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U.S. Supreme Court Holds Isolated Human Genes May Not Be Patented

Courtenay C. Brinckerhoff (Foley&Lardner LLP) · Tuesday, June 25th, 2013

On June 13, 2013, the U.S. Supreme Court issued its [long-awaited decision](#) in the “ACLU/Myriad” gene patents case (*Association For Molecular Pathology v. Myriad Genetics, Inc.*). In a unanimous opinion authored by Justice Thomas, the Court held that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.” Thus, the Court held that human genes may not be patented. 

Background

This case stems from a declaratory judgment action brought to challenge certain claims in seven patents related to Myriad’s discovery of the BRCA1 and BRCA2 genes, and the correlation between specific mutations in those genes and a heightened risk of developing certain breast and ovarian cancers. In 2010, Judge Sweet of the U.S. District Court for the Southern District of New York invalidated the challenged claims as not patent-eligible under 35 USC § 101. Myriad appealed to the U.S. Court of Appeals for the Federal Circuit, which reversed in a **divided decision** issued July 29, 2011. After the Supreme Court issued its decision in *Mayo v. Prometheus*, it granted *certiorari*, vacated the July 29, 2011 Federal Circuit *Myriad* decision, and **remanded** the case to the Federal Circuit for reconsideration in view of *Mayo*. The Federal Circuit issued its **Myriad remand decision** on August 16, 2012, essentially reiterating its first decision. The Supreme Court **granted certiorari** again, and heard **oral arguments** on April 15, 2013.

The U.S. Supreme Court Decision

The U.S. Supreme Court **granted certiorari** to answer the question, “Are human genes patentable?” The decision focuses on the “product of nature” exception to 35 USC § 101, and cites its 2012 decision in *Mayo v. Prometheus* for its discussion of the “considerable danger that the grant of patents [on laws of nature and natural phenomena] would ‘tie up’ the use of such [basic] tools [of scientific and technological work] and thereby ‘inhibit future innovation premised upon them.’”

Isolated Naturally-Occurring DNA Is Not Patent-Eligible

The Court framed the primary issue before it as whether “uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13 ... renders the

genes patentable.” Throughout its analysis, the Court emphasized that Myriad “did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes.” Considering the claimed subject matter in view of two earlier Supreme Court cases, *Diamond v. Chakrabarty* and *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, the Court found it to be more akin to that of *Funk Brothers*, where a composition of a combination of known microorganisms was held not patentable, than *Chakrabarty*, where a genetically modified microorganism was held patent-eligible. While *Chakrabarty*’s claims were patent-eligible because “[t]he *Chakrabarty* bacterium was new ‘with markedly different characteristics from any found in nature,’” the Court here found that “Myriad did not create anything.”

To be sure, [Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.

The Court emphasized that “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry,” nor does “extensive effort.” Rather, the Court seemed to require, as a condition of patent-eligibility, a new composition of matter that does not have a corollary in nature.

Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes “new . . . composition[s] of matter,” §101, that are patent eligible.

In his decision for the Federal Circuit upholding the validity of these claims, Judge Lourie reasoned that “isolated” DNA is not a product of nature, because “[i]solated DNA has been cleaved (i.e., had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule.” The Supreme Court did not find this difference to be relevant, stating, “Myriad’s claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.” Rather, as the ACLU had emphasized, “the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.”

cDNA Is Patent Eligible

The U.S. Supreme Court held that cDNA is patent eligible, because cDNA is “an exons-only molecule that is not naturally occurring.” (That is, cDNA does not include the regions of non-coding DNA that are present in naturally occurring DNA.) The Court was not persuaded by petitioners’ arguments that cDNA should not be patent eligible because “[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician,” noting that “the lab technician unquestionably creates something new when cDNA is made.”

Fragments Indistinguishable from Naturally Occurring DNA Are Not Patent Eligible

Notwithstanding its holding that cDNA is patent eligible, the Court cautioned that fragments of cDNA that are “indistinguishable from natural DNA” are not. Thus, claim 6 of Myriad’s U.S. Patent 5,747,282, which recites “[a]n isolated DNA having at least 15 nucleotides” of its cDNA sequence could be invalid if there is any 15-nucleotide span of cDNA that is indistinguishable from the naturally occurring sequence.

Method Claims Not At Issue

The U.S. Supreme Court makes clear that its decision does not implicate the patent-eligibility of any type of method claims. The opinion expressly notes that *Myriad* could have sought to patent any “innovative method of manipulating genes” that it invented while searching for the BRCA1 and BRCA2 genes. The Court also points out that “this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes,” such as new diagnostic methods. Of course, the patent-eligibility of such methods would have to be assessed in view of *Prometheus*, but it is noteworthy that the Court points out this option.

Thus, the Court concluded:

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.

USPTO Memo To Examiners

While the U.S. Supreme Court decision was not unexpected, it marks a significant change in U.S. patent law, and reverses the decades-old USPTO practice of granting patents on naturally-occurring substances as long as they are “isolated” from nature. By the end of the day on June 13, 2013, the USPTO had issued a memo to the Examining Corps, advising examiners of the Supreme Court decision. As noted in the memo:

Myriad significantly changes the Office’s examination policy regarding nucleic acid-related technology.

The memo provides this “preliminary guidance”:

As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated. Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101. Claims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally occurring nucleotides has been altered (e.g., a man-made variant sequence), remain eligible. Other claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance in MPEP 2106, Patent Subject Matter Eligibility.

Join Me In A Patent Nation Web Conference

I am pleased to be moderating a Foley & Lardner LLP Patent Nation Web Conference on the *Myriad* decision on Wednesday, June 26, 2013, at 12:00 noon eastern time. Our panelists, the Honorable Paul R. Michel (ret.), United States Court of Appeals for the Federal Circuit, Hans Sauer, Ph.D., Associate General Counsel for Intellectual Property, Biotechnology Industry Organization, and Kevin Noonan, Ph.D., Partner, McDonnell Boehnen Hulbert & Berghoff LLP, and co-founder, Patent Docs, will discuss the intricacies and likely impact of the *Myriad* decision and discuss what it means for the life sciences industry and the evolving area of patent-eligibility jurisprudence as a whole. The program is free but requires **preregistration**.

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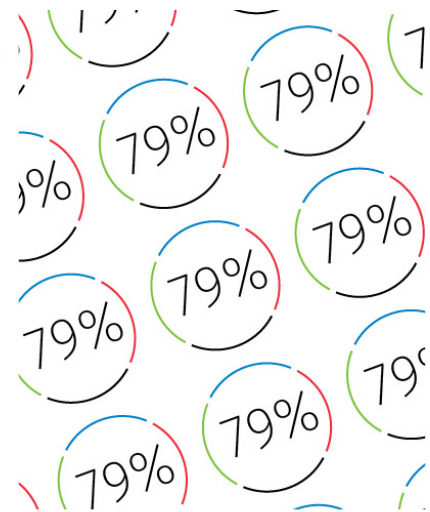
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