Ass'n for Molecular Pathology v. Myriad Genetics
133 S. Ct. 2107 (2013)

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BACKGROUND

Myriad Genetics, Inc. ("Myriad") is a molecular diagnostic company based in Salt Lake City, Utah. Myriad provides a number of exclusive technologies to medical facilities for evaluating patient susceptibility to certain diseases and tracking the progression of those diseases. Myriad frequently utilizes genetic material in both research and practice. Between 1995 and 1996, Myriad filed several patents for certain naturally occurring sequences of human deoxyribonucleic acid ("DNA") and synthetic sequences of complementary DNA ("cDNA").[1] Myriad discovered that the specific sequences, named BRCA1 and BRCA2 (collectively "BRCA1/2"), are useful in identifying an individual's predisposition to breast and ovarian cancers.

Certain DNA sequences code for the creation of specific amino acids, which, in turn, are used to build proteins within the body that serve particular functions. These coding portions are known as exons while the non-coding portions are referred to as introns. Messenger ribonucleic acid ("mRNA"), the naturally-created inverse image of the exon-only strand of DNA, is produced through a process called transcription and translation. The cDNA sequences are produced through a process that simultaneously creates an inverse image of the mRNA sequence, resulting in a replica of the exon-only DNA sequence. Although cDNA has been found to be naturally occurring in the human body,[2] such occurrences are rare, with the majority of cDNA recreated in a laboratory through "well understood" and "fairly uniform" manual processes.[3]

After Myriad's patents were granted in 1998, Myriad maintained an effective monopoly over the utilization of the BRCA1/2 genes and any testing associated with the genes.[4] Research facilities, laboratories, hospitals, doctors, and patients were required to send any genetic material

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1. *See* U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,837, 492 (filed Apr. 29, 1996).

2. These sometimes random, naturally occurring cDNA-like sequences are called pseudogenes. Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2119 n.8 (2013).

3. *Id.* at 2119.

4. *See id.* at 2114. Myriad successfully prevented the University of Pennsylvania's Genetic Diagnostic Laboratory ("GDL") from offering BRCA1 and BRCA2 tests to its patients by sending cease and desist letters to GDL claiming patent infringement. *Id.*

to Myriad's Utah labs if they wanted to uncover a predisposition to breast or ovarian cancers using either of the patented gene sequences. This allowed Myriad to charge a premium on the tests and prevented patients from obtaining a second opinion.

In May of 2009, the Association for Molecular Pathology and various other medical associations, advocacy groups, educational institutions, doctors, and patients (collectively "AMP") brought an action in the United States District Court for the Southern District of New York alleging violations under: (1) Section 101 of the Patent Act;[5] (2) Article I, Section 8, Clause 8 of the United States Constitution; and (3) the First and Fourteenth Amendments to the Constitution.[6] AMP specifically sought a declaration that Myriad's claims to the composition of the DNA, including the cDNA, were products of nature and thus unpatentable under 35 U.S.C. § 101. The district court found that neither the isolation of the DNA forms nor the claimed comparison process used to isolate them were patentable subject matter.[7]

The United States Court of Appeals for the Federal Circuit reversed the district court's ruling.[8] The central dispute among the three-judge panel was whether separating the sequence of nucleotides from the rest of the chromosome was manipulative of the genetic material enough to entitle Myriad to a patent on the BRCA1/2 DNA and cDNA sequences.

Judges Lourie and Moore agreed that the isolated DNA was patentable material but disagreed on the rationale. Judge Lourie found that because a DNA molecule, in its natural state, is held together at both ends by covalent bonds, the breaking of those bonds creates "new molecules with unique chemical compounds."[9] Judge Lourie found this chemical alteration to be dispositive despite the lack of any change to the information-transmitting quality of the DNA. Judge Moore concurred with Judge Lourie but also based her ruling in part on her desire not to disrupt the U.S. Patent & Trademark Office's practice of granting patents on genetic material. Moore highlighted the impact that an alternative ruling would have on investment in similar patents and the biotech industry in general.

Judge Bryson dissented, arguing that the isolated DNA strands are products of nature and thus ineligible for patent protection. Judge Bryson emphasized that "[t]here is no magic to a chemical bond that requires [the court] to recognize a new product when a chemical bond is created or

5. 35 U.S.C. § 101 (2012).

6. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

7. *Id.* at 185. The court required the DNA be transformed from that found in nature to be considered patentable subject matter. *Id.* In addition, the court found that the claimed process of comparing the BRCA1/2 gene sequences to other gene sequences was an "abstract mental process" and thus could not be patented. *Id.*

8. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012).

9. *Id.* at 1328.

broken."[10]

ISSUE

The Supreme Court addressed whether any of Myriad's patents for isolated naturally occurring gene sequences and lab-created gene sequences comprise of new and useful compositions of matter, or instead represent only naturally occurring unpatentable phenomena.

DECISION

The Court found that Myriad's identification of the BRCA1/2 genes constituted mere discovery and therefore could not be considered any new composition of matter eligible for patent protection under 35 U.S.C. § 101. The Court took a different approach towards the cDNA, however, highlighting the fact that the majority of cDNA is something new that is created in a lab by a technician. The Court stated that although the cDNA retains the naturally occurring exons of DNA, it differs from the original DNA from which it is derived. Thus, the Court held that the cDNA was not merely a product of nature and therefore was eligible for patent protection.

