

Update on Supreme Court Patent Case: Association for Molecular Pathology v. Myriad (2013)

June 17, 2013

ONE MINUTE CAPSULE

Isolated DNA from a natural source is not eligible for patenting in the United States, but cDNA can be patent eligible except in situations where short stretches of cDNA may be indistinguishable from naturally occurring DNA. Patent claims to just isolated DNA from a natural source are therefore generally invalid. Other gene-related types of patent claims may still be valid, and thus commercially relevant patent protection for gene-related inventions or discoveries may be possible. The impact of this case may be widespread, stretching from pharmaceuticals to diagnostics, from agribusiness to biofuels, and beyond.

MORE IN DEPTH

According to the U.S. Supreme Court, DNA is different! More specifically, isolated DNA as a composition of matter is apparently different than other chemical compounds which are isolated or purified from a complex mixture of substances, in the context of assessing whether the composition is eligible for patenting. On June 13, 2013, the Supreme Court released its decision in the case, *Association for Molecular Pathology v. Myriad*, 569 U. S. ____ (2013).

The result of this decision is that Myriad's patent claims to compositions of isolated DNA from a natural source are invalid under the U.S. patent laws, because the claims cover a product of nature. A product of nature is considered subject matter which is not eligible for a patent under the statutory requirement of 35 U. S. C. §101. On the other hand, Myriad's patent claims to synthetically created DNA known as complementary DNA (cDNA) represent subject matter that is patent eligible. This patent eligibility of cDNA may be further constrained, though, in situations involving short stretches of cDNA; these may be indistinguishable from natural DNA and thus unpatentable.

As stated succinctly in the case syllabus, the Court held: "A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring."

Section 101 of the U.S. patent laws states, "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 therefore, subject to the conditions and requirements of this title" (emphasis added). The Court acknowledged, however, that "We have 'long held that this provision contains an important implicit exception [:] Laws of nature, natural phenomena, and abstract ideas are not patentable.'" See *Association for Molecular Pathology v. Myriad*, 569 U. S. ____ (2013) (citing *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U. S. ____ (2012)).

For an estimated thousands of patents issued over the last three decades by the United States Patent and Trademark Office which have claims drawn to isolated DNA, this decision represents a significant change. While previously those claims would have been presumed valid, this decision appears to render all such claims invalid. From the perspective of the marketplace, the invalidity of such patent claims could create freedom to operate space for certain activities pertaining to compositions of isolated DNA, such as obtained from patient samples. In the *Myriad* case, the key activities centered around detecting whether the patient has a particular sequence or mutation associated with breast cancer. Importantly, though, the case may not adversely impact other types of patent claims. These other types of claims could include methods of use of isolated DNA, methods of manipulating DNA, new applications of knowledge about a gene, and compositions where the naturally occurring nucleotides have been altered. Such other types of claims were not at issue in the *Myriad* case. Thus innovators may still be able to obtain commercially relevant protection for inventions or discoveries relating to genes.

How is isolated DNA different than other isolated chemical materials, and what was the basis for the recent *Myriad* decision?

Here, compositions of isolated DNA were considered the same as the DNA existing in nature (such as in the human body for the BRCA1 and BRCA2 genes with relevance for breast cancer). The Court emphasized that isolating DNA from the surrounding genetic material of the natural source does not change the information-transmitting quality of that DNA. The Court stated, "It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes...Nor did Myriad create or alter the genetic structure of DNA."

It seems that either the Court considers isolated DNA in a fundamentally different light in comparison to other chemical compounds, or it draws a distinction in the treatment of the claims depending on how the claims are presented ("Myriad's claims are simply not expressed in terms of chemical composition"). While there is a hint of support for the latter view, the former view appears to receive prominent attention in the case. Isolated DNA may be considered fundamentally different than other chemical compounds because of its unique attribute of having the same genetic informational content as that of the DNA in a naturally-occurring state (Myriad's "claim is concerned primarily with the information contained in the genetic



sequence, not with the specific chemical composition of a particular molecule").

This essentially identical correspondence of the informational aspect of DNA, whether in isolated form or as found in the natural material, may contrast with the properties of another famous example of a chemical compound. A cancer fighting compound was discovered upon isolation from the bark of the Pacific yew tree of the northwestern United States. The resulting purified chemical compound of taxol has different properties, e.g., therapeutically and pharmacologically, than a crude naturally occurring form. In one sense, the isolation or purification changed the properties of the material, but did the structure of taxol itself change? The *Myriad* case raises intriguing questions for patent eligibility of subject matter in other scenarios such as the hypothetical discovery of a new drug like taxol.

At this point, the U.S. Supreme Court has demonstrated active interest in the question of what subject matter is patent eligible. Although the words "policy" or "pre-emption" do not appear explicitly in the *Myriad* case, the Court states that it is concerned with the "considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'" The Court recognized that patent protection "strikes 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'" (citing *Mayo v. Prometheus*). In this balance, isolated DNA is different than other chemical compounds. The case concludes, "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 impact of this case may be widespread, stretching from pharmaceuticals to diagnostics, from agribusiness to biofuels, and beyond. The outcome of this case illustrates that it can be valuable to invest in the planning and review of claim strategies, analysis, and taking a comprehensive approach to the development and assessment of new and existing patent assets in intellectual property portfolios. We will continue to monitor this developing area of the United States patent laws regarding what subject matter is eligible for patenting.

Lathrop Gage LLP has a strong team of practitioners, having a variety of deep backgrounds, serving clients in the life sciences. Please feel welcome to contact us if you would like to discuss this case or any aspect of intellectual property law.

Links to case opinion via the U.S. Supreme Court website:

<http://www.supremecourt.gov/opinions/slipopinions.aspx?Term=12> (search for "Myriad"); http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf