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NATURE OR NURTURE?

MYRIAD DECODED FOR NON-BIOCHEMISTS

Gene patents became unstable with a clearly worded U.S. Supreme Court decision: “We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.”¹ With this declaration in *Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad)*, the Supreme Court charted the future both for an industry and for the law of patent-eligible subject matter.

Whether your practice is related to genetic research, familiarity with *Myriad* will be critical to your complete understanding of this fundamental patent law concept.

The Statute

Under 35 U.S.C. § 101, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent . . .” An important exception provides that, “[L]aws of nature, natural phenomena, and abstract ideas, are not patentable.”²

Scientific Background

The science underlying *Myriad*, though complex, was largely undisputed. The district court,³ Federal Circuit⁴ and Supreme Court⁵ all outlined the relevant scientific principles. Like Justice Antonin Scalia, you may be “unable to affirm these details on my own information or even my own belief,”⁶ but they provide helpful context for understanding the Court’s decision.

- Genes form the basis for hereditary traits in living organisms.⁷ Each gene is responsible for a single trait such as skin tone, eye color and gender.⁸ The human genome⁹ contains approximately 25,000 genes.¹⁰ Information regarding the creation of a protein, the basic building block of the human body, is encoded in a gene.¹¹
- A gene is composed of several segments of DNA. DNA is a chemical molecule composed of repeating chemical units known as “nucleotides.” Each gene is typically thousands of nucleotides long. The specific linear order of DNA nucleotides is referred to as the “DNA sequence”

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1 *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398, 2013 WL 2631062, *10 (U.S. June 13, 2013) (“*Myriad*”).

2 *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, ___ U.S. ___, 132 S. Ct. 1289, 1293 (2012) (citing *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

3 *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F. Supp. 2d 181, 192-200 (S.D.N.Y. 2010).

4 *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1310-14 (Fed. Cir. 2012).

5 *Myriad*, 2013 WL 2631062, at *2-3.

6 *Id.* at *11.

7 *Id.* at *2; *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 194.

8 *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 194.

9 Genome is defined as “the totality of genetic information belonging to a cell or an organism.” *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 194 n.6 (citation omitted).

10 *Id.* at 194.

11 *Id.* at 193, 194 (a gene “encodes” one or more proteins).

Myriad sought and obtained patents using composition and method claims based on the location and sequencing of the BRCA1/2 genes. Ultimately, nine composition claims from three patents were at issue in Myriad. Those claims, if held valid, gave Myriad the exclusive right to (1) isolate an individual's BRCA1/2 genes, and (2) synthetically create BRCA cDNA.

or the "gene sequence." The gene sequence is determined by nature, although scientists may use inventive steps to extract and read that sequence.¹²

- DNA, known by its familiar "double-helix" configuration, is packaged in complex structures known as chromosomes which are located in the human body's cells.¹³ Genes may be extracted from the cell using well-established laboratory techniques.¹⁴
- Information encoded in a gene is transmitted through a molecule called RNA in two steps known as transcription and translation.¹⁵ Genetic information transmitted through RNA is used to direct the creation of strings of amino acids which, in turn, are used by the body to build proteins.¹⁶
- Variations in the human genome are known as mutations.¹⁷ Some mutations can cause disease or increase disease risk.¹⁸ The correlation between a particular mutation and disease susceptibility is not evident from the mutation itself, so it must be established through extensive statistical analysis.¹⁹
- DNA may be synthesized in a laboratory through processes well known in the field of genetics.²⁰ Synthetic DNA is known as complementary DNA (cDNA).²¹

Factual Background

After lengthy and expensive research, defendant Myriad Genetics, Inc. (Myriad) discovered the precise location and sequence of the BRCA1 and BRCA2 genes on human chromosomes 17 and 13.²² Mutations in the BRCA1/2 genes correlate with a substantially increased risk of breast and ovarian cancer. Thus, the existence of BRCA1/2 gene mutations can become an important consideration when determining and providing clinical care.²³

