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The Supreme Court Rules on Myriad

June 14, 2013

In a unanimous decision on June 13, 2013, the Supreme Court distinguished between patent-ineligible DNA and patent-eligible cDNA, and held that DNA that has been merely isolated from its natural environment but not otherwise altered is not patent eligible subject matter.

At issue in this case were composition claims from several patents owned by Myriad Genetics, Inc. that claim the DNA and cDNA for the BRCA1 and BRCA2 genes. Myriad's patents have garnered considerable attention and controversy since these genes are associated with an increased risk of breast cancer, with opponents arguing that these patents blocked access of patients to screening.

Myriad discovered the precise location and sequences of these genes, and in their patent disclosure describe the process whereby these sequences were discovered and isolated. The Court's rationale for finding isolated DNA unpatentable was that isolated DNA contains the same genetic information as that found in the genome; the act of breaking covalent bonds to release a particular gene from its surrounding DNA does not create a new composition of matter. Since Myriad did not create or alter any of the genetic information encoded in BRCA1 and BRCA2, and the location and order of the nucleotides in the genes existed in nature before Myriad found them, the DNA is not eligible to be patented under 35 U.S.C. § 101.

Conversely, the Court found that cDNA does not present the same obstacles to patentability. cDNA is created in a laboratory from mRNA and results in an exons-only molecule that is not naturally occurring. Because the intron-less cDNA is distinct from the intron-containing DNA from which it was derived, it is not a product of nature and is therefore patent-eligible.

The decision highlights that the Court did not consider the patentability of DNA which has been manipulated so that it is distinguishable from naturally occurring DNA. The decision also stresses that new methods and applications of the knowledge of the newly identified genes would still be patentable subject matter. The Court merely holds that simply isolating a gene does not render it, or the information it encodes, a new composition of matter that is eligible for patenting.

In press releases issued after the decision, Myriad noted that the claims in this case represent only a small portion of Myriad's portfolio and the company retains many other patents that protect their BRACAnalysis® test. The Patent & Trademark Office issued Preliminary Guidelines for examination yesterday afternoon instructing examiners to reject "product claims drawn solely to naturally occurring nucleic acids and fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. §101" but affirming patent eligibility of claims to cDNA sequences and man-made variant sequences.

Stay tuned for a more detailed analysis in the near future regarding this decision and the impact it will have on patent prosecution and litigation. Read the full decision of ***Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.***

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