USPTO Provides Guidance in Response to Myriad Decision

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The U.S. Supreme Court recently issued its decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, which clarifies what types of DNA claims are patent eligible. Only a few days later, the U.S. Patent and Trademark Office (USPTO) issued <u>preliminary guidance</u> to its patent examining corps.

As noted by the USPTO, "Myriad significantly changes the Office's examination policy regarding nucleic acid-related technology." The Supreme Court held that a naturally occurring DNA segment is a product of nature and <u>not patent eligible</u>merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring.

In accordance with the Myriad decision, the USPTO advises it examiners: As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated. Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101. Claims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturallyoccurring nucleotides has been altered (e.g., a man-made variant sequence), remain eligible

The USPTO further added that it is closely reviewing the decision in *Myriad* and will issue more comprehensive guidance on patent subject matter eligibility determinations, including the role isolation plays in those determinations.

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