

Supreme Court Invalidates Patents on Breast and Ovarian Cancer Genes

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WASHINGTON – The U.S. Supreme Court today unanimously invalidated patents on two genes associated with hereditary breast and ovarian cancer in response to a lawsuit filed by the American Civil Liberties Union and the Public Patent Foundation (PUBPAT) on behalf of researchers, genetic counselors, patients, breast cancer and women's health groups, and medical professional associations representing 150,000 geneticists, pathologists, and laboratory professionals.

The patents allowed a Utah company, Myriad Genetics, to control access to the genes, known as BRCA1 and BRCA2, thereby giving them the right to limit others from doing research or diagnostic testing of the genes, which can be crucial for individuals making important medical decisions. The patents also allowed Myriad to set the terms and cost of testing and made it difficult for women to access alternate tests or get a comprehensive second opinion about their results.

"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."

The court found that the patents on human genes are invalid, which represents a major shift in patent law and overturns current Patent Office policy. The court also found that patents on complementary DNA, or cDNA, are patent-eligible. Scientists can provide genetic testing without relying on cDNA. Thus, the court's ruling lifted the patent obstacle to offering genetic diagnostic testing.

"The court rightfully found that patents cannot be awarded for something so fundamental to nature as DNA," said Daniel B. Ravicher, executive director of PUBPAT and co-counsel in the lawsuit.

The restrictions on examining the BRCA genes can have devastating results. Kathleen Maxian of Buffalo, N.Y. is suffering from late-stage ovarian cancer that she believes could have been prevented. Her sister, who is a breast cancer survivor, obtained a test from Myriad that did not look for all known genetic mutations associated with cancer and was told she was negative for mutations. Years later, her sister learned that she did, in fact, have a BRCA genetic mutation – information that Maxian could have relied on to seek preventive surgery. Numerous labs across the country have stated that they are capable of providing this comprehensive screening and would do so were it not for Myriad's patents.

Lisbeth Ceriani, a breast cancer survivor and plaintiff in the case, was faced with having to pay over \$4,000 for Myriad's testing to determine if she carried a genetic mutation associated with hereditary ovarian cancer because Myriad had refused to enter into a contract with her insurance company. She was forced to wait 18 months before she was able to obtain the test through a grant, at which point she learned she did indeed carry a mutation.

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

A federal district court invalidated all of the challenged patents in 2010. In 2012, a federal appeals court ruled for the second time that the patents on the genes were valid. Its 2-1 decision followed a Supreme Court order directing the appeals court to reconsider its initial decision in light of a related patent case decided by the Supreme Court last spring.

For more information on this case, please visit:

aclu.org/genepatents

This press release is available at:

aclu.org/womens-rights/supreme-court-invalidates-patents-breast-and-ovarian-cancer-genes