Supreme Court rules that human genes cannot be patented; A medical breakthrough that isolates a genetic mutation does not amount to an invention meriting a patent, the US Supreme Court ruled Thursday. The decision makes it easier for researchers to engage in genetic research.

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The US Supreme Court ruled on Thursday that human genes and the information they contain cannot be patented by medical researchers, a holding that is expected to make it easier to engage in genetic research and cheaper for medical patients to obtain genetic testing.

The unanimous decision came in a case involving patents protecting genes with certain genetic mutations that scientists say can signal a higher risk of breast and ovarian cancer in women.

The genetic testing issue has been in the news recently with the disclosure that actress Angelina Jolie consented to a double mastectomy after undergoing a genetic test from the same company involved in the Supreme Court case that showed she had a high risk of ovarian and breast cancer.

In invalidating patents held by the genetic testing and research firm, Myriad Genetics, the high court said that while the company's discovery concerning the genetic mutations was an important breakthrough, it did not amount to a patentable invention.

The decision raises doubts about the validity of some 4,000 other patents currently held on human genes. But the high court noted that synthetically created complimentary DNA, also called cDNA, which is used widely in research, remains eligible for a patent because it is not naturally occurring. This was seen by analysts as tempering the potential impact of the high court's decision.

Writing for the court, Justice Clarence Thomas compared Myriad's discovery with a similar case before the Supreme Court in 1980. In that case, a scientist had found a way to induce bacteria to consume and break down crude oil through a natural process. (This was seen as an important advance, given the danger of massive oil spills.) Justice Thomas said the resulting oil-eating bacterium was new with markedly different characteristics from any found in nature.

"In this case, by contrast, Myriad did not create anything," Thomas said. "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."

Myriad uncovered the precise location and genetic sequence of the mutations that researchers associate with a higher risk of breast and ovarian cancers. But that alone did not create anything new or invent any new thing, Thomas said.
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Myriad applied for and received patents protecting its discovery. The company used the patents to force other researches to stop certain lines of scientific inquiry. The company also used its patents to prevent others from developing cheaper, more efficient ways to screen women for the identified genetic mutations.

A group of researchers and medical patients filed a lawsuit challenging the validity of Myriad's patents. On Thursday, they claimed victory.

"Today, the court struck down a major barrier to patient care and medical innovation," said Sandra Park, a lawyer with the ACLU's Women's Rights Project. "Myriad did not invent the [mutated] 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 [by Myriad]," Ms. Park said.

One of the plaintiffs in the case was Harry Ostrer, a genetic researcher and professor at the Albert Einstein College of Medicine at Yeshiva University in New York. He predicted the decision would expand access to genetic testing and reduce the cost of such testing.

"We will see a much more even playing field with regard to genetic testing going forward," he said in a teleconference with reporters. "It will drive down costs and improve quality."

Another plaintiff, breast cancer survivor Lisbeth Ceriani, said she is relieved by the ruling. "We are just glad that our genes are not being held hostage by a private corporation anymore," she said.

Ms. Ceriani faced having to pay more than $4,000 for Myriad's test to discover whether she carries the genetic mutation signaling a higher risk of ovarian cancer. She faced that cost because the company refused to enter into a contract with Ceriani's insurance company.

Ceriani had to wait 18 months to get the test after receiving a grant. The test showed she does carry the mutated gene.

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

In a statement, Myriad president and CEO Peter Meldrum focused on the portion of the ruling most favorable to Myriad.

"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 [gene mutation] test moving forward," he said.

He noted that more than 250,000 women rely on the company's cancer screening process each year. "We remain focused on saving and improving people's lives and lowering overall health-care costs," Mr. Meldrum said.

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

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