

# PUBLICATION

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## U.S. Supreme Court's Myriad Decision on DNA Patents is In

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The Supreme Court has held that "isolated" nucleic acids that correspond to naturally-occurring sequences are not eligible for patenting, but that nucleic acids containing non-naturally-occurring sequences – including cDNA – are patent-eligible.

The case– *Association for Molecular Pathology v. Myriad*, 569 U.S. \_\_\_\_ (June 13, 2013)– was brought by the ACLU on behalf of various groups of patients and doctors seeking to invalidate Myriad Genetics, Inc.'s patents claiming "isolated nucleic acids" corresponding to various genomic sequences of the *BRCA1* and *BRCA2* genes. *BRCA1* and *BRCA2* are strongly linked to predisposition for breast and ovarian cancers, making them valuable targets for diagnostic assays.

According to the court, 35 U.S.C. § 101 implicitly excludes "products of nature" from patent-eligibility. Under this principle, the court held that Myriad's isolated nucleic acids corresponding to genes are "products of nature," and thus patent ineligible:

*It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosome 17 and 13.*

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*Myriad's [patent claims thus fall squarely within the law of nature exception]. Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes "new . . . composition[s] of matter," § 101, that are patent eligible.*

*Myriad*, at 11-12, 13.

In contrast, cDNA is patent eligible because it "results in an exons-only molecule that is not naturally occurring." *Myriad*, at 13.

The Court expressly noted that its opinion does not implicate: (1) method claims; (2) "new applications of knowledge about the *BRCA1* and *BRCA2* genes"; and (3) DNA in which the order of the naturally-occurring nucleotides has been altered.

Obviously, this case will have serious implications for any company that currently holds patents related to nucleic acids or other products of nature. If you have any questions, please contact one of our experienced life sciences patent attorneys.