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Federal Circuit Finds Method of Preparation Claims Patent Eligible

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On March 17, 2020, a divided Federal Circuit panel ("CAFC") reversed a District Court decision and found that claims directed to a method of preparing a fraction of fetal cell-free DNA were patent eligible under 35 U.S.C. § 101. Importantly, the CAFC found that the claims were directed to methods of preparation and were not directed to diagnostic method claims or method of treatment claims. The CAFC drew a distinction between the claims at issue and diagnostic method claims (which have been consistently held to be patent ineligible post-*Mayo*) and method of treatment claims (which are patent eligible), potentially creating a new pathway for protection of diagnostics.

In 2015, U.S. Patent No. 6,258,540 ("the '540 patent"), which disclosed the discovery that a very small fraction of cell-free fetal DNA exists in maternal plasma and serum, was held invalid under §101 by the CAFC because the claims 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 *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, the claims at issue were directed to methods of preparing a fraction of cell-free DNA that is enriched in fetal DNA by size discrimination and selective removal of larger maternal DNA fragments (e.g., > 500 bp) to enrich the smaller fetal DNA fragments (e.g., < 500 bp). The CAFC found that, under step one of the Supreme Court's two-part test for patent eligibility, the claims were directed to eligible subject matter that exploits the discovery of the natural phenomenon, rather than the natural phenomenon itself. The CAFC said the claims include specific process steps to increase the amount of fetal DNA as compared to maternal DNA. In contrast to the earlier case concerning the '540 patent, where additional claim limitations were found to cover natural phenomenon, the CAFC found that the present claims were patent eligible because the "inventors used these concrete process steps, not merely to observe the presence of the phenomenon that fetal DNA is shorter than maternal DNA, but rather to exploit that discovery in a method for preparation of a mixture enriched in fetal DNA."

A take home message from *Illumina, Inc. v. Ariosa Diagnostics, Inc.* is that method of preparation claims that exploit natural phenomena may be patent eligible. The CAFC specifically emphasized that the claims under consideration were not directed to a diagnostic method. The CAFC analogized the claims at issue to claims found patentable in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, No. 15-1570 (Fed. Cir. July 5, 2016), relating to freezing of specific cell types. Unlike other fetal DNA testing methods that have been found invalid, the CAFC highlighted that the claims at issue were directed to a specific method of harnessing a natural phenomenon, and could be patentable even if the claimed method included conventional process steps.

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