



## **ACMG NEWS**

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## **The U.S. Supreme Court Hears Arguments Challenging Patents on Breast and Ovarian Cancer Genes: ACMG Is Plaintiff**

April 17, 2013 -Bethesda, MD | The U.S. Supreme Court heard arguments Monday in a case seeking to invalidate patents on two genes associated with hereditary breast and ovarian cancer. ACMG was one of the first plaintiffs to sign onto this historic legal case.

ACMG was also the first professional medical association to establish a position against gene patenting. In its 1999 ACMG Position Statement on Gene Patents and Accessibility of Gene Testing, which was reaffirmed in 2005, ACMG stated that: "It is the American College of Medical Genetics' position that genes and their mutations are naturally occurring substances that should not be patented."

Wayne Grody, MD, PhD, immediate past-president of the ACMG was actually in the courtroom on April 15 and he said, "While it is always dangerous to try to predict the eventual ruling of the U.S. Supreme Court from listening to an hour of oral argument, I came away from today's hearing guardedly optimistic that the Justices, or most of them, do 'get it' and may see the issue largely along the lines of ACMG's long-held policy. Though the first half of the discussion got a little bogged down in parsing the difference between particular forms of natural and extracted DNA, toward the end the focus was clearly on human gene sequences, in whatever form, as products of nature and no more patentable than any other part of the body."

The lawsuit was 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 allow a Utah company, Myriad Genetics, to control access to the genes, thereby enabling them to limit others from doing research or diagnostic testing, which can be crucial for individuals making important medical decisions.

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.

The patents granted to Myriad Genetics and the University of Utah Research Foundation give the company the exclusive right to perform diagnostic tests on the BRCA1 and BRCA2 genes and thus to control the medical care provided to hereditary breast and ovarian cancer patients and people at high risk for these diseases. Myriad's monopoly on the BRCA genes allows it to set the terms and cost of testing and makes it impossible for women to access alternate tests or get a comprehensive second opinion about their results. It also allows Myriad to prevent researchers from even looking at the genes without first getting permission from Myriad.

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The case is the first challenge brought to human gene patents in the United States. For more information on this case, please visit <http://www.aclu.org/free-speech-technology-and-liberty-womens-rights/association-molecular-pathology-v-myriad-genetics>.

### **About the ACMG**

Founded in 1991, the American College of Medical Genetics and Genomics ([www.acmg.net](http://www.acmg.net)) advances the practice of medical genetics and genomics by providing education, resources and a voice for more than 1600 biochemical, clinical, cytogenetic, medical and molecular geneticists, genetic counselors and other healthcare professionals committed to the practice of medical genetics and genomics. ACMG's activities include the development of laboratory and practice standards and guidelines, advocating for quality genetic services in healthcare and in public health, and promoting the development of methods to diagnose, treat and prevent genetic disease. ACMG's website ([www.acmg.net](http://www.acmg.net)) offers a variety of resources including Policy Statements, Practice Guidelines, Educational Resources, and a Find a Geneticist tool. The educational and public health programs of the American College of Medical Genetics and Genomics are dependent upon charitable gifts from corporations, foundations, and individuals.

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