

Jolie's mastectomy spotlights legal battle over genes

May 16 2013, by Kerry Sheridan

Movie star Angelina Jolie tested positive for a "faulty gene" at the center of a high-profile legal battle in the United States that challenges whether human genes can belong to a corporation.

Experts say it is unlikely that Jolie's story of how she decided to have a preventive <u>double mastectomy</u> will sway the Supreme Court, which is expected to rule in June on whether Myriad Genetics can hold patents on the BRCA1 and BRCA2 genes.

But lawyers for the plaintiffs applauded the 37-year-old actress for mentioning that the cost of the tests is out of reach to many women.

"Her highlighting of the barriers to testing, particularly cost, is one of the issues that is at the heart of our case," said Sandra Park, one of the lead attorneys on the case from the <u>American Civil Liberties Union</u>.

The ACLU is representing patients and geneticists who challenge Myriad's right to patent the genes in question, saying the process has stalled research and made the test too expensive.

The patents allow the Utah-based company to be the sole provider of a test for the <u>rare mutations</u> that may lead to cancer.

Jolie, whose mother died of ovarian cancer, did not wade into the legal fray in her New York Times op-ed Tuesday, but mentioned that the \$3,000 cost of the genetic testing she underwent "remains an obstacle for



many women."

Jolie and about 0.2 percent of women on the planet carry a harmful BRCA genetic mutation that raises their <u>lifetime risk</u> of breast or ovarian cancer to as high as 80 percent compared to about 10 percent for women without the gene.

"The central legal question is: did Myriad invent anything here? And in our perspective, they did not," Park told AFP.

"They did add to scientific knowledge because they identified the connection between these genes and <u>breast cancer</u>. But you don't get a patent for just identifying something in nature."

Money is also a central issue to Myriad. The company says it has invested \$500 million in developing its test, called BRACAnalysis, which spokesman Ron Rogers said "offers patients the highest quality test with the fastest turnaround time."

Myriad says 95 percent of US patients have access to the test through private insurance or other coverage, making its out-of-pocket cost an average of \$100.

Myriad also insists that it has never "sought to patent genes in anyone's body."

"Rather, Myriad created synthetic molecules of DNA in the laboratory that are used to test patients for increased risk of breast cancer and <u>ovarian cancer</u>," the company said in a statement.

Myriad's lawyers have argued that the 1952 Patent Act was intended to include "anything under the sun that is made by man," meaning anything that is "a product of human ingenuity."



They also point out that Myriad is not alone—the US Patent and Trademark Office has granted nearly 3,000 patents related to isolated DNA molecules such as Myriad's.

Rogers said it was a "falsehood" that Myriad has stifled research, citing the existence of 2,000 peer-reviewed articles on BRCA1 and BRCA2, "making them the most studied genes in history."

"What we haven't allowed is commercial testing because we have patents on the commercial testing," he said.

Myriad's BRCA patents are set to expire in two years. Whatever the court's decision, Rogers said "we do not expect a material impact on our operations either way."

The case drew dozens of women's health advocates to the Supreme Court steps last month, including breast cancer survivors and "previvors," a group of women who have undergone preventive mastectomy like Jolie. Some hoisted signs that decried corporate greed.

"I think it is time for us to move past ownership of human DNA," said Andrea Downing, 32, who found out at age 25 that she carried a BRCA mutation and had a preventive double mastectomy last year.

"We need to open up research in a way that is collaborative and not competitive. That is the key to finding smarter ways to prevent cancer for women who carry this mutation."

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