

Genetics Corner



The Cause and Effect of the Supreme Court's Ruling on the Myriad Genetics Patent

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As discussed in previous articles, BRCA1 and BRCA2 gene mutations confer a significant increased risk for female breast cancer, ovarian cancer, as well as an increased risk for prostate cancer, male breast cancer, pancreatic cancer and other cancer types. Knowledge of whether an individual has a mutation is important in taking steps to reduce her/his risk of developing cancer. Until recently, Myriad Genetics' held a patent that prevented other labs from offering BRCA1/2 gene testing. This article describes the history and controversy over Myriad Genetics' patent and the impact of the recent Supreme Court's ruling against it.

A Brief History:

In 1990, Mary-Claire King, Ph.D. at University of California, Berkeley found an area on chromosome 17 that was associated with an increased risk for breast cancer. This was soon to be called the BRCA1 gene. In 1994, Mark Skolnick at Myriad Genetics partnered with researchers at the National Institute of Health and researchers at the University of Utah to discover the specific DNA sequence of the BRCA1 gene. Later that same year, the BRCA2 gene was found (on chromosome 13) by Professor Michael Stratton and Dr. Richard Wooster at the Institute of Cancer Research in the United Kingdom. Shortly after, BRCA2 was sequenced by Skolnick at Myriad Genetics and the University of Utah. Additional companies had found the BRCA 1/2 genes around the same time as Myriad Genetics, including institutions in Tokyo and Canada and other companies in the US, like OncorMed(Williams-Jones, 2002).

The Patents:

After discovering the BRCA1/2 genes, many companies and institutions tried to patent the genes. In 1994, OncorMed, the National Institute of Health(NIH) and Myriad all applied for patents for the BRCA1/2 genes and found deleterious mutations within their sequences. In 1997 and 1998 Myriad Genetics, the University of Utah, and the NIH were granted the patents on both the BRCA1 and BRCA2 genes. At the same time the US patent office granted OncorMed an overlapping patent for the BRCA1/2 genes. Myriad purchased these patents from OncorMed to prevent any other lab from having access to clinical testing. Myriad also had an agreement with the NIH and University of Utah that both institutions would be allowed to have access to the genes for research as long as they did not offer any clinical services(Williams-Jones, 2002).

Myriad Genetics' patent caused issues for many who wanted to be tested. Due to limited competition, the cost of testing was high. Also, if patients wanted a second opinion regarding their test results they were unable to do so. In addition, the patents prohibited scientists from doing further research on the BRCA1/2 genes(National Society of Genetic Counselors, 2013).

Myriad Genetics goes to Court:

The Association for Molecular Pathology filed a lawsuit against Myriad Genetics to challenge the validity of these patents. In March 2010 the U.S. District Court ruled the patent invalid(Begley, 2010). The Court of Appeals for the Federal Circuit reversed the decision in July 2011, stating that the genes were actually eligible for patents because the genes can be isolated from the rest of genetic code(New York Times, 2012). The American Civil Liberties Union (ACLU) then filed a petition to the Supreme Court which took on the case in March of 2012. The Supreme Court finally ruled on the case, *Association for Molecular Pathology v. Myriad Genetics*, on June 13, 2013 stating that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated" causing some of MyriadGenetics' patents to become invalid. However, the Supreme Court said that manipulation of the gene, such as complementary DNA(coda), is eligible for a patent(Lepta, 2013).

Competition Enters the Market:

Following the ruling by the Supreme Court two laboratories, Ambry Genetics and Gene By Gene, LTD, have begun offering BRCA1/2 testing. Myriad Genetics is now taking the two companies to court, stating that other patents that they hold regarding the BRCA1/2 genes that have not been deemed invalid (Conley, 2013).These patents cover their "methods- of-use," which includes products they have created to treat health issues and their patent on BRCA1/2 coda. Also following the ruling of the Supreme Court, the National Society of Genetic Counselors (NSGC) released a statement in support of the ruling. They say that without the patent, patients will be able to get high-quality testing for an affordable price and will allow researchers access to the genes for new discoveries and testing(National Society of Genetic Counselors, 2013).

New Directions:

In spite of Myriad Genetics' efforts to fight back, other labs have entered the BRCA1/2 testing market. Additionally, other labs have begun offering BRCA gene testing within hereditary panel tests. Gene panel testing enables clinicians to order a single test for multiple hereditary predisposition genes concurrently rather than requiring several separate tests. Although panel testing is not the best option for all patients, it may be a more cost-effective choice.

The landmark Supreme Court ruling in June, 2013 has threatened the monopoly Myriad Genetics has had over BRCA gene testing. Now that multiple labs have entered the BRCA1/2 testing market, pricing has become more competitive. Although it is unclear at this point whether labs other than Myriad Genetics will be able to continue to offer BRCA1/2 gene testing due to the pending countersuit, the recent ruling has helped to accelerate the evolution of hereditary testing.

Contact Information:

As always, if you have any questions or would like to refer a patient to UT Southwestern's cancer genetics team in Dallas or Fort Worth at the Moncrief Cancer Institute, please call (214)645-2563.

References:

- Begley, S. (2010, 3 29). In Surprise Ruling, Court Declares Two Gene Patents Invalid. *Newsweek*.
- Conley, J. (2013, July 16). Undeterred by the Supreme Court, Myriad Starts Suing. *Genomics Law Report*.
- Liptak, A. (2013, 6 14). Supreme Court Rules Human Genes May Not Be Patented. (www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html?_r=0). Last accessed September 20, 2013.
- Myriad Genetics, Inc. (<http://www.myriad.com>). Last accessed September 20, 2013.
- National Society of Genetic Counselors. (2013). NSGC Responds to Supreme Court's Decision on Gene Patents. *Press Release*.
- New York Times. (2012, August 16). Court Reaffirms Right of Myriad Genetics to Patent. *New York Times*. (www.nytimes.com/2012/08/17/business/court-reaffirms-right-of-myriad-genetics-to-patent-genes.html) Last accessed September 20, 2013.
- Williams-Jones, B. (2002). History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing. *Health Law Journal*, 10(123).