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# LEGAL ALERT

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## Isolated Genes No Longer Patentable: Supreme Court Reverses Federal Circuit in *Myriad* Case

In a thinly worded unanimous decision in *Assn. for Molecular Pathology v. Myriad Genetics*, *Inc.* on June 13, 2013, the U.S. Supreme Court held that patent claims directed to genes are not patent eligible despite being claimed in an isolated form. The Court indicated that in order to qualify for patentability, a composition must be not only non-naturally occurring, but also have markedly different characteristics from any found in nature. An isolated naturally occurring DNA gene sequence, or amplification fragment, though made useful to provide a diagnosis for disease propensity, is apparently not modified sufficiently through isolation from its chromosomal environment to meet the standard for patentability.

The Court distinguished the patent eligibility of cDNA molecules, which are copies of RNA molecules encoding for a protein, but having certain non-useful corresponding original DNA (introns) removed. The Court also distinguished the patent eligibility of novel DNA sequences that are not found in nature but are instead engineered. Therefore, despite the surprising nature of this decision, there remains numerous ways in which patent eligible DNA claims can be drafted and protected, such as by claiming cDNA or including the native DNA in association with other components.

The Court noted that the decision does not affect patentability of methods of using genes. However, the Supreme Court's ruling in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* in March 2012 held that patent claims reciting diagnostic methods that "essentially claim natural laws" by adding routine steps are patent ineligible. Therefore, the protected uses of genes referred to by the Court in *Myriad* appear to be for uses related to the growth of transformed cell cultures and the expression of gene products, more than their use for detection and diagnosis.

The *Myriad* decision reversed the U.S. Court of Appeals for the Federal Circuit which had previously held that isolated genes (such as mutated versions of BRCA1 or BRCA2 indicating a predisposition for breast or ovarian cancer) were patentable. The Supreme Court did not take up the issue decided by the Federal Circuit that the claims directed to methods of merely analyzing or comparing a patient's gene sequence with a wild-type sequence for a diagnosis are patent ineligible as encumbering natural laws.

The Court's reasoning in *Myriad* relied on an expansive reading of the Supreme Court's landmark 1980 *Chakrabarty* decision, which held that "[t]he relevant distinction for purposes of [patent eligibility] is . . . between products of nature . . . and human-made inventions." In *Chakrabarty,* a genetically modified bacterium made to digest oil spills was found to be patent eligible. The Supreme Court in *Myriad*, however, emphasized and relied upon an additional observation made in *Chakrabarty* that the invention also had markedly different characteristics from any found in nature. Although isolating DNA sequences from their native context converts them to a useful form for diagnosis, this transformation was apparently not convincing for the Court.

Further reliance upon the earlier *Funk Brothers* case demonstrates the Court's concern with obviousness issues, instead of patent eligibility. The *Myriad* case cites *Funk Brothers* for the proposition that preferred mixtures of naturally occurring strains of bacteria assisting in nitrogen fixation of legumes were not patentable. However, a careful reading of *Funk Brothers* reveals that patentability was denied not for the composition's failure to be patent eligible, but rather for lack of inventiveness in its application of known

properties. The *Myriad* analysis is also notably missing a more robust discussion of other recent Supreme Court cases related to the patent eligibility issue (e.g., *Bilski, Prometheus)*.

The *Myriad* case seems to expand the scope of categorical exclusions from patent eligibility, which historically have prohibited patenting only laws of nature, natural phenomena and abstract ideas. Now, apparently "products of nature" have been added to the list of exclusions, despite the distinctive capabilities conferred by isolating and harnessing a product of nature for a useful purpose. Therefore, this case may be used by future patent infringement defendants in other contexts where a naturally occurring agent is claimed, such as a naturally occurring isolated medicinal compound or isomer.

This decision most directly affects the burgeoning field of individualized healthcare. In the short term, the cost for determining the presence of the BRCA1/BRCA2 genetic mutation, and other genetic diagnostic tests, will be reduced as a result of increased competition. In the longer term, however, the Supreme Court's decision in *Myriad* has removed a significant incentive to identify and commercialize other diagnostic genetic markers, thereby impeding the development of individualized medicine which could otherwise more dramatically reduce overall healthcare costs.

The potentially far-reaching effects of this *Myriad* decision are belied by the perfunctory length of the opinion. In the meantime, genetic diagnostic patent applicants are advised to include composition claims directed to novel detection molecules and reagents, and method claims with physical steps, such as sample isolation and laboratory testing, for their claims to be patent eligible.

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*If you have any questions about this Legal Alert, please feel free to contact either of the attorneys listed below or the Sutherland attorney with whom you regularly work.*


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