ARE Patent Law Alert: Federal Circuit Holds that Methods for Enriching Cell-Free Fetal DNA from Maternal Blood are Patent Eligible under 35 U.S.C. Â§101

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On March 17, 2020, in Illumina, Inc. v. Ariosa Diagnostics, Inc., a three judge panel of the U.S. Court of Appeals for the Federal Circuit in a split decision reversed a District Court ruling and held that claims directed to methods for enriching cell-free DNA from maternal blood are not invalid under 35 U.S.C. §101 as directed to ineligible natural phenomenon.

As background, maternal blood contains both cell-free maternal DNA and cell-free fetal DNA. The claims of an earlier patent, U.S. Patent No. 6,258,540, were previously held to be invalid under 35 U.S.C. §101 because they were allegedly only directed to the natural phenomenon that cell-free fetal DNA exists in maternal blood. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015).

In contrast, the claims in the patents at issue, U.S. Patent Nos. 9,580,751 and 9,738,931, are directed to methods of preparing a fraction of cell-free DNA that is enriched in fetal DNA. The methods are based on the finding that the majority of cell-free fetal DNA found in maternal blood has a relatively small size of about 500 base pairs or less, whereas the majority of cell-free maternal DNA has a size greater than about 500 base pairs (a base pair is a pair of nucleotides connecting complementary strands of a DNA molecule). The key step in the method claims is separating DNA based on size.

The majority considered that this is not a diagnostic case nor a method of treatment case, but rather that the claims are directed to methods of preparing a DNA fraction. The majority acknowledged that “[t]he claimed methods utilize the natural phenomenon that the inventors discovered by employing physical process steps to selectively remove larger fragments of cell-free DNA and thus enrich a mixture in cell-free fetal DNA.” Importantly, the majority went on to state that “[t]hough we make no comment on whether the claims at issue will pass muster under challenges based on any other portion of the patent statute, under §101 the claimed methods are patent-eligible subject matter.”

The dissenting judge opined that the claims are directed to a natural phenomenon and are thus patent ineligible subject matter.

We will continue to monitor and report on developments in this area. In the meantime, please feel free to contact us to learn more.