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Supreme Court Unanimously Rules That "Gene Patents" Are Invalid

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In a highly anticipated decision issued today in *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court unanimously ruled that isolated DNA sequences are not eligible for patent protection. The Court simultaneously held that cDNA can be patent eligible subject matter – as long as it is distinguishable from natural DNA. Justice Thomas, writing for the Court, clarified that the mixed ruling did not implicate methods, applications of knowledge about genes or alteration of sequences.

The Court held that Myriad's isolated DNA claims were not patent eligible, acknowledging that while Myriad "found an important and useful gene, [] separating that gene from its surrounding genetic material is not an act of invention." The Court illustrated the differences between invention and discovery by revisiting its precedential decisions in *Chakrabarty and Funk Brothers Seed Co.* Under the Court's analysis, Myriad's claims to "isolated DNA" were merely trying to protect "hitherto unknown natural phenomen[a]," i.e., the discovery of the BRCA1 and BRCA2 sequences. The Court contrasted these DNA sequences to cDNA which is a "nonnaturally occurring... composition of matter – a product of human ingenuity 'having a distinctive name, character [and] use." The Court held that the breaking of chemical bonds required to isolate the DNA did not save the isolated DNA claims because those claims focused not on the chemical changes, but on the genetic information encoded by the genes.

While the Court's decision offers some clarity on how to draft composition claims going forward, it undoubtedly affects issued and pending claims. According to the Supreme Court, the claims must recite something beyond mere isolation. However, one needs to carefully consider how much is enough to cross the line from merely being a "product of nature" to a patentable invention. Patent applicants and patent owners with affected inventions should analyze the recent developments because, in many cases, corrective action is necessary to salvage patent claims from the reach of *Myriad*.

Nutter attorneys will continue to keep you informed regarding the developments in this area.

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