Supreme Court Decision on Gene Patents

Supreme Court Holds Naturally Occurring, Isolated DNA Is Not Patentable, While Synthetic DNA Is Patentable

SUMMARY
In a decision having implications for the healthcare, biotechnology, and pharmaceutical industries, on June 13, 2013, the U.S. Supreme Court held that a naturally occurring DNA sequence is not patentable simply because it has been isolated from surrounding genetic material. Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. ___ (2013). The Court observed that Myriad’s claims to naturally occurring, isolated DNA sequences are primarily claims to the “information contained in the genetic sequence,” and found such sequences to be unpatentable “products of nature” notwithstanding minor changes in chemical composition as a result of the isolation process. While acknowledging the importance of discovering the location and sequence of useful genes, the Court explained that “groundbreaking, innovative, or even brilliant discovery” does not render a product of nature patentable.

The Court also held, however, that synthetic “complementary” DNA (cDNA) – which contains only the protein-coding nucleotides of a DNA sequence and omits the non-protein coding sections – is not naturally occurring and constitutes a “new and useful . . . composition of matter” that is patent eligible as long as the claimed cDNA sequence does not occur naturally.

BACKGROUND
In Association for Molecular Pathology v. Myriad Genetics, Inc., the Court explained that Myriad Genetics had discovered the precise location and sequence in the human genome of breast cancer susceptibility genes 1 and 2 (BRCA1 and BRCA2). Following that discovery, Myriad Genetics obtained a number of patents, including the three patents at issue, which claimed compositions of matter consisting of (1) isolated DNA sequences for naturally occurring BRCA1 and BRCA2, (2) isolated DNA sequences for cDNA versions of BRCA1 and BRCA2, and (3) all isolated DNA sequences that include any series of 15 nucleotides that appear in (1) or (2). A number of organizations challenged those patent claims on the basis that the subject matter of the claims was not patent eligible under 35 U.S.C. § 101.

THE SUPREME COURT’S DECISION

In Myriad Genetics, the Court, citing with approval both Mayo and Chakrabarty, resolved two issues related to Myriad’s disputed patent claims: (1) whether naturally occurring DNA sequences are patent eligible under 35 U.S.C. § 101 when they have been isolated from surrounding genetic material; and (2) whether cDNA is patent eligible under 35 U.S.C. § 101.

As to the first issue, the court noted the undisputed fact that Myriad “did not create or alter any of the genetic information” in the isolated BRCA1 or BRCA2 genes, and the genetic information in the isolated state is the same as the genetic information in its natural state. The Court then explained that Myriad’s “principal contribution” was discovering the location and sequence of the BRCA1 and BRCA2 genes in the human genome, and held that no matter how brilliant or useful that discovery, the genetic information contained in the DNA sequences is an unpatentable product of nature.

The Court also addressed Myriad’s argument (and the underpinning of the Court of Appeals majority decision, which, in this respect, was reversed) that isolating the DNA sequence from surrounding genetic material severs chemical bonds and thereby creates an isolated molecule that does not exist in nature. In response, the Court observed that Myriad’s claims were “concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule” or with chemical changes to the DNA molecule as a result of isolation. Since Myriad’s patent claims at issue focus on naturally occurring genetic information, and not the chemical characteristics of the isolated DNA molecule, the Court found that minor chemical changes as a result of isolation were irrelevant to the question of patent eligibility. The Court thus concluded that naturally occurring, isolated DNA sequences are products of nature that are not entitled to patent protection under 35 U.S.C. § 101.

With respect to the second issue considered by the Court – the patent eligibility of cDNA – the Court explained that cDNA “does not present the same obstacles to patentability as naturally occurring, isolated DNA segments.” While acknowledging that cDNA retains the naturally occurring coding sections of DNA, the Court explained that cDNA is distinct from naturally occurring DNA because cDNA eliminates from the claimed nucleotide sequence the nucleotides that are not related to protein production. By eliminating non-coding nucleotides, cDNA consists of a sequence that does not occur in nature. The Court therefore
concluded that cDNA is patent eligible under 35 U.S.C. § 101. The Court, however, expressed no opinion on whether cDNA meets the other statutory requirements for patentability, such as novelty/obviousness, and the Court noted that short segments of cDNA that do not alter the DNA sequence as it occurs in nature are not patent eligible.

Finally, the Court highlighted that the *Myriad* holding is narrow and does not concern (1) method claims, such as an “innovative method of manipulating genes,” (2) patents on new applications of knowledge about the BRCA1 or BRCA2 genes, or (3) claims for DNA sequences in which the “order of the naturally occurring nucleotides has been altered.” The Court emphasized that it “merely” held that “genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.”

**IMPLICATIONS**

*Myriad* is a mixed result. The decision eliminates patent protection for naturally occurring, isolated DNA sequences, which are claimed in many patents. While the decision is likely to invalidate numerous patents that claim naturally occurring DNA, and thus likely reduce the costs of certain diagnostic tests, its implications are otherwise uncertain. The decision may very well cause numerous patentees to pursue narrower re-issued claims, cause a renewed emphasis on trade secret protection of discoveries, and/or alter the way in which related genetic-discovery patents are prosecuted. This uncertainty was reflected in the stock market, as Myriad’s shares rose in the hours following the release of the Court’s opinion, but eventually dropped and closed down 5.6% at the end of the day.

As for the healthcare issue at the heart of the challenge to Myriad’s patents – whether an inventor can claim exclusivity over tests to examine potential genetic mutations that rely on an examination of a particular nucleotide sequence (and thereby limit access and reduce cost-lowering competition in conducting such tests) – it is clear that infringement assertions based on claims to a DNA sequence that occurs in nature will no longer impede diagnostic testing by others. Although the decision leaves open the possibility of claimed inventions that improve such diagnostic tests (e.g., the efficacy or efficiency of such tests), it is likely that the immediate effect of the decision will be to lower the cost of such diagnostic tests and make them more widely available. The significance of the opinion may depend, at least in part, on the degree to which such diagnostic tests rely on the creation of cDNA, which is not naturally occurring. Since cDNA remains patent eligible following *Myriad*, the owner of a patent claiming isolated cDNA for a particular gene might still have significant power to exclude others from practicing diagnostic tests that rely on the creation of such cDNA.

While the holding of *Myriad* is, on its face, narrow and specifically affects only the patentability of naturally occurring, isolated DNA, the decision may be used to attempt to invalidate any chemical composition or pharmaceutical that occurs in nature. The success of such challenges remains to be seen. *Myriad*’s holding does not necessarily resolve the patentability of naturally occurring, isolated macromolecules.
other than DNA. Patent composition claims for naturally occurring, isolated macromolecules – such as isolated insulin or adrenaline – for which chemical changes to the molecule as a result of isolation are more significant may still be valid following Myriad.

Finally, beyond the fields immediately impacted by the Court’s holding, the Myriad decision may be cited in support of a lower level of deference to the USPTO’s determinations of patent eligibility. Myriad had asked the Court to defer to the USPTO’s past practice of awarding gene patents, a significant factor to one of the judges on the Court of Appeals that decided the case. Based largely on the position of the Solicitor General, who disagreed with the position of the USPTO, the Court suggested that little deference was warranted because the USPTO’s position on eligibility had not been endorsed by Congress.
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