clear you can have patents for cloned genes in certain circumstances" Gilbert said. "Modern methods of cloning genes will still be patentable."

"I'm not convinced it will have a major impact. It is hard to assess."

She pointed out that shares in Myriad Genetics went up after the ruling that blocked the patenting of human genes but allowed the patenting of synthetically created genetic material, or cDNA.

Myriad shares were up 10.3%, or \$3.48, at to \$37.40, at midday trading on Thursday.

Lisbeth Ceriani, a breast cancer survivor and plaintiff in the Myriad case, was faced with a bill of \$4,000 for a test to determine if she carried a genetic mutation associated with hereditary ovarian cancer, because Myriad had refused to enter into a contract with her insurance company. She had to wait 18 months before she was able to obtain the test through a grant, at which point she learned she did indeed carry a mutation.

"I'm relieved that no other women will have to go through what I went through," said Ceriani. "I'm so glad that the supreme court agrees that women deserve full access to vital information from their own bodies."

Myriad has argued that it needs the patents to recoup the money it has spent on isolating the genes.

Patent lawyers in the UK warned that the US supreme court ruling would deter many firms from pursuing research. Dr Gareth Williams a partner at the firm Marks & Clerk, said: "It would be an understatement to describe this ruling as disappointing news for worldwide biotech research. It represents a volte-face in the approach to intellectual property rights around genetics and its effects will be felt well beyond US borders.

"By declaring isolated forms of human DNA patent ineligible, it robs genome research companies of a huge commercial incentive to continue researching into DNA. This research is vital if we are to develop effective DNA-based treatments or diagnostics for diseases like cancer or inheritable illnesses."

Justice Thomas noted there were still ways for Myriad to make money from 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.

Jolie revealed last month that her mother died of ovarian cancer and that her maternal grandmother also had the disease. She said she carries a defective BRCA1 gene that puts her at high risk of developing breast and ovarian cancers, and that led her to decide to have both of her healthy breasts removed to try to avoid the same fate.