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Myriad's Effect On Drafting "Gene Patents"

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Legal Update

In a highly anticipated decision issued on June 13, 2013 in *Ass'n for Molecular Pathology v. Myriad*, the U.S. 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's holding affects composition claims for patent owners and applicants, but both patent owners and applicants can take various actions to best protect their interests in view of *Myriad*.

The Court held that Myriad's isolated DNA claims were not patent eligible, contrasting these DNA sequences to cDNA, a "nonnaturally occurring… composition of matter – a product of human ingenuity 'having a distinctive name, character [and] use,'" which the Court held to be patentable. The Court found 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.

According to the Supreme Court, the claims must recite something beyond mere isolation. Chemically modified sequences should remain valid, but, one needs to carefully consider how much is enough to cross the line from merely being a "product of nature" to a patentable invention. One way to address the uncertainty going forward, which Myriad employed, is to use a claiming strategy that includes various types of claims. Another strategy is to use multiple and diverse narrower claims as back-up strategies. Caution should be exercised, however, to prevent inadvertently pointing the competition to the most valuable commercial embodiments through narrowly focused claiming, should such concerns outweigh an applicant's desire to perhaps more quickly receive an issued patent that has relatively narrow claims.

Interested parties should also be mindful to take positions with respect to third party patents that are consistent with their own patents. In other words, patent holders' positions that competitor patents are invalid under *Myriad* can be turned against the patent holders to invalidate their own patents.

While the Court's decision offers some clarity on how to draft composition claims going forward, it undoubtedly affects issued and pending claims. Patent applicants and patent owners with affected inventions should analyze the recent developments because, in many cases, corrective action will be necessary to salvage patent claims from the reach of *Myriad*.

This advisory was prepared by Nutter's Intellectual Property practice. For more information, please contact your Nutter attorney at 617.439.2000.

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