

## Patenting genes: Justices tackle big health issue (Update 2)

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In this June 27, 2012 file photo, an American flag flies in front of the Supreme Court in Washington. DNA may be the building blocks of life, but can something taken from it be the building blocks of a multimillion-dollar medical monopoly? The Supreme Court will grapple with that question Monday, April 15, 2013, as it delves into an issue that could reshape medical research in the United States, in the fight against diseases like breast and ovarian cancer, and the billion-dollar medical and biotechnology business: Can human genes be patented? The court's decision could have a wide-ranging effect. (AP Photo/Alex Brandon, File)

The Supreme Court seemed worried Monday about the idea of companies patenting human genes in a case that could profoundly reshape the multibillion-dollar biomedical industry and U.S. research in the fight against diseases like breast and ovarian cancer.

Justices argued not only about snipping DNA strands but also about chewing the leaves of Amazonian jungle plants, the shaping of baseball bats and the ingredients of chocolate chip cookies as they tried to figure out whether companies can gain government protection—and profits—for their work with human genes.

The ability to claim control of genetic information found inside every American could hang on the nine justices' decision later this summer, a ruling that could affect the intersection of science and the law for years to come.

"The issue here is a very difficult one," Justice Samuel Alito said.

Abstract ideas, natural phenomena and laws of nature cannot be awarded patents, 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 two genes linked to an increased risk of breast and ovarian cancer say such protection should not be given to something that can be found inside the human body.

"Finding a new use for a product of nature, if you don't change the product of nature, is not patentable," said lawyer Christopher Hansen, arguing against the patents. "If I find a new way of taking gold and making earrings out of it, that doesn't entitle me to a patent on gold. If I find a new way of using lead, it doesn't entitle me to a patent on lead."

Several organizations, including the American Civil Liberties Union, the Association for Molecular Pathology, a number of doctors and researchers and some people at risk for hereditary breast and ovarian cancer, have challenged the patents.

But Myriad argues—and the patent office and a federal appeals court have agreed—that the company's genes can be patented because the DNA that Myriad isolated from the body has a "markedly different chemical structure" from DNA within the body.

"What was 'merely snipped' out of the body here is fundamentally different in kind from what was in the body," Myriad lawyer Gregory A. Castanias said. "The most important reason it's different in kind is that it cannot be used in the body to detect the risk of breast and ovarian cancers."

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

Myriad sells the only BRCA gene test. Opponents of its patents say the company can use its patents to keep other researchers from working with the BRCA gene to develop other tests.

In such matters, companies can have billions of dollars of investment and years of research on the line. 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. That concerned several justices.

"Why shouldn't we worry that Myriad or companies like it will just say, 'Well, you know, we're not going to do this work anymore?'" Justice Elena Kagan asked.

Hansen said that a company could get recognition for its work and that money for research would always be available, a statement that Justice Anthony Kennedy said wasn't sufficient.

"I don't think we can decide the case on, 'Don't worry about investment. It'll come,'" Kennedy said.

Justices attempted to break the argument down to an everyday level by discussing things like chocolate chip cookies, baseball bats and jungle plants.

Castanias, the Myriad lawyer, argued that the justices could think about the gene question like a baseball bat. "A baseball bat doesn't exist until it's isolated from a tree. But that's still the product of human invention to decide where to begin the bat and where to end the bat," he said.

That didn't work for Chief Justice John Roberts.

"The baseball bat is quite different. You don't look at a tree and say, well, I've cut the branch here and cut it here and all of a sudden I've got a baseball bat. You have to invent it, if you will," Roberts said. "You don't have to invent the particular segment of the strand. You just have to cut it off."

The court moved on to body parts. Said Justice Sonia Sotomayor, "If you cut off a piece of the whole in the kidney or liver, you're saying that's not patentable, but you take a gene and snip off a piece, that is? What's the difference between the two?"

Castanias tried again, comparing the company's patented genes to medicine.

"It's important to note that molecules have been patented for a very long time. That's what drugs are. And drugs are often made by taking one molecule and another molecule, both of which are known, reacting them in a test tube," he said. "Reactions have been around 100 years just like snipping has been, but they make something new and useful and lifesaving from that."

Roberts still wasn't convinced. "Well, I don't understand how this is at all like that, because there you're obviously combining things and getting something new. Here you're just snipping, and you don't have anything new, you have something that is a part of something that has existed previous to your intervention," he said.

That was the ruling of the original judge who looked at Myriad's patents after they were challenged by the ACLU in 2009. U.S. District Judge Robert Sweet said he invalidated the patents because DNA's existence in an isolated form does not alter the fundamental quality of DNA as it exists in the body or the information it encodes. But the federal appeals court reversed him in 2011, saying Myriad's genes can be patented because the isolated DNA has a "markedly different chemical structure" from DNA within the body.

The Supreme Court threw out that decision and sent the case back to the lower courts for rehearing. That came after the high court unanimously threw out patents on a Prometheus Laboratories Inc. test that could help doctors set drug doses for autoimmune diseases like Crohn's disease. The justices said the laws of nature are unpatentable.

But the federal circuit upheld Myriad's patents again in August, leading to the current review.

The court will rule before the end of the summer.

The case is 12-398, Association for Molecular Pathology v. Myriad Genetics, Inc.

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