REASONING

The Court began its analysis by examining the language of § 101, which provides for patent eligibility of any "new and useful . . . composition of matter, or any new and useful improvement thereof."[11] Laws of nature, natural phenomena, and abstract ideas have long been excluded from this classification because they are often "basic tools of scientific and technological work."[12] The rationale behind this natural law exception evolves from a fear that an exclusive right to such tools would ultimately inhibit future advancement and be at odds with the very point of patent protection: to promote innovation. The exclusion balances incentivizing innovation against the flow of information that might permit other inventions. Notably, too broad of an interpretation of the natural law exception might eviscerate patent protection altogether. Walking this fine line, the Court analyzed Myriad's claims for the BRCA1/2 genes.

First, the Court acknowledged that there was no dispute that the BRCA1/2 genes contained information identical to that found in natural DNA sequences. Turning to its holding in *Diamond v. Chakrabarty*,[13] the Court highlighted the general rule that in order for naturally occurring entities, such as bacterium or genes, to be patent eligible, the claim language must identify the manufacture of a composition of nature as having a distinct name, character, and use.

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10. *Id.* at 1351 (Bryson, J., dissenting).
11. 35 U.S.C. § 101 (2012).
12. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1301 (2012).
13. 447 U.S. 303 (1980).

In *Chakrabarty*, the Court held that modified bacterium were patentable subject matter.[14] There, the bacterium had been given the capacity to degrade crude oil through the addition of extra plasmids. This remarkable ability was not one found in nature at that time. Relying on *Chakrabarty* precedent, the Court distinguished the BRCA1/2 genes as not constituting any creation or alteration of material. Rather, the Court found Myriad had merely discovered an association of specific information that had a new application as a method of testing for certain types of cancers.

The Court next turned to *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[15] to find further support for its decision. In *Funk Brothers*, the Court held that the discovery of an inoculant combining several nitrogen-fixing bacteria was not patentable subject matter because the bacteria had merely been combined and not manipulated in any way. The Court analogized Myraid's claims to those found in *Funk Brothers*, noting that Myriad's disputed organic material did not contain markedly different characteristics from any found in nature. In fact, the BRCA1/2 genes were identical to those found in nature. The Court likened the BRCA1/2 genes to the combination of naturally occurring bacteria in *Funk Brothers* and not the newly created bacterium in *Chakrabarty*. Although not expressly recognized, the Court relied on an underlying assumption to reconcile *Funk Brothers* and *Chakrabarty*: while the nitrogen-fixing bacterium in *Funk Brothers* could be found in nature, the bacterium in *Chakrabarty* could not.

Next, the Court analyzed Myriad's claim language, which highlighted Myriad's extensive research process. The Court found that Myriad's explanation of the processes and procedures that led to the discovery of the BRCA1/2 genes did not identify any changes to the DNA information itself but instead merely detailed the iterative process by which Myriad narrowed the location of the BRCA1/2 identifiers. As stated by the Court, "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."[16] The Court further found that because the claims discussed informational material, rather than chemical or molecular compositions, the mere severance of the chemical bonds that hold the DNA sequences together did not constitute sufficient manipulation to grant patent eligibility. It is unclear whether the Court would have found differently had Myriad claimed the specific chemical composition of the DNA sequence after isolation rather than simply the informational material.

In addressing the last of Myriad's arguments for protection of the BRCA1/2 genes, the Court disagreed with Myriad that the U.S. Patent and Trademark Office's practice of awarding gene patents should be given any deference with regards to human gene sequences. Although Myriad cited to *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*[17] to support its argument, the Court distinguished *J.E.M.* by noting that the patents granted

14. *Id.* at 310.
15. 333 U.S. 127 (1948).
16. Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2117 (2013).
17. 534 U.S. 124 (2001)

in *J.E.M.* were utility patents for new plant breeds, not human genes. Furthermore, the Court found Myriad's argument that Congress supported the granting of human gene patents lacked merit. Taking into account its rather brief analysis of the various and scientifically complex issues, the Court found that the BRCA1/2 genes were not patentable subject matter, and thus Myriad's challenged claims were held invalid.

With regards to the cDNA, the Court took a much different view. Since the cDNA was primarily created synthetically through a process that took natural mRNA and created inverse copies to result in exon only molecules, the cDNA was not found to be a naturally occurring material. The Court highlighted, and the Petitioners conceded, that in cDNA molecules, the non-coding regions, or introns, had been entirely removed. However, the Petitioners argued that although the introns in the cDNA had been removed, this process was purely a natural process. The Court stated that even if this were true, the lab technician "unquestionably creates something new" when cDNA is made.[18] Since the cDNA is distinct from the DNA from which it is derived, the Court did not consider it to be a product of nature. Thus, the Court found cDNA to be patent eligible under § 101. The Court closed with the caveat that where DNA sequences were short enough to only contain exons prior to separation, they would not be a synthetic creation and thus not entitled to protection. This caveat did not apply to the BRCA1/2 genes.

18. *Myriad*, 133 S. Ct. at 2119.