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In June of 2013, the United States Supreme Court ruled 9-0 in favor of the American Civil Liberties Union (ACLU) and others in a case arguing against the patentability of human genes. Critics of gene patenting had long suggested that instead of promoting innovation, human gene patents posed a significant roadblock to the development of important diagnostics and therapeutics, and had a negative impact on public health. Myriad Genetics, Inc., the opposing party, argued that the patenting of human genes encouraged researchers and scientists to try to find alternate paths to reach end goals. However, Myriad Genetics strictly defended patents on breast and ovarian cancer-causing BRCA genes not only stymied research by other institutions, but constituted a monopoly on testing methods. Furthermore, ethical questions were raised over ownership of human genes, and whether public money could be used to fund private business interests. Through an examination of the case against Myriad Genetics and their patents on BRCA genes, this article takes a look at the important questions of who owns our genes, and whether our genes should be owned.

Overly stringent enforcement of patents threatens not only the development of vital diagnostics and therapeutics, but raises ethical questions regarding ownership of human genes.

Are human genes patentable? This was the question brought before the United States Supreme Court in 2013 by the American Civil Liberties Union (ACLU) in the landmark case *Association for Molecular Pathology (AMP) v. Myriad Genetics, Inc.* In it, the ACLU, with AMP and a broad coalition of patients and medical experts, argued that the patenting of human genes significantly hinders research and development of diagnostics and therapeutics. Additionally, they argued that the patenting of human genes not only negatively impacts patients' rights, but violates laws preventing the patenting of materials that occur in nature (Simoncelli & Park, 2015). Following the Supreme Court's ruling in *Diamond v. Chakrabarty* in 1980, which had allowed for the patenting of a genetically modified bacterium,

As an undergrad in the philosophy department with a strong interest in ethics, I believe it is important to examine how new technologies are shaping both how we view ourselves, and how we view the world around us. When I began writing this article for my junior seminar honors class, I had limited experience with GMOs. However, as my research progressed, I became fascinated by the arguments both for and against patenting human genes. My advisor Dr. Zoia Stoytcheva was enormously helpful in navigating this complex and challenging subject.

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the United States Patent and Trademark Office (USPTO) had issued more than 50,000 patents related to genes, DNA fragments, oligonucleotides, and many others (Printz, 2009; Williams-Jones, 2002). With the Supreme Court's 9-0 ruling in favor of AMP, the doors that had once been opened to the patenting of human genes had finally closed.

The *AMP v. Myriad* case was significant for a number of reasons, and touches upon a number of important issues that are still of concern today. Science is cumulative, collaborative, and concurrent. Researchers worldwide frequently work on projects with a shared base or end goal. However, once a patent is granted, patent owners can prevent any and all licensing or overlap, such as with Myriad Genetics patents on the BRCA1 and BRCA2 genes. In 1994, the BRCA genes were discovered by Mark Skolnick and researchers at Myriad in conjunction with colleagues from University of Utah, McGill University, and the National Institutes of Health (NIH). Both genes had been strongly linked to hereditary breast cancer (Williams-Jones, 2002). This was a significant breakthrough that helped to determine whether women were at risk for certain types of breast and ovarian cancers. However, by 2000, Myriad's strict enforcement of their patents and testing methods had garnered condemnation from health organizations, research institutions, and patient advocacy groups worldwide. Following a defensive patent of BRCA2 filed by the charity Cancer Research UK, Myriad's refusal to license their patent was again criticized for being antithetical to the results of the Human Genome Project as the "common heritage of mankind" (Caulfield, Bubela, & Murdoch, 2007). Furthermore, the ethical and legal issues surrounding the commercialization of BRCA1 and BRCA2 testing, along with Myriad's vigorous enforcement of their patents, brought to the foreground questions of whether an isolated gene qualifies as something that occurs in nature, and is therefore unpatentable.

When the BRCA genes were discovered, the research was funded in part by pharmaceutical company Eli Lilly, in addition to a $5 million grant by the NIH to look specifically for BRCA1 (Williams-Jones, 2002). Once the patents had been granted, Myriad only permitted testing for the genes through their own labs, at $3000 or more per test. Any competition was met with immediate cease-and-desist letters or litigation (Caulfield et al, 2007; Holman, 2008; Printz, 2009). This raised significant ethical concerns regarding the use of public money to fund private commercial interests, and ethical questions about whether Myriad was working contrary to the public's health and welfare. Furthermore, Myriad's monopoly on testing and their refusal to share results allowed them to carry on for years using an incomplete test. By 2001, the Curie Institute in France had found other cancer-causing arrangements in the BRCA genes not covered by Myriad's testing. Due to a lack of competition, Myriad had no incentive to improve the quality and comprehensiveness of their testing methods (Printz, 2009; Simoncelli & Park, 2015).

Finally, and perhaps most importantly, concerns over Myriad's patents raised questions about whether human genes, even in isolation, should be patentable. At the time of *AMP v. Myriad*, there had been few studies on how gene patents had impacted innovation and patient rights (Merz & Cho, 2005). Even more troubling, when the ACLU team began building their case against Myriad, the attitudes of the many legal and biotechnology experts they consulted were pessimistic. The USPTO had been issuing patents on genes for more than twenty years, and courts typically ruled in favor of patent holders (Simoncelli & Park, 2015). However, in the District Court ruling on *AMP, et al v. USPTO, et al,* Judge Robert W. Sweet agreed with the ACLU that "genes, products of nature, fall outside the realm of things that can be patented. The patents . . . stifle research and innovation and limit testing options" (Schwartz & Pollack, 2010). When Myriad appealed and argued their position again, this time before the Supreme Court, again the court ruled in favor of the ACLU and others. An answer had finally been reached: human genes, even in isolation, are a material occurring in nature and are therefore not patentable.

The ruling in favor of the ACLU was undoubtedly a significant victory for researchers and patients in the US and worldwide. However, the concerns raised by the Myriad case are still prevalent. Aggressive enforcement of patent rights over biological materials and testing methods can be harmful to scientific inquiry and patient care. They can also result in monopolies such as with Myriad's test for the BRCA genes. Additionally, they can delay important findings and the development of new methods of testing and treatment. Moving forward, it may become necessary to consider legislative reform to prevent unfair advantage taken by profit-centered institutions. But for the time being, at least we know our genes are safe.

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