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SUMMARY

U.S. Supreme Court holds that unmodified genes cannot be patented, but modified genes can be.

If you have any questions regarding the issues raised by the *Myriad* decision, please contact:

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U.S. SUPREME COURT HOLDS THAT UNMODIFIED GENES ARE PRODUCTS OF NATURE AND NOT PATENTABLE

On June 13, 2013, the U.S. Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.* (referred to as “*Myriad*”) held that unmodified genes are “products of nature” and not patentable, but that modified genes are still patent eligible.

In the 1990s, scientists at Myriad Genetics, Inc. (“Myriad”) studied two human genes (called BRCA1 and BRCA2) linked to hereditary breast and ovarian cancer, and extracted the genes from their naturally occurring location in the DNA of the human body. After extracting the genes, the scientists used them to create modified genes (called cDNA), as well as tests that screen for BRCA gene mutations. Because patients who carry BRCA gene mutations have a higher risk for breast and ovarian cancer, the tests can be used to assess a patient’s risk for these cancers. The modified genes (cDNA) differed from the naturally occurring DNA in a human body; the modified genes were shorter than the naturally occurring genes, and differed in DNA sequence, as well. Myriad and others obtained several patents (“Myriad patents”) on the BRCA genes and related methods, including the tests. Myriad is the sole provider of the tests.

In 2009, a coalition led by the American Civil Liberties Union (ACLU) filed a lawsuit to challenge the Myriad patents. The ACLU argued that genes are “products of nature” and are not patentable. The trial court agreed with the ACLU, but the Court of Appeals for the Federal Circuit (Federal Circuit) disagreed and found that genes were patentable. The ACLU then appealed to the U.S. Supreme Court.

The Supreme Court’s decision focused on the difference between naturally occurring (unmodified) DNA and modified DNA (cDNA). The Court then held that unmodified DNA is a “product of nature” and thus not patent eligible under 35 U.S.C. §101. The Court noted that Myriad created nothing new in finding the location of the BRCA genes, extracting them, or determining their DNA sequences. In contrast, the Court noted that Myriad had created cDNA that was not identical to naturally occurring DNA, and concluded that this cDNA was not a “product of nature.” Ultimately, the Court held that cDNA is patent eligible, except when a very short cDNA is “indistinguishable from natural DNA.” The Court did not comment on the patentability of genetic tests; in particular, the Court noted that the *Myriad* case “does not involve method claims” or “patents on new applications of knowledge about the BRCA1 and BRCA2 genes.”

The *Myriad* decision has mixed impact on the University. Post-*Myriad*, unmodified genes are not patentable, so University researchers will have more freedom to explore them. However, in general, modified genes and new uses of (unmodified or modified) genes remain patent eligible. Thus, if a company controls patents to a modified gene or a new use of a gene, it may limit what tests University clinicians can offer to patients, and what areas University researchers are free to explore. Likewise, the *Myriad* decision preserves the ability of the University and its patent licensees to bring modified genes and new uses of genes (developed by University inventors) to the marketplace for the public good, in biotech-related areas such as human and animal health.