Client Alert.

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Judges Don't Budge in *Myriad*:
Federal Circuit Again Finds Isolated Gene Sequences are Patent-Eligible Subject Matter

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INTRODUCTION

The Federal Circuit today issued its opinion in *Assoc. for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al*. *("Myriad")*, in which it re-affirmed its prior ruling, despite the Supreme Court's instruction to revisit that ruling in light of its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, ___U.S.___ (March 20, 2012) ("*Prometheus*").

MYRIAD BACKGROUND

At issue in *Myriad* are both composition claims directed to isolated DNA sequences, specifically the BRCA-1 and BRCA-2 genes, and method claims directed to screening for the presence of mutations in those genes. By some estimates 5-10% of women who develop breast cancer are likely to have a mutation in their BRCA-1 or BRCA-2 genes, and it has been estimated that women with one of these mutations can have an approximately 40-85% lifetime risk of developing breast cancer. These inherited mutations can also be an indicator of an increased risk of ovarian cancer. Genetic tests are available to determine if a person carries one of these mutations. On May 12, 2009, a coalition of groups and individuals brought a declaratory judgment action against the U.S. Patent Office, Myriad Genetics, Inc., and the University of Utah Research Foundation over several U.S. patents with claims directed to the BRCA genes.

THE FEDERAL CIRCUIT'S JUNE 29, 2011 OPINION

In its previous 2-1 decision, the Federal Circuit concluded that the isolated DNA molecules coding for certain BRCA sequences were patent-eligible subject matter under 35 U.S.C. § 101. [See our previous client alert here.] The court held that because the isolated DNA molecules are chemically cleaved from native DNA, they have "markedly different" characteristics and therefore do not fall within the "products of nature" exception to § 101. The Federal Circuit also held that all but one of Myriad's method claims were not patent-eligible, rejecting the method claims that cover simply "analyzing" or "comparing" a patient's BRCA sequence with a normal one to determine whether cancer-predisposing mutations exist. Finally, the court found that only one of the plaintiffs, Dr. Ostrer, a researcher at New York University, had standing to bring a declaratory judgment action.

The Supreme Court's one paragraph grant, vacate, and remand ("GVR") order, issued on March 26, 2012, and directed the Federal Circuit to reconsider its opinion in light of *Prometheus*, where the Court found certain method claims, specifically methods of "determining" the levels of certain metabolites in patients with autoimmune disorders and "comparing" those levels to threshold values that indicate the drug's efficacy or toxicity, were not patent-eligible. [See our previous client alert here.] The Court reasoned that the correlation between the presence of metabolites and either harm on the one hand, or efficacy on the other, simply describes a relationship that "sets forth a natural law." The Court also advised that, "to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do

more than simply state the law of nature while adding the words 'apply it.'"

TODAY'S *MYRIAD* DECISION

Confirming the observations of many after July's oral arguments, none of the three judges moved from their previously stated positions. Just as in its last *Myriad* opinion, the panel split 2-1, with Judge Lourie writing the opinion for the majority, Judge Moore writing a separate concurrence-in-part, and Judge Bryson concurring-in-part and dissenting-in-part.[1]

As to jurisdiction, the panel again found that Dr. Ostrer had standing to pursue a declaratory judgment action because he remained ready, willing, and able to conduct BRCA screening should the Myriad patents be invalidated. Thus, the court found that Dr. Ostrer had alleged a "controversy of sufficient reality and immediacy" to grant him declaratory judgment standing under *Medimmune, Inc. v. Genentech, Inc.* 549 U.S. 118, 127 (2007).

COMPOSITION CLAIMS

Turning to the patentability of isolated DNA molecules, the Federal Circuit again held that the claims to the BRCA isolated DNA are drawn to patent-eligible subject matter. The majority noted that *Prometheus*, which addressed only method claims, "does not control the question of patent-eligibility" of the composition claims.[2] The majority thus rejected the Plaintiffs' argument that, under *Prometheus*, the differences between the isolated gene sequences and the native DNA "do not add 'enough' to the underlying genetic sequences" to render them patent-eligible under § 101.[3] Instead, the majority again found that because the covalent bonds that connect the claimed DNA sequence must be "chemically cleaved" in order to isolate it, that act of human intervention "impart[s] on that isolated DNA a distinctive chemical identity as compared to native DNA."[4] Finally, the majority rejected Plaintiffs' argument that allowing patents on isolated DNA would "preempt a law of nature," noting that all seven challenged patents expire by December 18, 2015, so any period of preemption would be brief, and emphasizing that isolated DNA is not a law of nature, but instead the sequences "are the products of man, albeit following, as all materials do, laws of nature."[5]

METHOD CLAIMS

Turning to the method claims, all three judges once again agreed that claims directed to "analyzing" and "comparing" certain DNA sequences were non-patent-eligible as claiming only abstract mental processes.[6] The panel found that these claims "are indistinguishable from the claims the Supreme Court found invalid under § 101 in *Mayo*," which also did not contain a sufficiently transformative step.[7]

Moving to the claims directed to methods of screening potential cancer therapeutics, the panel again concluded that, despite the fact that the claims involved the mental steps of "determining" and "comparing" the cells' growth rate, the step of growing transformed cells in the presence or absence of a potential cancer therapeutic was sufficiently transformative

[1] Judge Bryson's and Judge Lourie's concurring and dissenting opinions largely tracked their previous opinions filed with the July 29, 2011 decision. [See our previous client alert here.]

[2] *Slip op.* at 38.

[3] *Id.* at 40.

[4] *Id.* at 45.

[5] *Id.* at 51-52.

[6] *Slip op.* at 55-56.

[7] *Id.* at 58-59.

to render the claims patent-eligible under § 101.[8] In so holding, the panel rejected Plaintiffs' argument that these claims were indistinguishable from the claims found invalid in *Prometheus.* The panel concluded that the Myriad claims, unlike those in *Prometheus*, involved applying mental steps to "transformed cells that … are a product of man, not of nature[,]" and thus were patent-eligible under § 101.

CONCLUSION

Today's decision represents a significant victory for both Myriad and those segments of the industry that rely upon protection of novel genes as part of their business model. However, the court's decision is unlikely to create any long lasting sense of certainty as many commentators expect the parties to attempt rehearing at the Federal Circuit and eventually a return to the Supreme Court.

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[8] *Id.* at 60-61.