

CASE 11: Myriad Genetics Case

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Myriad Genetics' patents on human genes have led to intense controversy and several lengthy court battles. Some of these patents, specifically of the genes (BRCA1 and BRCA2) responsible for predicting susceptibility to certain breast and ovarian cancers, were invalidated by the Supreme Court as a result of a suit filed by the ACLU and the Public Patent Foundation (PUBPAT). The suit was filed on the grounds that genes, as products of nature, cannot be patented and because of the excessive limitations such patents create for crucial biomedical procedures and research worldwide.

In response to the Supreme Court's decision, Sandra Park, senior staff attorney with the ACLU Women's Rights Project said, "Today, the court struck down a major barrier to patient care and medical innovation." She added, "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."⁴ The ACLU claims that the patents not only allowed Myriad Genetics to limit the scope of research on these genes and to limit patient access to diagnostic testing, but that the company was also able to control the pricing and the terms of testing performed by other companies and research institutions. Lisbeth Ceriani, a breast cancer survivor and plaintiff in the case, wanted to discover if she carried a genetic mutation associated with hereditary ovarian cancer, and she was charged \$4,000 for diagnostic testing by Myriad because the company had refused to enter into a contract with her insurance provider. Instead Ceriani had to wait an agonizing 18 months for a grant to go through with Myriad; she eventually learned that she does 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."

Some argue that granting these patents to Myriad was preposterous to begin with given that the studies revealing the relevance of these genes to breast cancer were funded by the public. However, Myriad claims that they, along with other pharmaceutical, biotechnology, and diagnostic companies, "invest the hundreds of millions of dollars and decades of time to develop ground-breaking medicines and diagnostics that have saved and enhanced countless lives."⁵ It is these patents, they argue, that provide incentive for such large investments of time and money. Furthermore, Myriad argues that they aren't patenting products of nature, rather they are patenting *copies* of parts of human DNA. Their researchers produce "man-made copies" of the particular isolated segments of the gene that provide "instructions for making proteins (only about 2% of the total DNA in your body)." Their researchers produce these "man-made copies, called 'isolated DNA,'" which are "unique chemical compositions not found in nature or the human body."

⁴ "Supreme Court Invalidates Patents on Breast and Ovarian Cancer Genes," ACLU, June 13, 2013. <<https://www.aclu.org/womens-rights/supreme-court-invalidates-patents-breast-and-ovarian-cancer-genes>>

⁵ "Common Myths and Facts About Gene Patents," Myriad.com, Accessed December 8, 2013. <<https://www.myriad.com/common-myths-about-gene-patents/>>

Because Myriad has so many patents on their discoveries related to the BRCA genes, they are still able to sue companies who provide diagnostic testing for breast and ovarian cancer. While many universities and hospitals have offered testing for a much lower cost, Myriad has forced them to stop, seemingly leading to stark increases in cost for patients.

Myriad maintains, however, that their patents do not actually drive up the price of testing. This, they claim, is one of the many myths about their gene patents. Their website provides this proof in defense of the claim:

The Health and Human Services SACGHS' Committee released its report on gene patents clearly stating: "The per-unit price of the full-sequenced BRAC test, which often is cited as being priced very high, was actually quite comparable to the price of full- sequence tests done on colon cancer for which associated patents are non-exclusively licensed." Additionally, the total average out-of-pocket cost for patients taking a Myriad test is less than \$100.

The low cost, they claim is the result of testing they've done that has allowed for this sort of procedure to be covered by insurance companies. Myriad states that "approximately 95% of all appropriate patients have access to breast cancer susceptibility testing through private insurance, Medicare, Medicaid or Myriad's Financial Assistance Program." In addition, they have a Financial Assistance Program which tests "low-income, uninsured patients at no charge and [has] provided free testing to over 5,000 patients just in the past 3 years."

As Myriad continues to sue those in violation of their patents, many companies are counter-suing and at least one has filed a pre-emptive lawsuit against the company, alleging the company holds an illegitimate monopoly on BRCA testing.

Questions:

1. Myriad provides an economic justification for holding these patents, arguing they are necessary to incentivize research. But are there moral concerns associated with holding these patents that suggest all patents of this kind should be invalidated?
2. Are there ethical concerns raised by Myriads' patents if they are patents of only "man-made copies" of portions of human DNA as opposed to full sequences of human DNA?
3. Myriad doesn't acknowledge any problems associated with their holding exclusive patents related to these genes, but despite their stance are there moral problems that the company should be addressing?

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<http://nubc2014.files.wordpress.com/2014/01/bb-case-packet-20141.pdf>