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Surprise Reversal of U.S. Government Position Frames the Issues in Myriad Genetics' Federal Circuit Appeal

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INTRODUCTION

The past two weeks have seen important developments in Myriad Genetics, Inc.'s appeal to the United States Court of Appeals for the Federal Circuit in *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, No. 2010-1406, a case with significant implications for the biotechnology industry. Myriad's appeal challenges the ruling of the United States District Court for the Southern District of New York that patent claims directed to isolated DNA molecules and diagnostic methods using those isolated molecules are invalid because they do not claim patent-eligible subject matter.

On October 22, 2010, Myriad filed its Brief in the Federal Circuit. On October 29, 2010, the United States filed a brief as *amicus curiae*, nominally in support of neither party. Although the United States agreed with Myriad that the district court erred in invalidating patent claims directed at synthetic complementary DNA molecules (cDNA), the United States argued that the district court correctly found that isolated and purified DNA molecules are not patentable. The United States acknowledged that this position was contrary to the long-standing positions and practices of several government agencies, including the PTO, but argued that it was consistent with older Supreme Court precedent regarding patentable subject matter.

There will be additional briefing in the case, and oral argument is expected in the spring of 2011, with an opinion likely in late summer or early fall of 2011.

The results of this case have potentially profound impacts on significant portions of the biotechnology industry that rely upon protection of novel genes as part of their business model. Eliminating or curtailing the patentability of DNA sequences would have an immediate effect on, for example, biotechnology companies that produce diagnostic assays directed to proprietary targets and biological therapeutics.

CASE BACKGROUND

On May 12, 2009, a coalition of groups and individuals brought a declaratory-judgment action against the PTO, Myriad, and the University of Utah Research Foundation over several U.S. patents with claims directed to the human genes *BRCA*1 and *BRCA*2. On April 2, 2010, the district court granted summary judgment in favor of the plaintiffs, holding that each of the disputed claims was invalid because the isolated and purified genes sequences of *BRCA*1 and *BRCA*2 were non-patent-eligible subject matter under 35 U.S.C. § 101.

MYRIAD'S BRIEF

Myriad makes three arguments in its opening brief:

Declaratory Judgment Jurisdiction. Myriad's lead argument attacks the jurisdiction of the district court, rather than the merits of the court's decision. This argument rests on the assertion that the original case was not between parties with "a substantial controversy and adverse legal interests of sufficient and immediate reality" to warrant the district court's limited jurisdiction. This procedural ground could provide the Federal Circuit with a means for disposing of the case without ever reaching the merits of the underlying decision.

Composition Claims. Turning to the merits of the district court's decision, Myriad next argues that isolated DNA molecules are "compositions of matter" under 35 U.S.C. § 101, and therefore entitled to patent protection. This argument challenges the district court's conclusion that the isolated DNA molecules are within the scope of exceptions to Section 101. According to Myriad, the recognized exceptions to Section 101 are "laws of nature, physical phenomena, and abstract ideas," but the district court incorrectly stretched these exceptions in finding that the isolated and purified genes, which the court called a "product of nature," fall within them. Myriad further argues that allowing the district court's decision excluding DNA molecules from patent protection to stand would disregard standard United States Patent and Trademark Office (PTO) practice, since over 2,645 patents have been issued with claims to "isolated DNA" and over 50,000 with claims to nucleotide sequences. In support of its argument, Myriad also cites the PTO's 2001 Utility Examination Guidelines, the legislative history of the 1995 Amendments to the Patent Act, and plaintiffs' own district court briefing. According to Myriad, the district court's holding also ignores the fact that the *BRCA*1 and *BRCA*2 molecules are purified, chemically extracted (breaking their covalent bonds) and isolated from the native DNA resulting in a new composition that is structurally and functionally different from native DNA. Myriad warns that the district court's decision, if allowed to stand, would make un-patentable a wide range of new and useful inventions derived from naturally-occurring sources.

