Client Alert.

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Myriad Finally Gets Its Day in (the Supreme) Court

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INTRODUCTION

The Supreme Court today granted certiorari in *Assoc. for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al*. *(Myriad)*, to address the issue of whether human genes are patentable. This will be the second time the Court considers *Myriad*, but the first in which it takes up the patent-eligibility of human genes. The first time around, the Court granted certiorari, reversed, and remanded ("GVR") to the Federal Circuit with instructions that it revisit its ruling in light of the Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, ___U.S.___ (March 20, 2012) (see our client alert).

That remand resulted in the Federal Circuit's wholesale re-affirmance of its prior ruling, now on review. Specifically, the Federal Circuit ruled that (1) isolated DNA molecules are patent-eligible, (2) Myriad's method claims including only the steps of "analyzing" and "comparing" certain DNA sequences were not patent-eligible in light of *Prometheus*, and (3) Myriad's method claim including the step of growing transformed cells in the presence or absence of a potential cancer therapeutic was sufficiently transformative to render the claim patent-eligible under § 101.

GROUNDS FOR CERTIORARI

Plaintiffs' petition for certiorari sought review of all three of the Federal Circuit's holdings. Today, the Court granted certiorari, but limited its review to the first issue: whether human genes (or isolated DNA sequences) are patent-eligible subject matter. Although it previously remanded the case for consideration in light of *Prometheus*, because the *Prometheus* holding involved only method claims, the Court provided no guidance for the Federal Circuit on patent-eligibility of the composition claims. Thus, as the Federal Circuit concluded, *Prometheus* "does not control the question of patent-eligibility" of the composition claims. The Court will now resolve the question of whether isolated DNA sequences, which must be chemically cleaved from native DNA, have undergone enough of a transformation to render them patent-eligible subject matter.

Notably, the Court chose not to review the Federal Circuit's rulings on *Myriad*'s method claims, despite the fact that many observers believed the Court's GVR was an instruction to the Federal Circuit to invalidate Myriad's last viable method claim based on the Court's ruling in *Prometheus*. Its decision to consider the composition claims may leave some wondering whether the Court plans to depart from (or even reverse) the longstanding PTO practice of issuing patents to isolated DNA.

CONCLUSION

The Court's grant of certiorari in *Myriad* provides an opportunity to clarify whether isolated gene sequences are patent-eligible subject matter. That the Supreme Court has accepted certiorari will undoubtedly reverberate through the life sciences community, and the briefing and argument will be closely watched.[1]

[1] This decision also provides additional evidence of the Supreme Court's renewed interest in life sciences patents, as demonstrated by its opinion in *Prometheus*, as well as its recent grant of certiorari in *Bowman v. Monsanto*, a case involving whether patent exhaustion applies to self-replicating plant seed technologies (see our client alert).

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