Client Alert.

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Uncertainty Prevails: *Myriad* Back to the Federal Circuit

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Once the Supreme Court issued its opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, __ U.S. __ (March 20, 2012) ("*Prometheus*"), many commentators believed the fate of the petition for certiorari in *Association for Molecular Pathology v. Myriad Genetics, et al.* ("*Myriad*") was sealed. Today, the Supreme Court confirmed that assumption by granting certiorari in *Myriad*, vacating the Federal Circuit's decision and remanding the case for further consideration in light of its decision in *Prometheus*.

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. In a 2-1 decision, the Federal Circuit concluded that the isolated genes were patentable subject matter under 35 USC § 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 unpatentable, 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. The court also examined whether the coalition of groups and individuals bringing suit against Myriad had standing to bring a declaratory judgment action and found that only Dr. Ostrer, a researcher at New York University, had standing, because he was ready, willing, and able to perform BRCA1/2 screening in the event Myriad's claims were invalidated.

THE *PROMETHEUS* DECISION

The Supreme Court's one paragraph opinion directed the Federal Circuit to follow *Prometheus* on remand, and did not provide any further guidance. In *Prometheus*, the Court considered only the patent-eligibility of 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. [See our previous client alert here.] The Court found those claims unpatentable under 35 U.S.C. § 101, reasoning 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." It explained that "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm." However, "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.'" The Court then examined whether the claimed diagnostic methods included additional steps that transformed otherwise-unpatentable laws of nature into patent-eligible applications of those laws, and found that they did not.

THE FEDERAL CIRCUIT ON REMAND

On remand, the Federal Circuit must apply this principle to the claims at issue in *Myriad*. Although the Federal Circuit previously found all but one of the method claims unpatentable, the Supreme Court seems to be mandating a finding that they are unpatentable based on its reasoning in *Prometheus*. It is unclear how the *Prometheus* opinion, which deals only with method claims, will guide the Federal Circuit when dealing with the composition claims directed to the isolated DNA sequences themselves. Because the Supreme Court provided no guidance, the Federal Circuit is free to find (as it did previously) that isolated DNA sequences are patentable, because the requirement that they be chemically cleaved from native DNA remains a transformative step. This outcome seems likely given the Federal Circuit's prior reliance on the longstanding practice of the PTO, which has been issuing DNA molecule patents for over 30 years. On the other hand, the Federal Circuit could apply the Supreme Court's broader finding that applications of the laws of nature are unpatentable where "the relation itself exists in principle apart from any human action," and find that isolated DNA sequences, although cleaved from their natural state, nonetheless exist in nature before they are separated from native DNA.

Finally, the opinion provides no guidance on how the Federal Circuit should approach the standing issue raised by Myriad in its petition for rehearing en banc, when it challenged Dr. Ostrer's standing anew based on the fact that he had left New York University and may no longer be able to perform BRCA1/2 testing in the event of invalidation. The Supreme Court's failure to address this issue, along with the Federal Circuit's denial of Myriad's petition for rehearing en banc, make it unlikely the standing issue will play a key role in the Federal Circuit's analysis on remand.

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