US SUPREME COURT RULES ON BRCA1 AND BRCA2 PATENTS

ASSOCIATION OF MOLECULAR PATHOLOGY v MYRIAD GENETICS – ISOLATED DNA SEQUENCES ARE NOT PATENT ELIGIBLE BUT cDNA IS PATENT ELIGIBLE

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On June 13, 2013, in a unanimous decision, the U.S. Supreme Court ruled that '[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring.'[1]

Genes are encoded as deoxyribonucleic acid ('DNA') which consists of sequences of paired nucleotides. Some of the nucleotide sequences, known as 'exons', contain information that is used to create amino acid chains, the building blocks of proteins. Scientists are able to create sequences that contain exon sequences and omit any DNA segments that do not code for proteins. Such synthetically created DNA sequences are known as "complementary DNA" or "cDNA".

Myriad Genetics, Inc. ('Myriad'), 'discovered the precise location and sequence' of two mutations in what are now known as the BRCA1 and BRCA2 genes.[2] These genes can significantly increase the risk of breast and ovarian cancers. Myriad obtained patents on these genes' typical nucleotide sequence, which enabled it to develop medical tests useful for detecting mutations in these genes and assessing a person's cancer risk.[3] If valid, Myriad's patents would provide it with the exclusive right to isolate an individual's BRCA1 and BRCA2 genes, as well as to synthetically create BRCA cDNA.[4]

Association of Molecular Pathology, medical patients, advocacy groups and various doctors filed a lawsuit seeking a declaration that Myriad's patents are invalid under the Patent Act. Section 101 of the Patent Act permits patents to be issued to '[w]hoever invents or discovers any new and useful … composition of matter' with certain exceptions.[5] Concluding that Myriad's claims were invalid because they covered products of nature, the District Court granted summary judgment to the petitioners.[6] The Federal Circuit initially reversed the District Court's decision. When the case returned on remand in light of *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, 566 U. S. ___, the Federal Circuit again held that both isolated DNA and cDNA are patent eligible subject matter.[7]

An important implicit exception to 35 U.S.C. §101 is that 'laws of nature, natural phenomena, and abstract ideas' are 'basic tools of scientific and technological work' and are not patentable.[8] The Supreme Court used this exception to frame its inquiry: 'whether Myriad's patents claim any 'new and useful … composition of matter,' §101, or instead claim naturally occurring phenomena.'[9]

1) *Association of Molecular Pathology v Myriad Genetics*, 569 U.S. ___ (2013), slip. op. at 1.
2) *Id*. at 4.
3) *Id*. at 4-5.
4) *Id*. at 6.
5) *Id*. at 7.
6) *Id*.
7) *Id*. at 7-8.
8) *Id*. at 11.
9) *Id*.

The Supreme Court held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated. One of central elements of the analysis of whether something is patent-eligible is whether the subject of the patent is new 'with markedly different characteristics from any found in nature'.[10] In the Court's view, Myriad's 'principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes'.[11] In doing so, Myriad neither created nor altered either the genetic information encoded in the BCRA1 and BCRA2 genes or the genetic structure of the DNA.[12] The Court analogized the case at hand to *Funk Brothers Seed Co. v Kalo Inoculant Co.*, 333 U. S. 127 (1948), in which the Supreme Court held that a mixture of naturally occurring strains of bacteria was unpatentable because the patent holder did not alter the bacteria in any way. Here, the Court opined that a 'groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry'.[13] Although finding the location of the BRCA1 and BRCA2 genes was important, useful and required extensive effect, those factors alone were insufficient to render the genes patentable.

The Court examined Myriad's patent descriptions and claims and determined that the patent-eligibility of the claims is not 'saved by the fact that isolating DNA from the human genome severs the chemical bonds and thereby creates a nonnaturally occurring molecule.'[14]

In the Court's view, the claims focused on the information encoded in the genes. The claims were not expressed in terms of chemical composition or the chemical changes associated with isolation of the DNA. The Court also disagreed with Myriad's argument that the United States Patent and Trademark Office's (PTO)'s practice of awarding gene patents is entitled to deference. The Court distinguished a case in which Congress has recognized and endorsed the PTO's position in a subsequent amendment to the Patent Act. Here, the argument was further undermined by the United States Government's arguments in the Federal Circuit and in Supreme Court that isolated DNA is not patent eligible under §101.

Moving on to cDNA, the Supreme Court held that unlike isolated DNA, cDNA is patent eligible because it is not naturally occurring and is not a 'product of nature.' The creation of cDNA in the laboratory creates a molecule solely consisting of exons, which does not occur in nature. The removal of the other DNA to create the cDNA results in something new that is 'distinct from the DNA from which it was derived'.[15] In closing, the Court noted that the case does not implicate method or process claims, 'patents on new applications of knowledge about the BRCA1 and BRCA2 genes',[16] or 'the patentability of DNA in which the order of the naturally occurring nucleotides has been altered'.[17]

10) *Id*. at 12 citing *Diamond v Chakrabarty*, 447 U. S. 303, 310 (1980).
11) *Id*. at 12.
12) *Id*.
13) *Id*.
14) *Id*. at 14.
15) *Id*. at 17.
16) *Id*.
17) *Id*. at 18.