ARE Patent Alert:
Supreme Court Holds That Naturally Occuring DNA Sequences Are Not Patent-Eligible But cDNA May Be Patented

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On June 13, 2013, in *Association for Molecular Pathology v. Myriad Genetics, Inc*, No. 12-398, the Supreme Court unanimously ruled that Myriads claim to isolated naturally occurring human DNA sequences are not eligible for patent protection. By contrast, the Court ruled that Myriad's claims to cDNA, which includes DNA sequences that do not naturally occur in humans, are eligible for patent protection.

Myriad's Patents

Myriad is a company specializing in genetic testing. Myriad developed a test for determining a woman's likelihood of developing breast or ovarian cancer by examining two genes, known as BRCA1 and BRCA2. Certain variants of these genes are associated with a dramatic increase in the incidence of breast and ovarian cancer. By detecting which variants are present in a particular patient, Myriad's test can determine whether the patient has an increased risk of cancer.

In developing the test, Myriad identified the precise locations and DNA sequences of BRCA1 and BRCA2 within the human chromosomes. Myriad thereafter applied for several patents covering the genes. One set of patent claims covered the exact sequences of BRCA1 and BRCA2. A second set of claims covered corresponding "cDNA versions" of the same genes. The first set of claims was found to be patent-ineligible under 35 U.S.C. § 101. The second set of claims was allowed to stand.

Difference Between DNA and cDNA

The Court determined that, under 35 U.S.C. § 101, different results are reached for DNA and cDNA. As to DNA sequences, they are not patentable because they are naturally present within the human body. The Court focused on the fact that the sequence is produced through ordinary biochemical processes, without any human intervention. The Court also noted that "Myriad's patents would, if valid, give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes...." (Slip Op. at 6). By contrast, cDNA sequences for human genes do not occur naturally and do require human intervention to be produced.

To produce cDNA, a researcher first causes a gene of interest, such as BRCA1 or BRCA2, to be "expressed." In molecular genetics, "expression" means that a gene has been activated for the purpose of producing a corresponding protein molecule. One step in expression is "transcription," the synthesis of a derivative molecule known as mRNA. mRNA is effectively an intermediate molecule that "mirrors" the DNA sequence for the transcribed gene. Importantly, the RNA undergoes an "editing" process, in which certain portions of the sequences are discarded, and the remaining portions joined to form a shortened mRNA molecule. The discarded portions are called "introns," and the remaining portions are called "exons." Ordinarily, a mRNA molecule participates in subsequent steps of protein synthesis and does not persist. A researcher, however, can isolate a mRNA molecule and use laboratory processes to reverse the transcription process, effectively synthesizing a DNA molecule that "mirrors" the mRNA molecule. The DNA thus produced is known as cDNA (the "c" stands for "complementary"). It is important to note that the edited sequence does not normally exist in naturally occurring DNA form.

The Court's Ruling on DNA and cDNA

In the Court's view, DNA fell squarely within the long standing exception to patent eligible subject matter for "naturally occurring" material. The Court noted, "[i]t is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 or BRCA2 genes .... Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13." (Slip Op. at 11–12). The Court further noted that a "breakthrough" discovery, however significant, does not make the discovery patentable if the underlying subject matter is a product of nature. *Id.* at 12–13. Thus, Myriad's patent claims for isolated DNA sequences of BRCA1 and BRCA2 were invalid. By contrast, the patent claims for the corresponding cDNA sequences were not invalid because "an exons-only molecule [ ] is not naturally occurring." (*Id*.)

Implications for the Future

Interestingly, the Supreme Court gave some guidance on "what is *not* implicated by this decision." (Slip Op. at 17). First, the Court theorizes that if "Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent." (*Id*.) The Court, however, noted that the methods of manipulating the genes in this case were "well understood by geneticists at the time of Myriad's patents." (*Id*.) Second, the Court suggested that Myriad, being the first to know about the BRCA1 and BRCA2 genes, could seek patents to applications of that knowledge. (Slip Op. at 17-18). In fact, the Court pointed out that "[m]any of [the] unchallenged claims are limited to such applications." (*Id.*) Finally, the Court states that it did not consider and has no opinion on "the patentability of DNA in which the order of the naturally occurring nucleotides has been altered." (Slip. Op. at 18).

In reaction to the *Myriad*

decision, the U.S. Patent and Trademark Office issued the following memorandum: http://www.uspto.gov/patents/law/exam/myriad_20130613.pdf . It notes that "*Myriad* significantly changes the Office's examination policy regarding nucleic acid-related technology."

Myriad clearly holds that an unaltered, naturally occurring gene is not patent-eligible. *Myriad*, however, announces with equal clarity that altered DNA sequences remain patent-eligible. Derivative DNA sequences, such as cDNA sequences, remain patent-eligible.

We will continue to follow these interesting developments. If you would like further information or have questions regarding this issue, please do not hesitate to contact us.

Joseph Casino was a partner and Yin Huang is an associate at Amster, Rothstein & Ebenstein LLP. Their practice specializes in intellectual property issues. Our firm drafted Amicus Briefs for the New York Intellectual Property Association at the Federal Circuit and Supreme Court, see http://www.arelaw.com/publications/type/amicus-brief/.