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MEMORANDUM

DATE: June 13, 2013

TO: Patent Examining Corps

FROM: Andrew H. Hirshfeld
Deputy Commissioner
For Patent Examination Policy

SUBJECT: **Supreme Court Decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.***

Today in *Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad)*, the Supreme Court held that claims to isolated DNA are not patent-eligible under 35 U.S.C. § 101. *Myriad* significantly changes the Office's examination policy regarding nucleic acid-related technology. The purpose of this memorandum is to provide preliminary guidance to the Patent Examining Corps.

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 naturally-occurring nucleotides has been altered (e.g., a man-made variant sequence), remain eligible. Other claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance in MPEP 2106, *Patent Subject Matter Eligibility*.

In *Myriad*, the Supreme Court considered the patent eligibility of several claims directed to isolated DNA related to the human BRCA1 and BRCA2 cancer susceptibility genes. The Supreme Court held that certain of Myriad Genetics' claims to isolated DNA are not patent-eligible, because they read on isolated naturally-occurring DNA that is a "product of nature." The Court held that isolating a "gene from its surrounding genetic material is not an act of invention." The Supreme Court held that other claims are patent-eligible, because they are limited to cDNA, which is a type of man-made DNA composition that is not naturally-occurring. The Court held that "cDNA is not a 'product of nature' and is patent eligible under §101."

The USPTO 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.