Life Sciences Alert: Unanimous Supreme Court Decision in *Ass'n for Mol. Pathology v. Myriad Genetics, Inc.*

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Today, a unanimous Supreme Court decision in *Ass'n for Mol. Pathology v. Myriad Genetics, Inc.*, held that Myriad's claims directed to "a naturally occurring segment of … [DNA]" are not patent eligible despite their "isolation from the rest of the human genome," but that claims directed to "synthetically created … [cDNA] remain patent eligible. 569 U.S. ___ (2013), Slip Op. at 1. In so holding, the Court continues its efforts to maintain "a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur invention." *Id.* at ___, Slip Op. at 11 (internal citations omitted).

At issue in *Myriad* is the patent eligibility statute, 35 U.S.C. § 101, which provides:

> Whoever invents or discovers any new and useful … composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. §101. *Myriad* addresses the scope of the judicially-created "product of nature" exception to broad statutory language, one of a trio of such exceptions (laws of nature, natural phenomena and abstract ideas). These exceptions exclude from patent eligibility subject matter considered to be "the basic tools of scientific and technological work" due to the "considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'" Slip Op. at 11 (internal citations omitted).

Relying on two precedents, *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), and *Diamond v. Chakrabarty*, 447, U.S. 303 (1980), the Court outlined the boundaries of the product of nature exception to patent eligibility. In *Funk Bros.*, the Court held that a claim to a composition of several bacteria that did not inhibit each other, and which were useful for improving nitrogen utilization by certain plants was patent ineligible. It noted that the bacteria were not altered by the patent holder and that combined bacterial isolates performed the same "nitrogen fixing" function as they did naturally. Slip Op. at 13.

Chakrabarty involved claims directed to an engineered "oil eating" bacteria that the Court upheld as patent eligible because they were directed to "a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity 'having a distinctive name, character [and] use.'" Slip Op. at 12.

In holding as patent-ineligible Myriad's claims to isolated nucleic acid molecules having naturally occurring sequences (*i.e.*, genomic DNA sequences), the Court declined to adopt the Federal Circuit's reliance on "isolating" the molecules, subtle chemical differences between the isolated molecules and their naturally-occurring counterparts residing within human chromosomes, or the extensive work Myriad carried out to identify the precise start and end of the BRCA1 and BRCA2 genes, which when mutated, greatly increase cancer risk. The Court noted that such chemical differences formed no part of the claim, and that the basic informatics function of the molecules was the same. "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…. [Myriad's] claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule." Slip Op. at 14-15(emphasis in original).

Nor did the Court give deference to the long-standing PTO practice of granting such claims. It noted that Congress had not endorsed the views of the PTO in subsequent legislation, and pointed out the United States's arguments as *Amicus Curiae* before the Federal Circuit and the Supreme Court that isolated (genomic) DNA should not be patent eligible. Slip Op. at 16.

In upholding the patent eligibility of cDNA molecules, DNA copies made from "messenger RNA," the Court noted that these sequences differ from those that occur naturally in the genome because they lack "introns" (non-coding portions of the genomic sequence that are removed during messenger RNA processing.) "Petitioners concede that cDNA differs from natural DNA in that 'the non-coding regions have been removed….' As a result, cDNA is not a 'product of nature' and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA." Slip Op. at 16-17.

The Court also noted that this decision did not implicate Myriad's ability to exploit claims directed to innovative methods of searching for genes, or for methods of applying knowledge about the BRCA1 and BRCA2 genes. Quoting Judge Bryson's Federal Circuit opinion:

> '[A]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.'

Slip Op. at 17-18.

The Court also made clear that its decision did not reach the question of "patentability of DNA in which the order of the naturally occurring nucleotides has been altered." *Id*. at 18.

What *Myriad* leaves unanswered is the impact of the Court's prior decision in *Mayo v. Prometheus*, 132 S. Ct. 1289 (2012), (which held patent ineligible as a law of nature the correlation between a drug metabolite level and the need to adjust dosages upward or downward) on the unasserted Myriad method claims directed to methods of assessing cancer risk based on the presence of certain gene mutations in the BRCA1 or BRCA2 genes. Also unanswered is the reach of this decision to other patent claims that rely on "isolation" as the basis for patent eligibility. Many useful drug products are isolated forms of naturally-occurring proteins and small molecules. To the extent *Myriad* calls into question the rationale of*Parke-Davis & Co. v. H.K. Mulford Co.*, 196 F. 496 (2d Cir. 1912), recognizing isolated or purified naturally occurring molecules as a basis for patent eligibility, the validity of claims directed to isolated recombinant proteins (*e.g.*, blood clotting factors, insulin, epogen) may also be called into question.

While the *Myriad* decision does disrupt the established expectations of the biotechnology community, industry executives and investors should take comfort in the fact that the Court provides guidance on strategies to preserve the patent eligibility of major classes of inventions important to the industry. In particular, the Supreme Court makes clear that inventions directed to the application of knowledge regarding naturally occurring DNA sequences may still be patent eligible. Furthermore, patent claims reciting molecules that differ chemically from their naturally occurring counterparts (labeled nucleic acids, recombinant nucleic acids, transformed host cells, *etc.*) may be another way to fall outside the subject matter now proscribed by today's decision.

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