

One Minute Memo®



United States Supreme Court Sets Genes Free

In a decision awaited with considerable trepidation by the biotech world, among others, on June 13, 2013 the Supreme Court handed down its unanimous decision (9-0) in *Association for Molecular Pathology v. Myriad Genetics, Inc.* The Court held “that genes and the information they encode are not patent eligible... simply because they have been isolated from the surrounding genetic material.”

Myriad discovered the precise location and sequence of what are known as the BRCA1 and BRCA2 genes. That information in turn enabled Myriad to develop medical tests useful for detecting mutations in patient’s genes, and therefore determine likelihood for certain cancers. Myriad obtained patents directed to “an isolated DNA coding” for those genes. Other Myriad patent claims were directed to “complementary DNA,” called “cDNA,” which omits portions of the genetic sequence within the naturally occurring DNA. Plainly stated, cDNA is a synthetic creation not present in nature.

As to the naturally occurring DNA patent claims, the court held “[i]t is undisputed that Myriad did not create or alter the genetic information” encoded in the naturally occurring genes. Determining the location and order of the nucleotides merely discovered what existed in nature. “[S]eparating that gene from its surrounding genetic material is not an act of invention,” Justice Thomas wrote for the Court. To hold otherwise “would be at odds with the very point of patents, which exist to promote creation.”

As to the cDNA (i.e. synthetic creation) patent claims, the Court had little difficulty affirming their patent eligibility. “[T]he lab technician unquestionably creates something new when cDNA is made.” Therefore, it is not a product of nature.

The Court acknowledged that the case did not involve method patents on “new applications” of knowledge about mutated genes or gene sequences that have diagnostic or therapeutic value. The Court noted in its decision that “as the first party with knowledge of the BRCA1 and BRCA2 sequences, Myriad was in an excellent position to claim applications of that knowledge.” Myriad’s patent claims to new applications of knowledge about mutated genes remain viable, as they were not challenged.

Justice Thomas concluded the majority opinion, saying “[i]t is important to note what is *not* implicated by this decision.” First, method claims were not implicated, which could, for instance “involve an innovative method of manipulating genes while searching for” a particular gene. Nor does this case “involve patents on new applications of knowledge about” some gene discovery. Further, the Court did “not consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered.” The latter may not be viewed as naturally occurring. “We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material.” Whether any of the foregoing would also pass muster under the patentability standards of novelty and unobviousness was likewise not before the Court.

The decision is being viewed by many as something of a victory for both sides. Myriad lost its isolated DNA patent claims, but maintained its patent coverage on the non-naturally occurring cDNA and its unchallenged claims directed to methods of using genetic sequences to aid in the diagnosis and treatment of diseases. cDNA, the synthetic creation not present in nature, is becoming increasingly important in experimentation, testing and the evolving use of synthetic DNA sequences

Seyfarth Shaw — One Minute Memo

for novel therapeutics. On the other hand, the victory for the parties opposing Myriad is that isolated DNA may have been freed as unpatentable subject matter by the Myriad decision, for anyone to use and build upon such discoveries. New and unobvious methods and applications that surround those discoveries, and clearly changes made to that isolated DNA not found in nature, remain as fertile ground for possible patent protection.

It remains to be seen what impact this may have on a company's interest in expending the kind of investment of time and money to make the discovery in the first place.

By: *John Serio* and *Michael Baniak*

John Serio is a partner in Seyfarth's Boston office and *Michael Baniak* is a partner in the firm's Chicago office and teaches Patent Law at Northwestern School of Law in Chicago. If you would like further information, please contact your Seyfarth Shaw LLP attorney, John Serio at jserio@seyfarth.com or Michael Baniak at mbaniak@seyfarth.com.



www.seyfarth.com

Attorney Advertising. This One Minute Memo is a periodical publication of Seyfarth Shaw LLP and should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The contents are intended for general information purposes only, and you are urged to consult a lawyer concerning your own situation and any specific legal questions you may have. Any tax information or written tax advice contained herein (including any attachments) is not intended to be and cannot be used by any taxpayer for the purpose of avoiding tax penalties that may be imposed on the taxpayer. (The foregoing legend has been affixed pursuant to U.S. Treasury Regulations governing tax practice.) © 2013 Seyfarth Shaw LLP. All rights reserved.

Breadth. Depth. Results.