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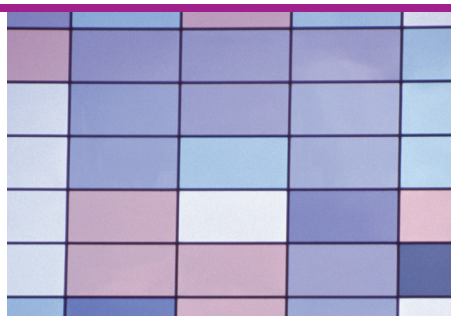

What Does the Future Hold in View of the Supreme Court Decision on Isolated Genes and cDNA?

In a long-anticipated ruling, the US Supreme Court acknowledged Myriad Genetics' contribution in discovering the location and sequence of the BRCA1 and BRCA2 genes but concluded that "Myriad did not create anything" when it isolated those genes. *Ass'n for Molecular Pathology* v. *Myriad Genetics, Inc.*, No. 12-398, slip op. at 12 (US June 13, 2013). The Court did, however, find that laboratory-engineered complementary DNA (cDNA) remains patent-eligible under 35 U.S.C. § 101. The Court explicitly stated that it did not address, among other things, the patent-eligibility of DNA sequences in which the naturally occurring nucleotides have been scientifically altered.

The Issue

Before the Supreme Court were Myriad's composition claims relating to isolated DNA sequences for the BRCA1 and BRCA2 genes and synthetically created cDNA related to these genes. Mutations in these genes are associated with a predisposition to breast and ovarian cancer.

Under the Patent Act, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor...." There are three judicially created exceptions to eligibility under § 101: laws of nature, natural phenomena and abstract ideas. These exceptions have been interpreted also to exclude as ineligible mental processes and products of nature. Here, the issues were whether i) isolated, naturally occurring genes and the information they encode fall under the "products of nature" exception, and ii) the related cDNA to these genes is patent-eligible.

Human DNA Sequences Are "Products of Nature" and Therefore Not Patent-Eligible

In an opinion delivered by Justice Thomas,[1] the Supreme Court reversed in part the Federal Circuit, holding that isolated coding sequences of DNA as found in nature are not eligible for patent protection because they are the "products of nature." Also ineligible are Myriad's claims to sequences as short as 15 nucleotides within the genes. The Court, however, affirmed the Federal Circuit in holding that cDNA is patent-eligible when cDNA is wholly human-made and distinct from the DNA from which it was derived.[2]

1 Roberts, C.J., and JJ Kennedy, Ginsburg, Breyer, Alito, Sotomayor and Kagan joined the opinion. Justice Scalia joined in part and filed a short opinion concurring in part and concurring in the opinion.

2 The Court recognized that a short strand of cDNA may be indistinguishable from natural DNA. Slip op. at 17.

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The Court rejected the argument that the PTO's past practice of granting gene patents deserved deference, noting that Congress had not endorsed the PTO's views and, in fact, the United States argued before the Federal Circuit and the Supreme Court that isolated DNA was *not* patent-eligible under § 101. In a footnote, the Court asserted that any reliance interests arising in the industry from that practice are better directed to Congress.

What Does the Future Look Like?

In *Myriad,* the Court purports to draw a bright line categorically excluding isolated, naturally occurring DNA sequences from patent protection. To fully appreciate the repercussions of this decision, as the Court expressly stated, "[i]t is important to note what is *not* implicated by this decision," namely:

- **The decision does not address any method claims.** Myriad did not advance any innovative methods it may have employed to locate and identify the BRCA1 and BRCA2 genes.
- **Myriad did not describe or claim any "new *applications* of knowledge" about the two genes at issue.** An example of such an application might involve novel therapeutic approaches that address the presence of these genes.

Slip op. at 17-18. What is clear is that *Myriad* does not foreclose all patents related to DNA sequences. *Myriad* does, however, represent a significant departure by the United States from the practice of several of its major trading partners. The European Union, Canada, Australia and Japan are among jurisdictions that have recognized the patent-eligibility of isolated sequences of DNA.

The Supreme Court has been active in reviewing patent cases in recent years. In *Myriad*, it again overrules the Federal Circuit (at least in part) and is dismissive of more than thirty years of PTO practice. Nevertheless, the Federal Circuit has clearly struggled in applying § 101, and its recent decisions have been characterized by inconsistency, confusion and a lack of consensus among judges. It remains to be seen whether the result in *Myriad* leads to greater coherence or greater confusion.

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