

ANNOUNCEMENT

Supreme Court Ruling Invalidates Myriads BRCA Gene Patents

By Anna Azvolinsky, PhD¹ | June 14, 2013

¹Freelance Science Writer and *Cancer Network* Contributor. [Follow Her on Twitter](#) 

The Supreme Court announced a unanimous 9–0 decision that genes cannot be patented. After a long legal battle, the high court ruled in favor of the plaintiffs—the American Civil Liberties Union (ACLU) and the Association for Molecular Pathology (AMP)—declaring that genes are indeed products of nature and cannot be treated as inventions. The ACLU, along with scientists, clinicians, and patient advocates, had challenged the patents of Utah-based Myriad Genetics on two of the breast cancer susceptibility genes, *BRCA1* and *BRCA2*. The patents on these genes allowed Myriad to have a monopoly on *BRCA* genetic testing, which is important for women to understand their risk of breast and ovarian cancers.



The Supreme Court’s decision invalidates five patents held by Myriad Genetics on these two genes. The decision has widespread implications, including allowing lower cost access to genetic testing for diseases and other health issues.

“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, in a statement released by the ACLU. “Myriad did not invent the *BRCA* genes and should not control them.”

Several labs have already announced that they will begin to offer *BRCA* testing, some as early as today. “An open, community-wide database is already being established,” Ellen Matloff, director of cancer genetic counseling at the Yale Cancer Center and plaintiff in the case, told *Cancer Network*. “The reign is over.”

Myriad charged \$3,000 or more for its BRACAnalysis test. Less frequent genomic rearrangements in the *BRCA* genes were tested for select patients as part of a second-tier BRACAnalysis Large Rearrangement Test (BART) that costs \$600 or more and was often not covered by insurance. The new tests aim to test for all possible mutational variants in the *BRCA* genes.

“I think this will allow more comprehensive cancer genetic testing for many more patients,” said Elizabeth Swisher, MD, professor of gynecologic oncology at the University of Washington School of Medicine in Seattle. “This will also increase access to better tests, and more groups will come in to have better tests because of the competitive marketplace.”

Ambry Genetics released a statement the same day as the court ruling, saying that the *BRCA* genes will be added to the company’s next-generation sequencing panel, BreastNext, which will now include 16 genes. The comprehensive BROCA test, developed by the University of Washington, will now add the genes to its 50-gene panel. Quest Diagnostics, a large diagnostics company, also came out with a statement that said that it will offer a genetic test to identify *BRCA* gene mutations.

While the court emphasized that genes are products of nature and not patent eligible, it did make a distinction between naturally occurring genes and complementary DNA (cDNA) that can be made in the laboratory. cDNA, according to the Supreme Court, is eligible for patent protection.

Clinicians do not see this distinction as a hurdle for companies and academic institutions to provide *BRCA* testing, although there are likely to be implications for other types of patents. “The cDNA patent claims are not important to clinical care or genetic testing,” said Matloff.

Myriad says its claims around *BRCA* testing remains strong. In a statement, Myriad said that although five of its patent claims were invalidated by the ruling, the company still has more than “500 valid and enforceable claims in 24 different patents conferring strong patent protection for its BRACAnalysis test.”

Myriad spokesperson Ronald Rogers emphasized the importance of the Supreme Court upholding the cDNA patent claim.

Whether or not Myriad would pursue legal action against companies providing *BRCA* testing is not clear—Rogers would not speculate on whether this is a possibility. Myriad’s BRACAnalysis test will be used as a companion diagnostic in a phase III trial of olaparib, developed by AstraZeneca. The two companies announced the development in early June.

As laboratories begin to incorporate the *BRCA* genes into their multi-gene testing panels, Myriad has also announced a broader testing goal. The company plans to roll out a more comprehensive test called myRisk Hereditary Cancer test. The test will be a panel of 25 genes implicated in various cancers. The test will be selectively available by the end of 2013 and will fully launch in 2014. Myriad expects this panel test to replace the BRACAnalysis test by 2015.

How the Supreme Court’s distinction between a naturally occurring gene and cDNA will shape development in the biomedical industry still remains to be seen. Reactions from opponents of gene patents see the ruling as a win. “Today will go down in the history books as one of the most important days in the evolution of genetic testing and personalized medicine,” said Matloff in the ACLU blog.