

## The Noneffect Of Myriad On Personalized Medicine

*Law360, New York (July 29, 2013, 12:08 PM ET)* -- One purpose of the legal system is to incentivize behaviors that are deemed good public policy. While it is not controversial that patent laws should not allow companies to own rights to our bodies, whether and to what extent patent law should provide incentives to research and develop products, including in the area of personalized medicine, has been the subject of debate.

The ability to personalize treatment, for example, by identifying patients at risk for particular diseases and by identifying those patients who will respond well to particular treatments, can lead to more efficacious treatment and drive down health care costs. The current debate centers on how best to strike a balance between granting patents to companies and research centers involved in gene discovery or genetic testing (as an incentive to continue to fund such discoveries) and providing access to affordable testing to patients.

Unfortunately, the recent U.S. Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics Inc.* leaves open more questions than it answered and will likely have limited impact on personalized medicine and diagnostic testing.

### The Myriad Decision

On June 13, 2013, in *Association for Molecular Pathology v. Myriad Genetics Inc.*, the Supreme Court held that naturally occurring, yet “isolated,” DNA is not eligible for patent protection but what it called “synthetic” DNA (e.g., cDNA) is patent eligible. 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.

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 *Myriad*, “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.’”

At issue in *Myriad* was the patent eligibility of certain claims in patents owned by *Myriad*, some of which were directed to isolated DNA “coding for” the BRCA1 or BRCA2 proteins and others directed to synthetic DNA that also coded for these proteins.

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.”

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.” 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 non-naturally 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 is 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.

### **The Real Impact of Myriad: Not Much to Crow About**

The immediate question following the Myriad decision centers on the impact this decision will have on the biotechnology industry and on personalized medicine specifically. While many commentators have interpreted the decision as opening the door to free personalized medicine, the court’s decision will likely not have such a broad impact.

First, the Myriad decision did not sound the death knell for all diagnostic patents. Even diagnostic testing using the BRCA1 and BRCA2 genes, which were isolated by Myriad, were not broadly freed by the Supreme Court from all patent protection.

The Myriad decision addressed the patent eligibility of Myriad’s DNA claims; however, the court itself stated that this case did not involve new applications of knowledge about the BRCA1 and BRCA2 genes. Such “new applications” are, in fact, the subject of several Myriad patents, which cover, inter alia, various methods for screening for mutations of BRCA1 and BRCA2 genes and for diagnosing breast cancer based on such screening.

Accordingly, it may be some time before Myriad’s competitors are able to offer BRCA1 and BRCA2 diagnostic tests. In fact, on July 9, 2013, Myriad (along with a number of co-plaintiffs) brought suit against Ambry Genetics, alleging that Ambry’s offering of laboratory services, including testing and analysis of BRCA1 and BRCA2 genes, infringes the claims of several patents owned by the plaintiffs.

The asserted claims include claims to DNA primers for amplifying BRCA1 and BRCA2 genes, methods of making isolated BRCA1 and BRCA2 genes by amplifying genomic DNA and methods of diagnosing or identifying individuals with a predisposition to breast cancer.

Most companies and institutions that seek patent protection for diagnostic inventions include claims to such primers, kits and methods and therefore will continue to have protection for their discoveries even if Myriad invalidates some or all of their DNA composition claims.

Indeed, the Myriad decision itself emphasized the narrowness of its own holding, explicitly disclaiming any impact on modified genes and stating the following:

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.

Very few patents claim DNA whose only distinction from nature is having been “isolated from the surrounding genetic material.” In his amicus curiae brief submitted to the Supreme Court in the Myriad case, Eric Lander (president and founder of the Broad Institute and one of the principal leaders of the Human Genome Project) noted that limiting patent eligibility to cDNA would not undermine the biotechnology industry.

According to Lander's brief, the majority of relevant biotechnology products are covered by patents on cDNA or recombinant DNA molecules. In fact, it is common practice for patent practitioners, when drafting gene patent applications, to include descriptions of and claims to cDNA, which the Myriad court explicitly found to be patent eligible. Patent practitioners should readily be able to revise "isolated DNA" claims to other types of claims that are patent eligible.

Thus, the Myriad decision may impact how some patent claims are drafted or presented in patent applications and will certainly put an end to "isolated DNA" claims of the form invalidated by the Myriad decision. However, because alternative claim strategies exist that do not rely on isolated DNA, this decision will not have a far-reaching effect on patents involving biotechnology or personalized medicine.

## **Issues of Biotechnology Patent Jurisprudence**

A more fundamental issue raised by Myriad involves the effect of a court's decision when a court does not necessarily have a broad technological background.

In Myriad, the court's holding that cDNA was patent eligible was based on its determination that cDNA, which is produced by "reverse transcribing" messenger RNA, includes only coding regions and is thus not naturally occurring. However, the coding portions of cDNA are identical to those of genomic DNA.

Furthermore, some of the methods of isolating DNA from the genome involve copying its sequences using enzymes very similar to those that make cDNA. Moreover, a scientist handed a tube of DNA that contains only coding sequences, which may well not be able to tell how it was made so that patentable cDNA could not be distinguished from unpatentable isolated DNA.

Unfortunately, the distinction articulated by the court in the Myriad decision simply does not make much technological sense. In many situations, it is a distinction without a difference.

Most judges are not scientific experts. In deciding cases involving complex technology, courts rely primarily on briefs, scientific experts and clerks to understand the technology at issue. Sometimes, a court's interpretation of such technology leads to a strained rationale for its decision.

In Myriad, for example, the lack of a clear technological distinction between Myriad's patent-ineligible isolated DNA claims and its patent-eligible cDNA claims does not resolve, and in fact increases, the uncertainty in this area of biotechnology. Until judges, including Supreme Court justices, have more comprehensive technological backgrounds, decisions like Myriad will not provide much guidance to those operating in the realm of biotechnology, and the rules they define will fail to incentivize the behaviors we want.

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