Myriad sought and obtained patents using composition and method claims based on the location and sequencing of the BRCA1/2 genes. Ultimately, nine composition claims from three patents were at issue in *Myriad*.²⁴ Those claims, if held valid, gave Myriad the exclusive right to (1) isolate an individual's BRCA1/2 genes, and (2) synthetically create BRCA cDNA.²⁵

Myriad developed and marketed medical tests to detect the presence of mutations in a patient's BRCA1/2 genes.²⁶ When competitors offered BRCA testing, Myriad asserted that they infringed its patents. In response, the competitors stopped testing, and Myriad solidified its position as the sole entity providing BRCA testing.²⁷

Procedural Background

District Court -- In 2009, multiple plaintiffs, including medical organizations, researchers, genetic counselors, and patients,²⁸ filed suit against the U.S. Patent and Trademark Office (PTO), Myriad and others alleging violations of 35 U.S.C. § 101, and Article I, Section 8, Clause 8 and the First and

¹² *Id.*

¹³ *Id.* at 195.

¹⁴ *Myriad*, 2013 WL 2631062, at *3; *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 194.

¹⁵ *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 193.

¹⁶ *Myriad*, 2013 WL 2631062, at *2.

¹⁷ *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 195.

¹⁸ *Myriad*, 2013 WL 2631062, at *3.

¹⁹ *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 195 n.9.

²⁰ *Myriad*, 2013 WL 2631062, at *3.

²¹ *Id.*

²² *Id.* (chromosome 17 has approximately 80 million nucleotides, while chromosome 13 has approximately 114 million).

²³ *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 203.

²⁴ *Myriad*, 2013 WL 2631062, at *4.

²⁵ *Id.* at *5.

²⁶ *Id.* at *3.

²⁷ *Id.* at *5.

²⁸ *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 186-89.

In ruling on the issue ultimately addressed by the Supreme Court, the district court concluded that Myriad's composition claims directed to isolated DNA and cDNA contained naturally occurring gene sequences that fell within the "products of nature" exception to § 101.

Fourteenth Amendments of the U.S. Constitution based on the issuance of the patents.²⁹

In an exhaustive opinion, the district court granted the plaintiffs' motion to declare 15 claims in 7 Myriad patents invalid based on 35 U.S.C. § 101.³⁰

In ruling on the issue ultimately addressed by the Supreme Court, the district court concluded that Myriad's composition claims directed to isolated DNA and cDNA contained naturally occurring gene sequences that fell within the "products of nature" exception to § 101.³¹ The mere purification of a product of nature cannot transform it into patentable subject matter. The purified product must have "markedly different characteristics" to satisfy § 101, which Myriad's claims did not.³² Thus, those claims were invalid because they were directed to non-patentable subject matter.³³

First Federal Circuit Opinion – On appeal, the Federal Circuit reversed the district court's holding on the composition claims for isolated DNA and cDNA claims, concluding that those claims were directed to patent-eligible subject matter (the issue the Supreme Court later addressed).³⁴

Mayo v. Prometheus -- The Supreme Court granted the subsequent petition for writ of certiorari,³⁵ then immediately vacated the Federal Circuit's judgment and remanded the case for further consideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*³⁶

The Court decided *Prometheus* after the Federal Circuit issued its first *Myriad* opinion. In *Prometheus*, the Court considered patent claims purporting to cover processes applying natural laws to therapeutic decisions.³⁷ Addressing the "laws of nature" exception to § 101, the Court confirmed its established rule that laws of nature are not patentable. Because natural phenomena are the basic tools of scientific and technological work, they are free to all men and reserved exclusively to none. To hold otherwise and allow patents on natural laws would impede innovation more than it would tend to promote it.³⁸

The *Prometheus* Court recognized that an overbroad interpretation of the "laws of nature" exception could eviscerate patent law. Thus, a process is not unpatentable merely because it contains a law of nature. The novel application of a law of nature to a process may deserve patent protection.³⁹

Federal Circuit Opinion on Remand -- On remand, the Federal Circuit again reversed the district court on the issue of patent-eligible subject matter. Each panel member authored a separate opinion. All three agreed that synthetic cDNA met the § 101 requirements and these claims could be patented.⁴⁰

Judge Alan Lourie found that the isolated DNA claims were patent eligible because the isolation process required breaking chemical bonds at both ends of the segment, thus creating a new chemical composition.⁴¹ Unlike Judge Lourie, Judge Kimberly Moore relied on the PTO's practice of granting such patents and on the reliance interest of patent holders to conclude that the claims were patentable.⁴²

²⁹ *Id.* at 186.

