Court Says Human Genes Cannot Be Patented

Jesse J. Holland, Associated Press Writer

The Supreme Court ruled Thursday that companies cannot patent parts of naturally-occurring human genes, a decision with the potential to profoundly affect the emerging and lucrative medical and biotechnology industries.

The high court's unanimous judgment reverses three decades of patent awards by government officials. It throws out patents held by Salt Lake City-based Myriad Genetics Inc. on an increasingly popular breast cancer test brought into the public eye recently by actress Angelina Jolie's revelation that she had a double mastectomy because of one of the genes involved in this case.

Justice Clarence Thomas, who wrote the court's decision, said that 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 could be patented. The court said that synthetically created DNA, known as cDNA, can be patented "because it is not naturally occurring," Thomas said.

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 has used its patent to come up with its BRACAnalysis 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 have a higher risk of ovarian cancer.

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 her doctor said that the test that turned up the faulty gene link led Jolie to have both of her healthy breasts removed to try to avoid the same fate.

The court's ruling on synthetic DNA leaves the door open for future genetic patent work for companies like Myriad, lawyers said.

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.

Most biotech companies have already 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."

Myriad's stock price jumped 10 percent after the ruling and was above $36 a share in early afternoon trading.

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."

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

"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."

Companies have 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.

But "genes and the information they encode area not patent eligible ... simply because they have been isolated from the surrounding genetic material," Thomas said.

In a concurring opinion, Justice Antonin Scalia said "the portion of the DNA isolated from its natural state sought to be patented is identical to that portion of the DNA in its natural state."

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

Source URL (retrieved on *07/28/2014 - 3:37pm*):
http://www.mdtmag.com/news/2013/06/court-says-human-genes-cannot-be-patented?qt-video_of_the_day=0