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Federal Circuit Rules Prenatal Diagnostic Patents as Patent Ineligible in *Ariosa*

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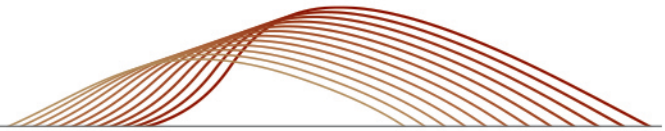
Last week, the Federal Circuit invalidated claims directed to a method of detecting fetal DNA in the maternal bloodstream as patent-ineligible in *Ariosa Diagnostics, Inc. v Sequenom, Inc.*, No. 2014-1139, 2014-1144. (June 12, 2015). The opinion for the Court, written by Judge Reyna and joined by Judge Wallach, shed light on several aspects of the two-part patent-ineligibility inquiry set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).

In step one of the *Mayo* inquiry, the Court concluded that the claims were all directed to a naturally-occurring phenomenon: the existence of paternally-inherited cell-free fetal DNA in the maternal bloodstream. In support of this conclusion, the Court noted that the method claims began and ended with natural phenomena and the patent's specification itself stated that the inventors "have demonstrated that foetal DNA is present in maternal plasma and serum," which "may be a useful source of material" for diagnosis.

Turning to step two of *Mayo*, the Court cited *Parker v. Flook* for the proposition that, "for process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful." Although acknowledging that the claimed method was a significant contribution to science, the Court ultimately found that the additional process steps in the claims applied conventional steps and methods which were admitted by the patentee as "a matter of routine for one skilled in the art for the analysis of DNA." Even a positive and valuable contribution to science, the Court noted, can fall short of being statutory subject matter under 35 U.S.C. § 101.

The Court also addressed the issue of preemption as a basis for judicial exceptions to patentability under *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014). Although concluding such concerns were fully addressed and moot based on its analysis under *Mayo*, the Court noted that demonstrating a lack of complete preemption through alternative methods of using a naturally-occurring phenomenon does not necessarily render the claims patent eligible.

Judge Linn concurred in the opinion, stating that "[b]ut for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason in policy or statute, why this breakthrough invention should have been deemed patent ineligible." Judge Linn further noted that *Ariosa* represented an unintended consequence of the broad language in *Mayo* "excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain." Specifically, *Mayo*'s dismissal of conventional post-solution steps did not adequately distinguish between instances where claimed



conventional steps were already being performed and, in the present case, where the patentee "effectuated a practical result and benefit not previously attained."

At times, a concurrence or dissent can inadvertently worsen the potential impact of a majority opinion based on its interpretation of that opinion. In that regard, innovators should be careful of the comment in the concurrence that new uses for existing drugs, though expressly stated to be patent eligible in *Mayo*, appears to be in tension with the *Ariosa* ruling. *See Mayo*, 132 S. Ct. at 1302 ("Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws."). Even though such an argument by generics may be in direct conflict with Supreme Court authority, we are seeing generic drug companies seek to attempt these sorts of arguments, and innovators should be fully prepared to respond accordingly.

Read the *Ariosa Diagnostics, Inc. v Sequenom, Inc*. opinion here. For a fuller analysis of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and practice tips for analyzing and litigating these issues, please see our previous published article on this subject, *Prometheus -- a new dawn for biotech patents*, which can be read here.

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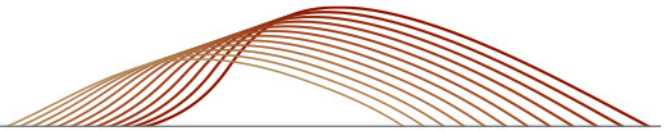

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