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Supreme Court Rules That Naturally Occurring DNA is not Eligible for Patent Protection

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What you need to know:
In the long-awaited decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.,* the US Supreme Court yesterday held that naturally occurring, yet "isolated" DNA, is not eligible for patent protection, but what it called "synthetic" DNA (*eg*, cDNA) is patent eligible.

What you need to do:
Although the Court attempted to draw a bright line between patent-eligible "synthetic" cDNA and patent-ineligible "isolated" DNA, differences found by the Court between these two forms of DNA are not easily resolved, given the technology utilized to generate these different forms. Although uncertainty remains, companies and research centers involved in gene discovery or genetic testing should consider revisiting their patent strategies in view of the *Myriad* decision.

Patent Eligible Subject Matter

Section 101 of the Patent Act provides:

> "Whoever 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, subject to the conditions and requirements of this title."

However, there are several exceptions for patent-eligible subject matter under §101. Laws of nature, natural phenomena and abstract ideas are not eligible for patents. Rather, these are considered to be "basic tools of scientific and technological work," the patenting of which would "inhibit future innovation premised upon them." As the Court recognized in this case, "patent protection strikes 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'."

Myriad Patents

At issue in this case was the patent eligibility of patents owned by Myriad, which were directed to "isolated" DNA "coding for" a particular protein (the BRCA1 protein) and were also directed to "synthetic" DNA that also coded for the BRCA1 protein.

Most of the Court's opinion focused on the question of the patent eligibility of "isolated" DNA. The Court framed the issue as "whether a naturally occurring segment of DNA is patent eligible…by virtue of its isolation from the rest of the human genome." In arriving at its decision that such DNA is not eligible for patenting, the Court first characterized Myriad's "principal contribution" as "uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13."

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The Court distinguished this "contribution" by Myriad from the invention at issue in the seminal biotechnology patent case, *Chakrabarty*. In *Chakrabarty*, the Court held that bacterium engineered to have the ability to degrade oil (by inserting foreign DNA into the bacterium) was patent eligible, because it was not a naturally occurring composition. Unlike Chakrabarty's bacterium, the Court here found that "Myriad did not create anything." Rather, the Court likened Myriad's invention to the patent-ineligible invention of Funk Brothers, where a mixture of naturally occurring bacterial strains was found not to be patent eligible because the bacteria were not altered in any way.

While acknowledging that Myriad "found an important and useful gene," the Court went on to state that "separating that gene from its surrounding genetic material is not an act of invention" (emphasis added). And although Myriad's patents described the "iterative process" of discovery used by Myriad to narrow the possible locations for the BRCA1 and BRCA2 gene sequences, the Court stated that "extensive effort alone is insufficient to satisfy the demands of §101."

Discussing the chemical changes that occur when DNA is isolated from the human genome, the Court stated that although this isolation "severs chemical bonds and thereby creates a nonnaturally occurring molecule," the Court found that Myriad's patent claims were not expressed "in terms of chemical composition." Rather, the claims focused on the "genetic information encoded in the BRCA1 and BRCA2 genes."

The Court then turned to the question of whether "synthetically created [cDNA], which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins" is eligible for patenting. In finding that synthetic cDNA is patent eligible, the Court summarily stated that the creation of cDNA results in a molecule that includes only coding regions (exons) that are not naturally occurring and is distinct from the DNA from which it was derived. Thus, the Court held that cDNA is not a "product of nature" and is patent eligible.

Finally, the Court addressed what was not decided in this case. First, this decision did not implicate method claims. The Court stated that "[h]ad Myriad created an innovative method of manipulating genes…it could have sought a method patent." Second, this case did not involve new applications of knowledge about the BRCA1 and BRCA2 genes. Further, the decision did not consider the patentability of DNA in which the order of naturally occurring nucleotides is altered.

Although the Court attempted to establish a bright line rule for the patent eligibility of DNA, uncertainty remains. For example, the Court's rationale for deciding the patent eligibility of synthetic cDNA is equally applicable to Myriad's "isolated" DNA. Just as cDNA includes only coding regions, so too does Myriad's claimed "isolated" DNA. As the Court pointed out, claim 1 of Myriad's US Patent No. 5,747,282 recites "[a]n isolated DNA coding for a BRCA1 polypeptide" having a particular amino acid sequence. Thus, Myriad's claimed "isolated" DNA may include only coding regions, exactly like Myriad's claimed synthetic cDNA. Such inconsistencies do not resolve, but rather increase, the uncertainty in this area of biotechnology. Moreover, the decision provides no guidance on the patentability of other molecules produced in nature, including protein therapeutics, or even small molecule drugs.

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