Method Claims. Myriad also argues for the patentability of its method claims directed at diagnostic and cancer-therapeutic methods that use the isolated *BRCA*1 and *BRCA*2 molecules. Looking to the guidance provided in the Supreme Court's recent decision in *Bilski*, Myriad argues that the method claims include "transformations" of a human sample and therefore constitute patent-eligible subject matter. Myriad analogizes to the Federal Circuit's recent *Prometheus* decision, which held that diagnostic methods involving transformations of human tissue and blood samples are patent-eligible under Section 101. According to Myriad, its method claims similarly require extracting, processing, and analyzing human tissue or blood using nucleotide sequences, transformative actions that constitute patent-eligible subject matter under *Prometheus*.

THE UNITED STATES' *AMICUS* BRIEF

One week after Myriad filed its brief—which relied in part on the PTO's long-standing practice of granting patents on isolated DNA molecules—the United States filed an *amicus* brief announcing that the government had reevaluated its position and had concluded that isolated but otherwise unaltered genomic DNA is not patentable. Despite the government's new position, published reports indicate that the PTO is not yet ready to change its practices, at least until the Federal Circuit issues its decision.

The United States acknowledges that its *amicus* position is "contrary to the long-standing practice of the Patent and Trademark Office, as well as the practice of the National Institutes of Health and other government agencies that have in

the past sought and obtained patents for isolated genomic DNA." However, the United States' brief explains that it reviewed these practices following the district court's judgment, and concluded that they were contrary to Supreme Court precedent.

Specifically, the United States relies on Supreme Court cases addressing the "law of nature" exception to patent-eligibility and concludes that the native *BRCA*1 and *BRCA*2 genes, their deleterious alleles, and their relationship to breast cancer are the result of "evolution, not human invention" and are therefore un-patentable "products and processes of nature itself."

According to the United States, the *BRCA*1 and *BRCA*2 molecules do not become patent-eligible when they are "isolated," "extracted," or "purified" from their natural cellular environment. Analogizing to coal found beneath the earth, cotton fibers mixed with cotton seeds, and the stigmas of the saffron flower, the United States argues that many natural products must be "isolated" or "purified" from extraneous matter found in their natural environments to be useful. The United States cites a number of cases from the first half of the 20th Century as supporting its position that this "isolation" or "purification" does not convey patent-eligibility on the DNA molecule. Instead, the United States concludes that patent eligibility only arises if the "isolation" or "purification" of the natural compound has so changed the substance that it is different in kind from the natural product. To the United States, the "fundamental question under section 101 is whether the inventor has created something through the application of human ingenuity or merely exposed something previously unappreciated in nature." In this case, the United States argues that, apart from the fact of the isolation itself, the *BRCA*1 and *BRCA*2 genes are structurally and functionally identical to that found in nature and are not patent-eligible.

Addressing concerns that its position would undermine the biotechnology industry, the United States takes pains to emphasize that many patent-eligible products and methods could arise from the biotechnological or pharmaceutical application of genomic DNA, assuming the other requirements of the patent laws were satisfied. First, the United States argues that molecules engineered by humans, including cDNAs, vectors, recombinant plasmids, and chimeric proteins would normally be patent-eligible subject matter because these molecules do not occur in nature and are the synthetic result of scientists' manipulation of the natural laws of genetics. For example, the United States acknowledges (contrary to the finding of the district court) that Myriad's claims that cover only cDNA are patent eligible under Section 101. Second, the United States emphasizes that processes for extraction and purification of DNA molecules are patent-eligible subject matter. Third, according to the United States, processes for industrial application of isolated genomic DNA would be patent-eligible subject matter.

The United States' brief does not address the district court's declaratory-judgment jurisdiction or the patent eligibility of Myriad's method claims.

CONCLUSION

Although the final outcome of this case will not occur for months, if not years, it has potential to present a watershed moment in biotechnology patent law. The issues raised in this case are of interest to a wide swath of society, as evidenced by the United States' *amicus* brief. Until some degree of certainty is achieved, the public, the biotechnology industry, and academia will be watching.

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