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Supreme Court Holds Myriad's "Naturally Occurring" DNA Claims Not Patentable

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In a unanimous decision with potentially widespread ramifications, the US Supreme Court held today that "[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring." See Association for Molecular Pathology v. Myriad Genetics, Inc., No. 12-398 (June 13, 2013). Specifically, the Court ruled that certain naturally occurring DNA segments claimed by Myriad, relating to the breast and ovarian cancer-associated genes BRCA1 and BRCA2, are not patentable under 35 U.S.C. §101.

The Court explained that, whereas §101 provides that patents may be granted to "[w]hoever invents or discovers any new and useful . . . composition of matter, or any new and useful improvement thereof," in this case "Myriad did not create anything," and although Myriad "found an important and useful gene, . . . separating that gene from its surrounding genetic material is not an act of invention." Slip Op. at 12. In addition, the court explained that although "Myriad found the location of the BRCA1 and BRCA2 genes, . . . that discovery, by itself, does not render the BRCA genes 'new . . . composition[s] of matter' that are patent eligible." *Id.* at 13, citation omitted. In reaching its decision, the Court refused to give deference to the

US Patent and Trademark Office's practice of awarding such gene patents in the past.

In contrast, the Court held that Myriad's claims to cDNA sequences are patentable. These cDNA sequences correspond to the naturally occurring DNA sequences except that certain non-coding sequences, or "introns," are removed. The Court found that such cDNA sequences are patent eligible because "the lab technician unquestionably creates something new when cDNA is made" because it is "distinct from the DNA from which it was derived" and "not a 'product of nature.'" *Id.* at 17.

Finally, although this decision will certainly lead to speculation regarding additional limitations on the patentability of biotechnology claims, the Court was careful to "note what is *not* implicated by this decision," making clear that "this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes" and that the Court did not consider "the patentability of DNA in which the order of the naturally occurring nucleotides has been altered." *Id.* at 17-18.