$1.50 VOL. 36 NO. 27 www.ocbj.com JULY 8-14, 2013

ORANGE COUNTY BUSINESS JOURNAL

Can Your DNA Be Patented? The Supreme Court Draws a Delicate Balance

by Stanley Gibson, Chairman; and Gregory Cordrey, Partner; Jeffer Mangels Butler & Mitchell LLP

In *Ass'n for Molecular Pathology v. Myriad Genetics Inc.*, the Supreme Court held that a naturally occurring, isolated segment of DNA is a product of nature and is not patentable. In contrast, the Supreme Court held that synthetically created DNA (cDNA) is patent eligible because it is not naturally occurring even if derived from DNA.

The Association for Molecular Pathology filed suit against Myriad Genetics Inc. seeking a declaration that Myriad's patents covering naturally occurring DNA segments as well as synthetic DNA were not patentable and therefore invalid under Section 101 of the Patent Statute. Myriad's patents covered the BRCA1 and BRCA2 genes which, when mutated, indicate a significantly higher risk in women for breast and ovarian cancer. Myriad asserted that certain tests for mutations in the genes infringed its patents.

In rejecting patentability of natural DNA segments, the Court concluded "[M]yriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes...Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes..." It held that "a naturally occurring DNA segment is a product of nature and not patent eligible."

Regarding the patentability of the synthetically created DNA, i.e., cDNA, the Supreme Court stated "cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments" because "creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring...it is distinct from the DNA from which it was derived. As a result, cDNA is not a 'product of nature' and is patent eligible under §101..."

The Supreme Court limited its decision by noting that method claims (e.g. methods for manipulating genes) were not before it. Its decision also does not extend to *applications* of sequences, which Myriad patented and which were not challenged. Finally, the Court's decision did not consider the patentability of DNA "in which the order of the naturally occurring nucleotides has been altered."

Thus, while affirming that products of nature are not patentable, the Supreme Court clarified – in the context of synthetic DNA – that products derived from naturally occurring products continue to be eligible for patent protection.

Gibson

Stanley Gibson and Gregory Cordrey

Stanley Gibson is the chairman and Gregory Cordrey is a partner of the Patent Litigation Group at Jeffer Mangels Butler & Mitchell LLP. They represent technology companies in patent litigation and licensing. Contact Stan Gibson at sgibson@jmbm.com or 949.623.7229 and Greg Cordrey at gcordrey@jmbm.com or 949.623.7236. Afua Adjei, JMBM summer associate and Stanford Law School student, contributed to this article.

Cordrey