SUPREME COURT RULES ON PATENTABILITY OF GENES IN MYRIAD

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- Isolated genes are not eligible for patent protection.
- cDNA is patent eligible under § 101.
- Patent eligibility requires an “act of invention.”
- United States Patent and Trademark Office issues guidelines for examination in view of Supreme Court decision.

The Holding
On Thursday, June 13, 2013, in a narrow, but historic decision, the Supreme Court held, in Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad), that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it had been isolated” from the rest of the human genome. Further, the Court held that a type of synthetic DNA, complementary DNA (cDNA), “is patent eligible because it is not naturally occurring.”

The Facts
As explained by the Court, “genes,” which are “sequences of DNA nucleotides [deoxyribonucleic acid], contain the information necessary to create strings of amino acids, which in turn are used in the body to build proteins.” Myriad Genetics, Inc. (Myriad) identified two genes, human breast cancer susceptibility genes 1 and 2 (BRCA1 and BRCA2), in which specific defects in the sequence of nucleotides, known as mutations, carry a significantly increased risk of breast cancer. In isolated form, BRCA1 and BRCA2 are very useful in screening for patients who carry mutations in those genes that indicate an increased likelihood of developing breast cancer. Myriad obtained several patents related to isolated DNA coding for short segments of proteins, known as polypeptides, expressed by BRCA1 and BRCA2 genes. Myriad also obtained patents on complementary DNA, known as cDNA, which is synthesized from messenger RNA (mRNA) and is the sequence of DNA that codes for proteins. Except as a consequence of cellular attack by retroviruses, cDNA does not exist in nature. It is often, however, usefully employed to substitute for isolated naturally-occurring DNA. Myriad’s patents excluded others from isolating or employing the isolated BRCA1 and BRCA2 genes, and related cDNA, to conduct diagnostic tests on patients without a license and payment of substantial fees.

The Opinion
The statutory basis for the Court’s decision was under Section 101 of Title 35 of the United States Code that provides, in part: “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.” Although isolated DNA would be a “composition of matter,” the Court held that a naturally-occurring sequence of nucleotides of isolated DNA fall within the well-established judicially-created exceptions to eligibility for patent protection, namely, laws of nature, natural phenomena, and abstract ideas. These exceptions exist because, as recited by the Court, “they are the basic tools of scientific and
technological work” and, “without this exception, 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.’” Quoting an earlier Supreme Court case, *Diamond v. Chakrabarty*, which upheld the validity of a patent claiming bacteria with “markedly different characteristics from any found in nature,” the Court stated that “products of nature are not created,” but, rather, are “free to all men and reserved exclusively to none.”

Realizing that “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” the Court stated that there is a “delicate balance between ‘creating incentives that lead to creation, invention, and discovery’ and ‘impeding the flow of information that might permit, indeed spur, invention.’” (Quoting *Chakrabarty*) As applied to Myriad’s isolation of naturally-occurring nucleotide sequences, the Court held that the methods employed to isolate genetic material are well-known and, therefore, use of those methods to break covalent chemical bonds linking Myriad’s sequences to nucleotides at either end to thereby obtain those sequences in isolated form is “not an act of invention.” Rather, the Court found that “Myriad’s principal contribution was uncovering the precise location of the genetic sequence of the BRCA1 and BRCA2 genes and identifying the mutations of those genes that increase the risk of breast cancer, but that “discovery, by itself, does not render the BRCA genes ‘new...compositions of matter,’ § 101, that are patent eligible.” The Court stated that Myriad’s “extensive effort alone is insufficient to satisfy the demands of § 101.” The Court also was not swayed by arguments that a decision to invalidate isolated genetic material as patent-eligible subject matter under § 101 would upset “reliance interests arising from [past] PTO determinations,” stating that such concerns “are better directed to Congress.”

In contrast to isolated genes, the Court held that “creation of a cDNA sequence...results in...[a] molecule that is not naturally occurring.” Instead, “the lab technician unquestionably creates something new when cDNA is made,” and, therefore, according to the Court, “cDNA is not a ‘product of nature’ and is patent eligible under § 101.”

Finally, the Court was careful to limit the scope of its opinion to isolated genes and cDNA. Other claims employing isolated genetic material, such as “an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes” were not embraced by the Court’s decision. Similarly, the Court found that “[s]cientific alteration of the genetic code presents a different inquiry” and, therefore, expressed “no opinion about the application of § 101 to such endeavors,” stating: “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.”

**The United States Patent and Trademark Office Responds**

On the same day that the Supreme Court handed down its opinion in *Myriad*, the United States Patent and Trademark Office (Patent Office) issued a memorandum, directing Examiners to “reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not.” The Patent Office further stated that non-naturally occurring nucleic acids, such as cDNA, remains patent eligible, and that methods employing naturally occurring nucleic acids may give rise to “eligibility issues” and should be examined under existing Patent Office guidelines.
Implications and Conclusions

Despite the intended limited scope of the Court’s decision, the subject matter of many patent claims in the biotechnology field “manipulate” isolated genes, and patentability of those claims relies on the discovery of the function of the genes that renders their isolation useful. If isolated genetic material cannot be considered to embody an “inventive concept” as a matter of law, it may be that the Supreme Court’s decision will impact the patentability of such “manipulations” and the “delicate balance” alluded to by the Court in ways that are unintended.

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