

## Myriad applied: More news for diagnostic patents

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Last week, in *Ariosa Diagnostics Inc v. Sequenom Inc*, a district court issued a declaratory judgement, finding that claims directed to a diagnostic method involving detection of cell-free fetal DNA (cffDNA) were invalid as unpatentable subject matter under 35 U.S.C. § 101. The case is only a district court decision which typically has no binding precedential effect. It is also likely to be appealed. The district court's opinion was based on the Supreme Court's recent decision in *Association for Molecular Pathology v. Myriad Genetics, Inc*, 133 S. Ct. 2107 (2013) discussed [here](#).

The patent in question related to the detection of paternally inherited cffDNA in maternal plasma or serum.

In this case the parties had agreed "that neither cffDNA nor the discovery of cffDNA in maternal plasma or serum is patentable, because the presence of cffDNA in maternal plasma or serum is a natural phenomenon".

The Court found that conventional techniques of DNA detection, known at the time of the invention, were applied to paternally inherited cffDNA as opposed to other types of DNA. Thus, the Court concluded that the only inventive concept contained in the patent was the discovery of cffDNA, which is not patentable. The Court's decision does not appear to adequately take into account that it often requires inventiveness to use DNA detection tools.

The Court also concluded that the claims in question also wholly preempted all known methods of detecting cffDNA at that time and that the claims at issue posed a substantial risk of preempting the natural phenomenon, which the court said supported its conclusion that the claims were not drawn to patent eligible subject matter.

If this decision is followed or upheld on appeal, it will add to the already existing hurdle to be surmounted for obtaining broad patent protection for diagnostic claims that rely on novel correlations. More insight on the patent eligibility of diagnostic claims is likely to be garnered in the not too distant future in light of the various lawsuits between Myriad and its competitors which are presently before the courts.