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The BRCA Gene Patent Rulings for Individualized Medicine Implications

Mark A Nelson*

Department of Pathology, University of Arizona, USA

Description

According to the National Institute of health, 12 percent of women in the general population will develop breast cancer in their lifetimes, compared to 60 percent of women who have inherited a mutation in either the BRCA1 or BRCA2 genes. In regard to ovarian cancer, 1.4 percent of women may be diagnosed in their lifetime, however the percentage rises to 15-40% women with a BRCA1 or BRCA2 mutation. Consequently, determining the BRCA1 and BRCA2 mutation status of women can markedly influence their risk of developing breast and or ovarian cancer.

Myraid Genetics identified these genes and subsequently built an estimated $300 million-a-year business testing women. Myriad holds 23 patents related to the BRAC1 and BRCA2 genes. Myriad's patent has been challenged on the basis that they discourage scientific research and development of new tests for ovarian and breast cancer and therefore threatened women's health. In fact no other company or commercial laboratory can perform the test, hence women cannot get second opinions.

The American Civil Liberties Union, Association of Molecular Pathologist, and the Public Patent Foundation filed a lawsuit against Myriad Genetics. The lawsuit, Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., charged that the challenged patents are illegal and restrict both scientific research and patients access to medical care, and that patents on human genes violate the First Amendment and patent law because genes are "products of nature."

The U.S. Patent & Trademark Office and Myriad Genetics have countered that the protections offered by patents create financial incentives for scientists and private enterprise to put in the time and effort it takes to come up with groundbreaking tests such as the BRCA screens in the first place. But for the prospects of the patent exclusively, Myriad Genetics would not have been established and been supported by investors.

Many investigators cheered last year when a federal judge ruled that human genes couldn't be patented. However a federal appeals court upheld Myriad Genetics exclusive rights to the BRCA1 and BRCA2 genes. The appeals court decided that "isolated DNA" is not the same as the natural DNA in ones body, and that this distinction allows companies to patent genes. In fact the U.S. Patent and Trade Office has been granting gene patents for decades and there are presently over 4,000 human genes that have been patented.

It is difficult for most scientists and clinicians to understand the Federal Circuits of Appeals court decision because we know that genes are part of the genome which is part of nature (recall that Mendel eloquently demonstrated that your genotype defines your phenotype). However, the Federal Circuit Court Appeals appears to have been influenced by the fact that gene-based patents have historically been important to biotech companies in their efforts to raise venture capital. Simone Rose Professor of Law at Wake Forest University suggests that the Appeals court should have upheld the lower courts invalidation of the BRCA gene patents. "If the BRCA gene patents were invalidated, Congress could then step in and legislate a new Constitutional framework of exclusive rights for this subject matter. Congress would likely gather industry, academic, and public stakeholders together to craft a hybrid statute that would promote innovation as well as provide much-need access to these basic upstream research tool- patented gene sequences." However this issue may likely be heard by the Supreme Court.

What does it all mean? The former Chair of my Pathology Department (Ronald Weinstein, MD) once told me "Always know what the rules are once you know what the rules are, you know how to proceed." With this in mind it is clear for now interrogating breast and ovarian cancer patients for BRCA gene status must occur according to our current laws. That is suspected BRCA cases must be sent to Myriad Genetics for testing.

For those who seek to patent protection for their gene discovery it will be important for the claims to include more steps than simply "analyzing" the gene and comparing the data from the sample to other known cases. Finally, as whole genome sequencing continues to become more cost-effective, it is conceivable that gene patents like BRCA genes could become unenforceable. Presently the law is not clear if sequencing an individual's whole genome (in which genes are within "natural environment") and then providing information on mutations in the BRCA gene would violate Myriad's patent on the "isolated genes".

***Corresponding author:** Mark A Nelson, Department of Pathology, University of Arizona1501 N. Campbell Avenue Tucson, Arizona, USA, Tel: 520 626 2619; Fax: 520 626 1027; E-mail: mnelson@azzc.arizona.edu

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