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Analysis of Association for Molecular Pathology V. Myriad Genetic

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ABSTRACT

Genetics is a crucial component of the Court's recent series of patent eligibility rulings, which also include Bilski v. Kappos, Mayo v. Prometheus, and Alice v. CLS Bank. These decisions have had a profound impact on the interpretation of patent eligibility under Section 101 of the Patent Act, garnering both praise and criticism. However, the Myriad case extended beyond its influence on Section 101 jurisprudence. It was perceived and litigated as a case that had implications for patient rights, healthcare access, scientific freedom, and human dignity. In this article, a detailed textual analysis of the Myriad decision is provided, addressing both its detractors and supporters. Furthermore, Myriad is contextualized within the broader landscape of biotechnology patenting, the commercialization of academic research, and the U.S. healthcare system. It is noted that the failure of public institutions and government agencies to regulate the private exploitation of publicly-funded innovations played a significant role in the healthcare access disparities highlighted by the case, in addition to the overly broad protection granted by the Patent and Trademark Office to genetic inventions. The article concludes by highlighting how cases such as Myriad exemplify the evolution of common law, especially in domains characterized by swift technological progress.

Since James Watson and Francis Crick unveiled the double-helix structure of DNA in 1953, genetic research has played a crucial role in advancing medical science, aiding in the understanding and combat of diseases. This research has also ignited a competitive race to publish, patent, and capitalize on discoveries in the limited arenas of time and resources, where scientific breakthroughs can make or break companies. In the case of Association for Molecular Pathology v. Myriad Genetics, Inc., the United States Supreme Court found itself in the fast-evolving realm of science, tasked with determining the patentability of research findings under federal law and the potential control over their future use.

During the early 1990s, extensive international research focused on the genetic underpinnings of breast cancer. In 1990, a research group at the University of California at Berkeley identified a gene on chromosome 17, known as BRCA1, which marked a significant link between specific genetic variations and breast cancer. The subsequent year, a team of researchers from the University of Utah's Center for Genetic Epidemiology, backed by pharmaceutical company Eli Lilly, established Myriad Genetics, a biotechnology firm. Myriad sequenced BRCA1 in 1994, obtaining patents covering the gene sequence, over 40 BRCA1 mutations or variations, and numerous diagnostic tests and methods for identifying gene mutations. Myriad also created a synthetic form of BRCA1, called cDNA, which contained only the functional segments of the gene essential for mRNA production in protein synthesis. Over the following four years, Myriad raced against a scientific group in the United Kingdom to sequence another breast cancer-related gene, BRCA2, eventually filing patents for its sequence, mutations, and diagnostic tests based on the gene.

The significance of this work cannot be overstated. While the average risk of breast cancer for an American woman is around 12 to 13 percent, those with genetic mutations like those found in BRCA1 and BRCA2 face dramatically elevated risks, ranging from 50 to 80 percent for breast cancer and 20 to 50 percent for ovarian cancer. Myriad, having secured patents on these genes, their mutations, and diagnostic tests, sought to leverage its competitive advantage through the sale of tests related to these genes and their mutations. The company sent cease-and-desist letters to researchers involved in gene isolation and filed patent infringement suits against parties engaged in BRCA testing. After years of turbulent relationships with the scientific community, healthcare organizations, physicians, patient advocacy groups, and individual patients, a lawsuit was filed against Myriad in 2010, challenging its patents on BRCA1, BRCA2, and other patents stemming from these two genes.

On May 12, 2009, several research groups and doctors filed claims in the Southern District of New York, alleging that Myriad's BRCA1, BRCA2, and cDNA patents were invalid under 35 USC section 101. The district court ruled in favor of the petitioners, declaring all three patents invalid under section 101 because the DNA segments were not significantly different from nature. However, Myriad appealed the decision, and the federal circuit court reversed it. After the reversal, the petitioners appealed to the US Supreme Court, which vacated the decision and sent the case back to the federal circuit court to be decided in light of Mayo Collaborative Services v. Prometheus Laboratories, Inc., which had established that items or processes are not patentable unless they are inventive or do not exist without artificial modification.

