Court: Human genes cannot be patented

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Washington (CNN) -- The Supreme Court unanimously ruled Thursday that human genes cannot be patented.

But in something of a compromise decision, all nine justices said while the naturally occurring isolated biological material itself is not patentable, a synthetic version of the gene material may be patented.

"Genes and the information they encode are not patent-eligible under [federal law] simply because they have been isolated from the surrounding genetic material," said Justice Clarence Thomas for the 9-0 court decision.

The case involves Utah-based company Myriad Genetics, which was sued over its claim of patents relating to two types of biological material that it identified -- BRCA1 and BRCA2, whose mutations are linked to increased hereditary risk for breast and ovarian cancer.

Since Myriad owns the patent on breast cancer genes, it is the only company that can perform tests for potential abnormalities.

Investors in Myriad were pleased with the ruling with the stock soaring as much as 9% before settling back. It was up more than 3% in midday trading.

Myraid had no initial reaction to the decision.

At issue is whether "products of nature" can be treated the same as "human-made" inventions, allowing them to be held as the exclusive intellectual property of individuals and companies.

The issue has deeply divided the scientific and business communities.

On one side, scientists and companies argue patents encourage medical innovation and investment that saves lives.

On the other, patient rights groups and civil libertarians counter the patent holders are "holding hostage" the diagnostic care and access of information available to high-risk patients.

Outside the court during oral arguments in April, several protesters held signs, such as "Your corporate greed is killing my friends" and "My genes are not property."

The issue gained greater public attention when actress Angelina Jolie announced last month she had undergone a double mastectomy after taking the BRCA tests from Myriad.

Court backs Obama administration position

The high court has long allowed patent protection for the creation of a new process or use for natural products. Whether "isolating" or "extracting" genes themselves qualifies for such protection became the issue.

The justices took the position offered by the Obama administration -- DNA itself is not patentable but so-called "cDNA" can be. Complementary DNA is artificially synthesized from the genetic template, and engineered to produce gene clones.

Use of this protein-isolating procedure, known as "tagging," is especially important in mapping and cataloguing the vast human genome.

The federal government had suggested Congress could create exceptions in the genetic or bio-tech testing arena, over so-called "use" patents for specific procedures.

But the justices decided that was not the case in the current dispute.

"Myriad did not create anything," said Thomas. "To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."

But Thomas said, "cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments."

The American Civil Liberties Union said the decision represents a major shift in patent law and overturns established policy.

"Today, the court struck down a major barrier to patient care and medical innovation," said Sandra Park, senior staff attorney with the ACLU 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."

Exclusivity on testing

The patent system was created more than two centuries ago with a dual purpose. One is to offer temporary financial incentives for those at the ground floor of innovative products like the combustible engine and the X-ray machine.

The second is to ensure one company does not hold a lifetime monopoly that might discourage competition and consumer affordability.

All patent submissions rely on a complex reading of applicable laws, distinguishing between abstract ideas and principles, and more tangible scientific discoveries and principles.

In the past 31 years, 20 percent of the human genome has been protected under U.S. patents.

All sides agree the science of isolating the building blocks of life is no easy task. Myriad has said it has spent several years and hundreds of millions of dollars in its research.

Since Myriad owns the patent on breast cancer genes, it was the only company that could perform tests for potential abnormalities.

An initial test catches most problems, but the company also offers a second, separate test, called BART, to detect the rest, a diagnostic that can cost several thousand dollars.

The company says 1 million patients have benefited from its "BRAC Analysis" technology, and that about 250,000 such tests are performed yearly.

And officials say the average out-of-pocket expense for the testing is only about $100, a figure disputed by the plaintiffs.

The case is Association for Molecular Pathology v. Myriad Genetics (12-398).

2009: How human genes became patented