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The Federal Circuit Deals Another Setback to Medical Diagnostic Patents

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On June 12, 2015, the Federal Circuit held certain prenatal diagnostic testing claims invalid under Section 101, concluding that the claims were directed to a natural phenomenon. *Ariosa Diagnostics, Inc. v. Sequenom, Inc*. (2014-1139). The decision follows on the heels of another Federal Circuit decision holding that methods of identifying certain gene mutations were invalid for claiming an abstract idea. *In re BRCA1 and BRCA2 Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755 (Fed. Circ. 2014) ("*Ambry*"). Together these decisions limit the scope of patentable subject matter for molecular diagnostics that are implemented using routine techniques.

The patent in *Ariosa* covered non-invasive prenatal diagnostic testing methods used for determining certain fetal characteristics such as gender or genetic defects. The basic technology involved the discovery that paternally inherited cell-free fetal DNA ('cffDNA') could be detected in the previously discarded serum and plasma of a pregnant woman's blood sample using existing DNA amplification techniques. The patent claimed methods for detecting a paternally inherited nucleic acid in a maternal serum or plasma sample by amplifying the nucleic acid and detecting its presence in the sample. Applying the Supreme Court's two-step *Mayo* framework, the Federal Circuit first determined that the patent was directed to 'detecting the presence of a naturally occurring thing or phenomenon, cffDNA in maternal plasma or serum,' noting that 'the claimed method begins and ends with a naturally occurring phenomenon.' In the second step, the Court found that the recited amplification and detection steps involved the use of well-known techniques that failed to supply the inventive concept necessary to transform the claims into patent eligible applications of a law of nature. In the words of the Court, 'appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept.' In a concurring opinion, Judge Linn distinguished the facts in *Ariosa* from those in *Mayo* by pointing out that the "conventional activities' in *Mayo* were the very steps that doctors were already doing,' whereas in Ariosa, 'no one was amplifying and detecting paternally inherited cffDNA using the plasma or serum of pregnant mothers.' Although Judge Linn saw '*no reason*, in policy or statute, why this breakthrough invention should be deemed patent ineligible,' he felt the Court was bound by *Mayo*'s sweeping language that 'discounted, seemingly without qualification, any '[p]ost-solution activity that is purely conventional or obvious." Judge Linn found that the Supreme Court's 'blanket dismissal of conventional post-solution steps [left] no room to distinguish *Mayo* from this case.' As Judge Linn's concurrence highlights, the Federal Circuit's recent decisions appear to erase any distinction between situations where the diagnostic techniques and specific application (as in Mayo) are both evidently routine, from the situation in *Ariosa* and *Ambry* where the techniques operate on unknown, albeit naturally occurring, structures. The result of these decisions may be that an application of a natural principle must itself constitute a separate invention in order to be patentable.

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