³⁰ *Id.* at 184, 238.

³¹ *Id.* at 220, 231.

³² *Id.* at 227 (relying *inter alia* on *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

³³ *Id.* at 220.

³⁴ *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329, 1333-34 (Fed. Cir. 2011).

³⁵ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, ___ U.S. ___, 132 S. Ct. 1794 (2012).

³⁶ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, ___ U.S. ___, 132 S. Ct. 1289 (2012).

³⁷ *Id.* at 1294.

³⁸ *Id.* at 1293 (citations omitted).

³⁹ *Id.*

⁴⁰ *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1326 (Lourie, J.), 1337 (Moore, J.), 1356 (Bryson, J.) (Fed. Cir. 2012).

⁴¹ *Id.* at 1328-31.

⁴² *Id.* at 1343.

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ABOUT SHB

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In his dissent, Judge William Bryson disagreed, arguing that isolated DNA was not patent eligible, in part, because the “structural similarity dwarfs the significance of the structural differences between isolated DNA and naturally occurring DNA, especially where the structural differences are merely ancillary to the breaking of the [chemical] bonds, a process that is itself not inventive.”⁴³

Supreme Court Opinion

The Supreme Court granted certiorari to determine whether Myriad’s patent claims as to human genes met the requirements of § 101 or instead claimed naturally occurring phenomena.⁴⁴ Relying on the rules confirmed in *Mayo*,⁴⁵ the Court held that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.”⁴⁶ The court reasoned:

- Myriad did not create or alter the genetic information in the BRCA1/2 genes. Myriad’s principal contribution was uncovering the precise location and genetic sequence of the BRCA1/2 genes which existed in nature before Myriad found them.⁴⁷
- *Chakrabarty* was central to the inquiry. That case allowed a patent claim to a modified bacterium when it concluded that the modified bacterium was new “with markedly different characteristics from any found in nature.” But Myriad did not create anything.⁴⁸
- “Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the requirements of § 101.”⁴⁹ Where a patent holder did not alter the bacteria claimed in a patent, it fell within the “law of nature” exception.⁵⁰ Myriad fell within the same exception for the same reason.
- Myriad’s own description of the patent highlighted the problems with its claims by focusing on the laborious process of discovery. “But extensive effort alone is insufficient to satisfy the demands of § 101.”⁵¹

The court also rejected arguments based on the severing of chemical bonds and the PTO’s practice of awarding gene patents.⁵²

Importantly, the Court specifically said its decision *did not* implicate (1) method claims (none of which were before the Court), (2) patents on *applications* of knowledge about the BRCA1/2 genes, or (3) future claims where the order of the naturally nucleotide has been altered.⁵³

Conclusions

Though much has been said about *Myriad*, keep these questions in mind:

- Does Justice Scalia’s statement about the complex science portend future difficulties, even though courts have always grappled with difficult technical issues?
- Where will the next challenge to the scope of patent-eligible subject matter arise (as it most certainly will)?

⁴³ *Id.* at 1355.

⁴⁴ *Myriad*, 2013 WL 2631062, at *7.

⁴⁵ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, ___ U.S. ___, 132 S. Ct. 1289 (2012).

⁴⁶ *Myriad*, 2013 WL 2631062, at *2.

⁴⁷ *Id.* at *8.

⁴⁸ *Id.* at *8 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

⁴⁹ *Id.* at *8.

⁵⁰ *Id.* (citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)).

⁵¹ *Id.* at *8.

⁵² *Id.* at *9.

⁵³ *Id.* at *10.