

## Haynes and Boone's Newsroom

### Not a Biotech Company? What Myriad Might Mean For You

06/18/2013

Lauren E. Sprouse, Jeffrey A. Wolfson

By Lauren Sprouse and Jeffrey A. Wolfson<sup>1</sup>

You've seen all the articles about the Supreme Court's decision in *Assoc. for Molecular Pathology v. Myriad Genetics Inc.* and the end of DNA patents, but what does this mean outside the biotech world? It means more insight into patent eligibility under 35 U.S.C. § 101. While *Myriad* does not affect business method and software patents, it is indicative of the general trend of the Supreme Court with respect to the threshold required to obtain a valid patent. Also, the decision may be directly applicable to composition-type claims directed to materials that occur in nature - even if such materials were isolated through human effort.

In a completely surprising outcome, the Supreme Court's decision in *Myriad* was authored by the Justice who rarely speaks - Thomas. The Court overturned the Federal Circuit in an effectively unanimous opinion, holding that claims to isolated DNA sequences are not patent-eligible subject matter. The Court further held that claims to cDNA (or synthetic DNA) sequences are, however, patent-eligible.

How did the Court get here? First, some background. Myriad developed a method for isolating and reading a DNA sequence to determine if two genes (BRCA1 and BRCA2) are present in the sample DNA. The presence of the genes indicates a person's predisposition for certain kinds of cancers. The disputed claims are composition claims directed to the specific sequences of nucleotides that indicate the presence of the BRCA1 and BRCA2 genes - like area codes at the beginning of a phone number that indicate the general area where a call originates. These patent claims, if valid, would give Myriad the exclusive right to isolate an individual's BRCA1 and BRCA2 genes until the patent expires. It would also give Myriad the right to create synthetic (cDNA) versions of the genes.

#### **Isolated DNA – Why is it different from other natural substances?**

The main dispute was whether Myriad deserved patent protection for simply isolating a naturally-occurring DNA sequence and identifying its contents. In its holding, the Court applied an incentive/preemption framework for analyzing the patentable subject matter issue under section 101: "[a]s we have recognized before, 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." (quoting *Mayo v. Prometheus*, at 23).

In holding that the isolated DNA sequences were not patentable, the Court looked to what, if any, inventive contribution Myriad made and determined that "[i]n this case, Myriad did not create anything. To be sure, it

found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention." This seems inconsistent with the fact that other naturally occurring materials have been isolated and patented, such as aspirin. Aspirin is also referred to as salicylic acid in its natural form, which is found in plants like willow and myrtle. While unclear, it is possible that the Court may view DNA differently from natural chemicals, e.g., due to the ongoing public outcry in some quarters over "patenting people," or may believe that the techniques for isolating natural chemicals and DNA are sufficiently advanced that doing so now requires only routine experimentation (and therefore cannot rise to the level of being patentable). In any event, *Myriad* is the latest word and suggests isolated natural materials are not patentable, particularly if they are genetic material.

### **Synthetic DNA**

The Court reached a different position on the issue of cDNA, holding that cDNA is patentable because it is not a "product of nature." As Justice Thomas explained, "cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived." That distinction will likely prove sufficient to protect properly drafted claims to compositions of matter that are naturally occurring but have been modified by a patentee.

### **General Implications**

For those without a Ph.D. in biology, the difference between claims directed to isolated DNA versus cDNA may be viewed (using a poor analogy) as akin to claims directed towards raw cotton that is harvested from fields versus a synthetic fiber like rayon or polyester or a fabric made from cotton. According to the Court's decision, patent protection is appropriate for your polyester shirt composition, but not for a raw cotton composition. The *Myriad* holding is narrow, however, in that it still permits patenting of methods of making your cotton shirt, methods of using the cotton shirt, and compositions using cotton with synthetic blends - assuming all the usual criteria for patentability are still met. The Court's holding should also permit patenting of natural cotton, not as a composition, but for example where the fibers have been re-arranged in a novel and non-obvious pattern that does not exist in nature, or where they are chemically treated, or when they are blended in with another material, etc.

The BRCA1 and BRCA2 genes at issue in the *Myriad* decision recently became newsworthy outside the patent world when Angelina Jolie revealed that she underwent a voluntary double mastectomy after discovering she had the precancerous markers using the test developed by Myriad. Jolie has been very vocal about her desire to make access to this test affordable to all, and the Court's holding may be one step in that direction. Currently, the test costs somewhere in the neighborhood of \$3,000-4,000 per gene, but the price is widely expected to fall (along with Myriad's stock price) as testing competitors roll out non-infringing tests.

The *Myriad* decision could also have implications for the testing and diagnostic efforts underway to control deadly epidemics, such as the Middle East Respiratory Syndrome (or MERS) currently circulating in Saudi Arabia. If a private entity determined the makeup of MERS and obtained a patent on the composition of the virus itself, rather than a specific treatment, it could in theory charge high premiums for the administration of any test to confirm the presence of MERS and any diagnostic actions taken thereafter. This could drastically hinder epidemic prevention and therapy due to legal concerns, and preempt an entire field of therapy - which the Court has been reluctant to permit. *Myriad* will likely stop private parties from patenting naturally occurring information in the United States, above and beyond certain international treaties and norms that may also prevent such patenting of a potential epidemic disease or enforcement for public health reasons. Because a virus is a "product of nature," the ability to isolate the virus and determine

its chemical identity should not give rise to patentable subject matter for the virus itself based on *Myriad*.

In light *Myriad*, one practice tip is the well-known tactic of including varied types of claims in patent applications while excluding composition claims directed solely to the natural material itself. Also, those pursuing composition claims might wish to review the USPTO's guidance memo indicating that "naturally occurring nucleic acids are not patent eligible merely because they have been isolated." Read the full memo here: [USPTO Memo](#).

If you have any questions regarding these matters, please contact us.

**Texas**

Randall C. Brown

214.651.5242

[randall.brown@haynesboone.com](mailto:randall.brown@haynesboone.com)

**California**

Tom Chen

949.202.3030

[tom.chen@haynesboone.com](mailto:tom.chen@haynesboone.com)

**Washington, D.C.**

Jeffrey Wolfson

202.654.4565

[jeff.wolfson@haynesboone.com](mailto:jeff.wolfson@haynesboone.com)

---

<sup>1</sup> Jeff Wolfson is a partner in the Washington, D.C. office and Lauren Sprouse is an attorney in the Dallas, TX office of the law firm of Haynes and Boone, LLP. Their practices emphasize patent and trade secret law, with a focus on strategic client counseling, patent procurement and management, and due diligence and IP-related agreements. Jeff may be reached at [jeff.wolfson@haynesboone.com](mailto:jeff.wolfson@haynesboone.com) or 202.654.4565 and Lauren may be reached at [lauren.sprouse@haynesboone.com](mailto:lauren.sprouse@haynesboone.com) or 214.651.5097.