ILLUMINA, INC. v. ARIOSA DIAGNOSTICS, INC., Appeal No. 2019-1419 (Fed. Cir. March 17, 2020). Before Lourie, Moore, and Reyna. Appealed from N.D. Cal. (Judge Illston).

Background:

In a 2015 decision,[1] the Federal Circuit held that the claims of a patent owned by Sequenom were invalid under 35 U.S.C. §101 because they were directed to the natural phenomenon that cell-free fetal DNA exists in maternal blood. Illumina is the licensee of two related Sequenom patents that are directed to distinguishing and separating the tiny amount of fetal DNA from the vast amount of maternal DNA present in a maternal blood sample for further analysis. Specifically, the patents claim methods of preparing a fraction of cell-free DNA that is enriched in fetal DNA by size discrimination and selective removal of DNA fragments that are above a specified size threshold, followed by analyzing the DNA in the obtained fraction. Illumina sued Ariosa for infringement of the two patents. Ariosa moved for summary judgment, arguing that the claims are directed to the patent-ineligible natural phenomenon that cell-free fetal DNA tends to be shorter than cell-free maternal DNA in maternal blood. The district court granted Ariosa's motion for summary judgment, holding the claims of the two patents invalid under 35 U.S.C. §101.

Issue/Holding:

Did the district court err in holding the claims invalid under 35 U.S.C. §101? Yes, reversed and remanded.

Discussion:

In a 2 to 1 decision, the Federal Circuit held that the claims are directed to a patent-eligible method that exploits the discovery that fetal DNA tends to be shorter than maternal DNA. The majority analogized the claims to those at issue in *CellzDirect*, finding that the size discrimination and selective removal step changes the composition of the mixture, resulting in a DNA fraction that is different from that naturally occurring in maternal blood. Even though the majority acknowledged that many size discrimination and selective removal techniques, such as centrifugation, electrophoresis, and chromatography, were well-known and conventional, they concluded that the methods are not directed to a patent-ineligible concept under step one of the *Alice*/*Mayo* test and thus there is no need to reach step two.

The majority also distinguished the patent claims at issue from those found ineligible in the Federal Circuit's 2015 *Ariosa* decision. According to the majority, the claims at issue in the 2015 decision were diagnostic method claims that merely observed the presence of cell-free fetal DNA in the mother's blood by amplifying and then detecting it. In contrast, the majority found that the claims at issue here recite more than just the correlation between a DNA fragment's size and its tendency to be either fetal or maternal. For instance, the claimed methods do not merely detect whether a DNA fragment is fetal or maternal based on its size, but instead remove some maternal DNA to prepare a fraction enriched in fetal DNA.

Judge Reyna dissented, arguing that the claims are directed to a natural phenomenon because the only "claimed advance" is the discovery of the natural phenomenon. He also argued that a method that merely changes the *composition* of a sample of naturally occurring substances without altering the naturally occurring substances themselves is not eligible. He cited the 2015 *Ariosa* decision, among others, finding that using PCR to amplify DNA in a sample before detecting it is not patent eligible.

[1] *Ariosa Diagnostics, Inc. v. Sequenom Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).