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Australian Federal Court Upholds Myriad's Gene Patent

By James J. Mullen, III and Mary Prendergast

While the question of patentability of isolated gene sequences awaits resolution at the U.S. Supreme Court, the Australian Federal Court today upheld Myriad Genetics' patent on methods for screening for cancer-predisposing mutations in the BRCA1 gene. *Cancer Voices Australia v. Myriad Genetics Inc.*, NSD643/2010, Federal Court of Australia (Sydney). The result is a significant win for Myriad and its Australian licensee Genetics Technologies Ltd., and provides long-awaited certainty for holders of patents directed to isolated gene sequences and for the Australian biotech industry as a whole.

Echoing the arguments made by petitioner Association for Molecular Pathology (AMP) in its recently filed Supreme Court brief in *Association for Molecular Pathology v. Myriad Genetics, Inc.* ("*Myriad*"), applicants Cancer Voices Australia and Yvonne D'Arcy, a Brisbane resident diagnosed with breast cancer, argued that Myriad's patent was not patent-eligible because it claims naturally occurring subject matter—DNA that is not materially different from DNA found in nature.

The Federal Court disagreed, finding that because the claimed nucleic acid is "isolated" from native DNA, the claimed nucleic acid is patentable under Australian patent law. The court found that isolated nucleic acid does not exist outside the cell in the absence of human intervention, and thus consists of an "artificially created state of affairs" as required for patent-eligibility. Specifically, the court held that "even if the physical properties of the material have not changed, the removal of the material from its natural environment and its separation from other cellular components may still give rise to what might reasonably be described as an artificial state of affairs." Although based on Australian case law, the court's reasoning closely paralleled the reasoning of the Federal Circuit in *Myriad*, which focused on the fact that isolated DNA must be chemically cleaved from native DNA, and thus has "markedly different" characteristics than native DNA.

The Australian Federal Court also referenced the fact that the Australian Parliament recently had rejected proposals to amend the Patent Act to exclude claims directed to DNA and RNA, evincing Parliament's intent not to limit their patent-eligibility. The court noted that this decision was in line with the law of the UK and U.S., specifically pointing out Myriad's success in its appeal at the Federal Circuit.

The fate of that Federal Circuit decision, however, is uncertain as it currently is under review by the U.S. Supreme Court. Petitioner AMP filed its brief in the Supreme Court on January 24, and respondent Myriad's brief will be filed March 7. More than 20 amicus curiae briefs have been filed, including a brief by the United States arguing that isolated DNA sequences that have not been otherwise modified are not patent-eligible. Oral argument will be held April 15, 2013, with a decision expected before July.

Contact:

James J. Mullen, III
(858) 720-7940
jmullen@mofo.com

Mary Prendergast
(858) 720-7973
mprendergast@mofo.com

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