The federal circuit court issued a new opinion, with two of three judges concluding that isolated DNA segments could be patented. Judge Alan Lourie reasoned that the isolation process involved altering DNA segments significantly, technically creating molecules that did not naturally occur. Judge Kimberly Moore also held that the BRCA1 and BRCA2 patents should stand due to Myriad's reliance on patent approval for profit and business development. Although Judge Bryson disagreed on the patent eligibility of isolated DNA segments, all three judges concluded that cDNA was eligible for patenting because it was created, not merely isolated, in a laboratory.

The decision upheld Myriad's patents, but the petitioners made a final move by asking the US Supreme Court to address the legal question of whether human genes are patentable. The central issue revolved around the court's interpretation of the Patent Act and previous precedents. The Supreme Court's unanimous answer was a resounding "no."

Justice Clarence Thomas, writing for the court, explained that while Section 101 of the Patent Act applies to inventors of new and useful compositions of matter or improvements thereof, the court had long held that laws of nature, natural phenomena, and abstract ideas lie beyond the domain of patent protection. Patents are meant to encourage innovation and protect ideas, but elements of nature are considered free to all and reserved exclusively to none.

Both Myriad and the opposing parties agreed on a crucial point: Myriad did not create or alter the genetic information within BRCA1 and BRCA2. Myriad's role was to locate and sequence these genes within their respective chromosomes. To determine whether such a discovery could be patented, the court examined two prior cases.

In Diamond v. Chakrabarty, the court addressed the addition of plasmids to a bacterium, making it capable of breaking down components of crude oil. The court deemed the modified bacterium patentable because the addition of plasmids transformed it into something new, with markedly different characteristics than any naturally occurring bacterium. However, the court cautioned that groundbreaking discoveries do not, by themselves, satisfy the "law of nature" exception under Section 101. In the case of Funk Brothers Seed

Co. v. Kalo Inoculant Co., a patent was sought for a mixture of naturally occurring bacteria strains that helped plants extract nitrogen from the air and fix it in the soil. The court rejected the patent because the bacteria were unaltered and fell within the law of nature exception.

The Supreme Court recognized the significance of Myriad's work on the BRCA1 and BRCA2 genes, noting that while these genes held substantial importance for researchers and clinicians working on breast and ovarian cancers, isolating these genes from their surrounding genetic material did not constitute an act of invention. Discovery alone did not make the BRCA genes eligible for patents. Justice Thomas even pointed to Myriad's own patent descriptions, which explained the process of locating and sequencing the genes but failed to mention changes to the genes' chemical structure or the creation of a unique molecule justifying patent eligibility.

The only product before the court deemed patent-worthy was cDNA, a synthetically created DNA containing the same protein-coding information as natural DNA but omitting non-coding portions. The justices concluded that creating cDNA constituted something new, distinct from a product of nature, even though its nucleotide sequence was similar to that of DNA.

The US Supreme Court's decision in Myriad Genetics is a pivotal ruling in a rapidly changing scientific landscape. It helps distinguish between discoveries found in their natural state and those resulting from human innovation and creation. This decision provides clarity for those working at the forefront of genetics and medicine, guiding them on which ideas can be celebrated for their public benefit and which can be pursued for private gain.

In conclusion, the case of the Association for Molecular Pathology v. Myriad Genetics was a landmark decision that clarified the boundaries of patent eligibility for genes and DNA sequences. The United States Supreme Court's unanimous ruling held that naturally occurring DNA segments, such as the BRCA1 and BRCA2 genes associated with breast and ovarian cancers, are not eligible for patents because they are products of nature. The court's decision emphasized that mere discovery and isolation of genes do not constitute acts of invention.

However, the court did recognize the patent eligibility of cDNA, a synthetic form of DNA that omits non-coding portions found in natural DNA. The justices determined that the creation of cDNA in a laboratory represented a genuinely innovative and patentable process. This decision had significant implications for the biotechnology and genetics industries, as it limited the ability to patent naturally occurring genetic sequences while preserving the potential for patents on synthetic DNA and other truly inventive discoveries.

In the broader context, the case highlighted the intersection of science, law, and ethics. It underscored the need to strike a balance between fostering innovation and ensuring that fundamental elements of nature remain accessible for further scientific exploration and public benefit. The ruling in this case set a precedent for future patent cases involving genetic and biotechnological innovations and offered guidance on the patentability of products derived from natural genetic material.

Keywords: Myriad Genetics, BRCA1 and BRCA2 genes, Patent eligibility, DNA patenting, cDNA, Gene patents, Natural DNA, Synthetic DNA, Gene sequencing.