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The Supreme Court Nixes Claims to Isolated Genomic DNA

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The U.S. Supreme Court decided today that claims to isolated genomic DNA are not patentable subject matter and thus invalid.[1] This decision rendered invalid patent claims owned by Myriad Genetics as well as thousands of patent claims of others to such molecules. However, Myriad's claims to complementary DNA (cDNA) molecules were held to be valid.

In the decision, authored by Justice Thomas, the Court held that claims to isolated genomic DNA molecules fell squarely within the law of nature exception to patentable subject matter. According to the Court, Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, did not render the BRCA genes a "new...composition[s] of matter" under §101. The Court was not moved by Myriad's argument that they undertook extensive effort to locate the gene sequences associated with an increased risk of breast cancer. The Court also rejected the argument that isolating DNA from the human genome severed chemical bonds and thereby created a non-naturally occurring molecule, pointing out that Myriad's claims did not rely on the chemical changes that result from isolation. Instead, the claims focus on the genetic information encoded in the BRCA1 and BRCA2 genes. The Court also rejected the argument that the U.S. Patent and Trademark's past practice of awarding gene patents was entitled to deference, pointing out that the U.S. government now argued to the Court that isolated genomic DNA was *not* patent eligible.

While important, this decision will not affect many patent claims relied upon by the biotech industry, including claims to methods of production of therapeutic proteins, and will certainly not affect genes to artificial proteins such as humanized or chimeric antibodies. The decision should also not affect claims directed to isolated genes in artificial vector constructs, transgenic cells and organisms, or artificially labeled isolated genes used in diagnostics. It will not affect gene therapy, as such therapy depends upon artificial gene constructs.

More concerning is the effect of today's decision on patents for other isolated natural products, such as those relied upon by the pharmaceutical industry (e.g. claims to isolated natural antibiotics) and nanotechnology industry (e.g., claims to isolated nanotubes). These patent claims are now in question and their validity is likely to be the subject of future patent litigation.

[1]The decision is *Association for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (June 13, 2013).

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