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August 1, 2011

IP Client Alert

Myriad Federal Circuit Decision Affirms Patentability of Claims to "Isolated" DNA but Methods Involving Only "Comparing" or "Analyzing" DNA Sequences Unpatentable and No Declaratory Judgment for Those Who Simply Disagree With Patent

On July 29, 2011, the Federal Circuit issued its long-awaited decision in the *Association for Molecular Pathology v. Myriad Genetics, Inc*. ("*Myriad*"). The plaintiffs in *Myriad* are an assortment of medical organizations, researchers, genetic counselors, and patients who challenged Myriad's patents under the Declaratory Judgment Act. The Federal Circuit Decision held that those parties who simply disagree with the existence of a patent or who suffer an attenuated, non proximate effect from the existence of a patent, do not meet the requirement for a legal controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment and, thus, do not have standing to be a plaintiff. The Court could not see how "the inability to afford a patented invention could establish an invasion of a legally protected interest for purposes of standing." However, with at least one plaintiff having standing, the Federal Circuit turned to the merits; namely, whether claims to "isolated" DNA and methods using that "isolated" DNA are eligible to be patented under Section 101 of the Patent Statute (35 U.S.C. § 101).

The Federal Circuit held that method claims directed to only "comparing" or "analyzing" DNA sequences are patent **ineligible** under Section 101 because they have no transformative steps and cover only patent-ineligible abstract, mental steps. However, the claim that recites a method that comprises the steps of (1) "growing" host cells transformed with an altered gene in the presence or absence of a potential therapeutic, (2) "determining" the growth rate of the host cells with or without the potential therapeutic and (3) "comparing" the growth rate of the host cells includes more than the abstract mental step of looking at two numbers and "comparing" two host cells' growth rates and is eligible for patent protection. The steps of "growing" transformed cells in the presence or absence of a potential therapeutic, and "determining" the cells' growth rates, are transformative and necessarily involve physical manipulation of the cells.

The Federal Circuit also held that isolated cDNA—DNA that has had introns removed, contains only coding nucleotides, and can be used to express a protein in a cell that does not normally produce it—while inspired by nature, does not occur in nature, and is likewise eligible to be patented under Section 101.

Most significantly, the *Myriad* Majority and Concurring Opinions concluded that isolated DNA molecules are patent-eligible under 35 U.S.C. § 101, and the Court reversed the previous holding by Judge Sweet of the Southern District of New York. Both the *Myriad* Majority and Concurring Opinions rely on U.S. Supreme Court precedent,

and the *Myriad* Concurring Opinion states that claims to isolated DNA had previously been held to be valid and infringed by the Federal Circuit.

The distinction between a product of nature and a human made invention for purposes of Section 101 turns on a change in the claimed composition's identity compared with what exists in nature. According to the Federal Circuit in *Myriad*, the US Supreme Court has drawn a line between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature and compositions that human intervention has given "markedly different," or "distinctive," characteristics.

In reaching the conclusion that isolated DNA molecules are eligible to be patented under Section 101, the *Myriad* Majority Opinion focused on the fact that isolated DNA was cleaved or synthesized to consist of a fraction of a naturally occurring DNA molecule and therefore does not exist in nature. The Court stressed that isolated DNA is not the same as purified DNA. Isolated DNA is not only removed from nature, but it is chemically manipulated from what is in nature—in the human body in this case. Accordingly, isolated DNA is a distinct chemical entity from that which is in nature. The *Myriad* Concurring Opinion views isolated DNA as truncations that are not naturally produced without the intervention of man and can serve as primers or probes in diagnostics; a utility that cannot be served by naturally occurring DNA.

The *Myriad* Majority and Concurring Opinions reject the Solicitor General's "child-like simpl[e]" suggestion that for determining patent-eligible subject matter the Court use a "magic microscope" test, under which, if one can observe the claimed substance in nature, for example, by zooming in the optical field of view to see just a sequence of fifteen nucleotides within the chromosome, then the claimed subject matter falls into the "laws of nature" exception and is unpatentable subject matter—including because an isolated DNA molecule has different chemical bonds as compared to the "unisolated" sequence in the chromosome (because the ends are different). Simply, according to the *Myriad* Majority and Concurring Opinions, isolated DNA is a different molecule from DNA in the chromosome.

The *Myriad* Majority and Concurring Opinions also give great deference to the grant by the United States Patent & Trademark Office ("USPTO") of numerous patents to isolated DNA over approximately the past thirty years, as well as that in 2001 the USPTO issued *Utility Examination Guidelines*, which reaffirmed the agency's position that isolated DNA molecules are patent-eligible, and that Congress has not indicated that the USPTO's position is inconsistent with Section 101. The Federal Circuit thus held that if the law is to be changed, and DNA inventions are to be excluded from the broad scope of Section 101, contrary to the settled expectation of the inventing community, **the decision must come not from the courts, but from Congress**.

In contrast, the *Myriad* Dissenting Opinion sought to hold isolated DNA as unpatentable and compared isolated DNA with a leaf snapped from a tree. The *Myriad* Majority Opinion addresses the Dissent's analogy by making clear that a leaf snapped from a tree is a physical separation that does not create a new chemical entity, whereas isolated DNA is a new chemical entity as compared with DNA in nature.

Myriad provides the biotechnology community with an immediate sigh of relief. However, it is expected that parties to *Myriad* will likely ask the Federal Circuit to review its divided Decision en banc and that whatever the result from that request, appeal to the US Supreme Court will also be inevitable. We expect there is more to come and that the July 29, 2011 *Myriad* Federal Circuit Decision may be only one step toward an ultimate Court decision finally concluding that isolated DNA is indeed patent-eligible subject matter.

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