

## Supreme Court Rules that Isolated Human Gene is Not Patent Eligible in *AMP v. Myriad*

On June 13, 2013, the Supreme Court unanimously held in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, that an isolated but otherwise unmodified segment of human DNA was not eligible for patent protection under 35 U.S.C. § 101. The Court ruled that a naturally occurring DNA segment is a product of nature and is not patent eligible simply because it has been isolated and removed from its natural cellular environment. The Court also held, on the other hand, that complementary DNA (“cDNA”) was patent eligible because it is a non-naturally occurring molecule in that it does not include the introns found in native DNA.

Defendant Myriad Genetics, Inc. (“Myriad”) discovered the location and sequence of the BRCA1 and BRCA2 genes and discovered that mutations in those genes are associated with a higher risk of developing breast and ovarian cancer. Myriad obtained several patents related to the BRCA genes, which included the nine composition claims at issue in this case. These composition claims covered isolated DNA defined in terms of the amino acid sequence that the DNA encodes. These claims, thus, included DNA having the same nucleotide sequence as the native BRCA genes (in their entirety or in partial segments as short as 15 nucleotides) or having sequences embodying common mutations of the genes. Myriad also had claims specifically directed towards cDNA, defined by its DNA sequence. That sequence contained only the protein-coding exon portions of the native BRCA gene sequences and omitted the non-coding intron portions. Myriad’s DNA claims, if valid, gave it the exclusive right to isolate an individual’s BRCA genes, which may be a necessary step in conducting genetic testing.

Plaintiffs, a coalition of institutions, doctors, researchers, and patients, wanted to conduct or undergo clinical BRCA genetic testing or conduct genetic research. They claimed that they were prevented from doing so by Myriad’s patents. Plaintiffs brought suit against Myriad, seeking a declaration that its BRCA gene patent claims were invalid under 35 U.S.C. § 101.

The Supreme Court agreed that Myriad’s claims to isolated segments of natural DNA fell within the product of nature exception to § 101 and were not patent eligible. Writing for the unanimous Court, Justice Thomas first noted that Myriad did not create or alter any of the genetic information encoded in the BRCA genes. This genetic code existed in nature before Myriad discovered it. The Court stated “Myriad did not create anything” and explained that “groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”

The Court’s decision reverses the Federal Circuit, which had held that claims to isolated, naturally-occurring DNA sequences were patent eligible. Writing for the Federal Circuit majority below, Judge Lourie had adopted a chemical perspective when analyzing this issue, holding that the act of isolating a gene—breaking the covalent bonds that joined it to the larger DNA molecule in the chromosome—created a new substance that did not occur in nature. The Supreme Court rejected this approach, stating that “separating a gene from its surrounding genetic material is not an act of invention.” The Court also cited language from Myriad’s patents, which detailed what the Court characterized as the “iterative process” of discovery that Myriad followed to “find” the location of the BRCA genes. While this discovery of an important and useful gene was a medical breakthrough, it did nothing to alter the naturally-occurring gene, the Court said. Moreover, the Court noted, Myriad’s claims were not expressed in terms of chemical composition nor did they rely on any chemical changes that resulted from isolation.

In contrast to the Federal Circuit’s chemical approach to the isolated DNA, the Court focused on the fact that an isolated gene and a gene in its natural state are nearly identical. Most importantly, they both contain

the same genetic information. According to the Court, something more than merely snipping off the ends of a DNA molecule (breaking of covalent bonds) is needed to satisfy the requirements of § 101.

The Court was also unmoved by the prospect of upsetting settled industry expectations and reversing the USPTO's practice of over thirty years of issuing patents claiming isolated DNA. In doing so, the Court reasoned that Congress had never expressly adopted the USPTO's view and relied on the Government's position at the Federal Circuit and before the Court that such naturally occurring genes are not patent eligible. The Court also noted that concerns about industry reliance arising from PTO determinations were better directed to Congress.

The Court suggested that any concerns about the incentives to conduct genetic research were assuaged by the fact that other claims, that included patentable applications of the BRCA genes, could have been (and were) allowed. Moreover, because the Court also held that cDNA molecules were patent-eligible, it did not foreclose the patent eligibility of all composition claims directed towards genetic material. The Court also emphasized that it was not considering the patentability of DNA in which the order of naturally-occurring nucleotides had been altered.

Justice Scalia wrote a separate concurrence, noting that his judgment was based on the expert scientific information presented regarding the "fine details of molecular biology," with which he could neither agree nor disagree.

The long term effect of the Court's decision on many existing patents and pending and future patent applications is unclear. Just as the Court's 1980 *Chakrabarty* decision opened the way to the patenting of living organisms and other advances in the then-fledgling biotechnology industry, the *Myriad* decision may have a chilling effect on biotechnology patents and the research underlying them. Indeed, the USPTO has already issued an initial guidance to Examiners regarding the unpatentability of product claims to naturally-occurring nucleic acids and reemphasizing that careful consideration should be given to the patent eligibility of method claims involving them.

A copy of the Supreme Court's *Myriad* opinion is available [here](#). To discuss further the potential impact of *Myriad* or the Court's other decisions related to patent eligible subject matter, please contact your usual Ropes & Gray attorney or one of the following Ropes & Gray attorneys:

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