US Supreme Court Declines to Review *Ariosa v. Sequenom*: A Missed Opportunity to Clarify the Eligibility of Diagnostic Patents

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The United States Supreme Court has denied Sequenom's petition to review the Federal Circuit's decision in *Ariosa Diagnostics Inc v. Sequenom Inc*[1]. This is discouraging news for stakeholders in diagnostics and personalized medicine who had hoped that the Supreme Court would step back from, or at least clarify, the current restrictions on obtaining patent protection for diagnostic methods.

In *Sequenom*, the Federal Circuit affirmed a district court's finding (discussed here) that claims directed to a diagnostic method involving detection of paternally inherited cell-free fetal DNA (cffDNA) in maternal plasma or serum were invalid as unpatentable subject matter under 35 U.S.C. § 101[2].

The inventors of the patent in question had discovered cffDNA in maternal plasma and serum, the portion of maternal blood samples that had previously been discarded as medical waste. While the Federal Circuit agreed that the patent at issue was a "breakthrough" and that it "combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care", the court noted that existence of cffDNA in maternal blood is a naturally occurring phenomenon and methods like PCR for detecting and amplifying cffDNA were well understood, routine and conventional at the relevant date. Accordingly, the patent was ineligible in view of the Supreme Court's ruling in *Mayo Collaborative Services v. Prometheus Labs*[3] which held that patent claims that do no more than incorporate a natural law or phenomenon and recite techniques that are well-known, conventional or routine are invalid.

The sole question presented to the Supreme Court was as follows:

> Whether a novel method is patent-eligible where (1) a researcher is first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?

In refusing to take the case, the Supreme Court has declined to reconsider their prior ruling in *Mayo*, which many consider to represent a significant departure from previous US patent practice. Accordingly, uncertainty surrounding the validity of diagnostic patents remains. The USPTO recently released a new guidance document on the patent eligibility of diagnostic methods[4]. It is possible that the USPTO may revisit this guidance in view of the Supreme Court's refusal to hear *Sequenom*. In the meantime, it appears that while diagnostic claims that are strictly based on correlations will be problematic, claims that include novel reagents, analytes and/or techniques should be patentable. In addition, interested parties are continuing to put pressure on the Government to introduce amendments to 35 U.S.C. § 101 to clarify the law of subject matter eligibility with respect to diagnostic methods.

[1] 788 F.3d 1371 (Fed. Cir. 2015); *Sequenom, Inc v. Ariosa Diagnostics, Inc et al,* in the Supreme Court of the United States, No. 15-1182.

[2] Prior to Sequenom's petition to the Supreme Court, the Federal Circuit also denied their petition for *en banc* rehearing of the Federal Circuit decision before all of the circuit judges (No. 14-1139 (Fed. Cir. 2015).

[3] 566 U.S. ___ (2012).

[4] http://www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf; see in particular Example 29 "Diagnosing and Treating Julitis".