Client Alert

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No More Isolated DNA Patents, the Supreme Court Rules

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In a unanimous decision, the U.S. Supreme Court today ruled that naturally occurring, isolated human gene sequences are a product of nature, and thus they are not patent-eligible subject matter under 35 U.S.C. § 101. The Court did, however, hold that synthetically created DNA (cDNA) is patent eligible because it is not naturally occurring. The decision comes as no surprise in light of the Justices' questioning during oral argument this past April.

BACKGROUND

Myriad Genetics, Inc., owns several U.S. patents with claims directed to the human genes BRCA1 and BRCA2. The presence of mutations in these genes correlates to as much as an 80% increase in a woman's risk of developing breast cancer, as well as a 50% increase of developing ovarian cancer. A coalition of groups and individuals brought a declaratory-judgment action over the patentability of the BRCA1 and BRCA2 claims.

On appeal, a divided Federal Circuit panel held that claims covering isolated DNA sequences are patentable subject matter under 35 U.S.C. § 101. In March 2012, the Supreme Court sent the case back to the Federal Circuit for that court to reconsider its decision in light of the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). In *Mayo*, the Supreme Court reaffirmed, in the context of method patents, the principle that laws of nature are not patentable. On remand, the Federal Circuit wholly reaffirmed its prior ruling, with each member of the panel filing a separate opinion.

The challengers petitioned the Supreme Court for review, and the Supreme Court granted certiorari to decide one question: "Are human genes patentable"?

At oral argument in April 2013, a majority of the Justices seemed poised to conclude that naturally occurring DNA was not patent-eligible. The Justices also appeared to agree with the Solicitor General of the United States' middle-road argument that only cDNA should be patentable, so as not to stifle the public's ability to study and use native DNA.

THE OPINION

As expected, the Supreme Court ruled unanimously that naturally occurring human DNA is a non-patent eligible product of nature, but also concluded that synthetically created cDNA is patent-eligible.[1]

The Court began by providing a history of the study of genetics, explaining the methods by which individual DNA sequences are identified and isolated. The Court concluded that the study of genetics "can lead to valuable

1 In a footnote, the Court also affirmed the Federal Circuit's decision that Dr. Ostrer, the NYU researcher that was "ready, willing and able" to continue BRCA testing should Myriad's patents be invalidated, had standing to sue under *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). *Slip op.* at 10 n.3.

medical breakthroughs," setting the tone for an opinion woven through with concern about stifling such innovation.[2]

The Court went on to describe Myriad's composition claims and the methods it employed to isolate the BRCA1 and 2 genes, noting that "[t]he location and order of the nucleotides existed in nature before Myriad found them" and thus "Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 gene."[3]

On the standard for patent-eligibility, the Court re-affirmed its holding in *Mayo* that laws of nature, natural phenomena and abstract ideas—the three exceptions to patent-eligibility—"are the basic tools of scientific and technological work that lie beyond the domain of patent protection." [4] Without these exceptions, the Court explained, "there would be considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'" [5] That, the Court concluded, "would be at odds with the very point of patents, which exist to promote creation." [6]

Against this backdrop, and citing its decision in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), the Court concluded that Myriad's composition claims "fell squarely within the law of nature exception." [7] The Court emphasized that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." [8] It held that "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,' that are patent eligible." [9]

Distinguishing Myriad's claims from those at issue in *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980), the Court again emphasized that "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention." [10]

BREAKING THE BONDS

The Court rejected the Federal Circuit's conclusion that isolated DNA is patent eligible because it requires "breaking the covalent bonds that connect the DNA to the rest of the individual's genome."[11] It explained that "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. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes." [12] The Court pointed out that Myriad likely would take the position that its patents were infringed even if the molecule cleaved from native DNA

2 *Slip op*. at 4.

3 *Slip op*. at 12.

4 *Id.* at 11.

5 *Id*.

6 *Id*.

7 *Slip op*. at 13.

8 *Id*. at 12.

9 *Id*.

10 *Slip op*. at 12.

11 *Id*. at 8, 14-15.

12 *Id*. at 14-15.

contained additional nucleotides—it would still contain within it the same genetic *sequence*, even if it was not the exact same molecule Myriad "invented." [13] The Court did not squarely address the Federal Circuit's reasoning that the human intervention of breaking the covalent bonds results in something that is "markedly different" from naturally occurring DNA.

LONGSTANDING PTO PRACTICE

Myriad's argument that the Court should defer to the Patent and Trademark Office's longstanding practice of granting gene patents also fell on deaf ears. The Court found that Myriad's analogy to *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), was not apt, since in *J.E.M.*, the Supreme Court deferred to the PTO's practice of granting patents to new plant breeds in part because it had been supported by Congress through subsequent legislation. On the issue of patent eligibility of human genes, the Court concluded, Congress has been silent. It examined the statute cited by Myriad and found that Congress had not even mentioned genes, "much less isolated DNA." [14] In addition, the Court noted that the United States took the position that isolated DNA is not patent eligible, and that the PTO's practice was not "a sufficient reason to hold that isolated DNA is patent eligible." [15] As a result, the Court concluded the PTO's practice of granting isolated DNA patents for over 30 years could not save Myriad's claims.

cDNA SURVIVES

Also as expected based on the Justices' questioning during oral argument, the Court agreed with the position advocated by the Solicitor General and concluded that synthetically created cDNA is patent eligible. Unlike isolation of a naturally occurring gene sequence, the Court explained, "creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring." [16] As a result, a lab technician "unquestionably creates something new when cDNA is made."[17] The Court expressed no opinion on whether Myriad's cDNA claims would meet any of the other statutory requirements for patentability under 35 U.S.C. § 101 *et seq.* [18]

THE SCOPE OF THE DECISION

The Court was careful to delineate the scope of its decision.[19] First, the Court pointed out that no method claims were before it. It stated that the techniques Myriad used to isolate the BRCA1 and 2 genes were well known in the art. Had Myriad discovered "an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent." [20] The Court also noted that its decision did not apply to new applications of the information learned about BRCA1 and 2, nor to DNA sequences in which the order of naturally occurring nucleotides had been altered. [21]

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13 *Id*. at 15.

14 *Slip op*. at 15.

15 *Id*. at 16.

16 *Slip op*. at 16.

17 The Court did note that a "very short series of DNA may have no intervening introns to remove when creating cDNA" and thus "a short strand of cDNA may be indistinguishable from natural DNA," thereby creating a possible exception to its ruling. *Slip op*. at 17.

18 *Id*. at 17 n.9.

19 *Slip op*. at 17.

20 *Id*.

21 *Id*. at 17-18.

CONCLUSION

The Supreme Court's decision finally brings closure to the question of whether isolated human DNA sequences constitute patent-eligible subject matter. A period of uncertainty will likely follow the decision as the biotechnology industry digests it and assesses the impact of the decision on patent estates. But going forward, the new rule regarding isolated DNA claims should create certainty for the industry.

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