CLIENT ALERT

Doing It That Way Is Natural . . . and Patentable

Aug.12.2020

On August 3, the Federal Circuitreissued its decision in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, holding that a method of ***preparing*** DNA before testing it is patentable even though that method relied on a naturally occurring phenomenon. Here, the Federal Circuit adds more language to clarify its reasoning for determining that the claims are patent-eligible and explains what distinguishes a claim directed to a natural phenomenon from one that merely uses such a phenomenon. It also distinguishes this method of preparation for performing a diagnostic as different from the diagnostic itself (which would not be patent eligible).

The patents at issue in *Illumina* acknowledge the natural phenomenon of cell-free fetal DNA existing in maternal blood but identify a problem of there being "no known way to distinguish and separate the tiny amount of fetal DNA from the vast amount of maternal DNA."[1] The patents provide a solution involving separating out circulatory extracellular DNA fragments that are smaller than about 500 base pairs, specifically claiming "methods of preparing a fraction of cell-free DNA that is enriched in fetal DNA."[2][1]

When Illumina filed suit for patent infringement, Ariosa, the defendant, claimed that the claims were patent-ineligible because they covered a naturally occurring phenomenon. Ariosa's argument was based on a previous decision, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, holding a claim identifying the existence of cell-free fetal DNA in maternal blood patent-ineligible.

In its reissued opinion, the Federal Circuit explains that for claims that involve a law of nature or a natural phenomenon, the limitations of the claim must transform the claim into one that is patent-eligible.[3][2] Here, the patent identifies a natural phenomenon, as the court adopts Illumina's definition, "that cell-free fetal DNA tends to be shorter than cell-free maternal DNA in a mother's bloodstream."[4][3] However, the claims are not *directed to* this phenomenon, but instead are directed to a patent-eligible method using it. Specifically, "[t]he claims include physical process steps that change the composition of the mixture, resulting in a DNA fraction that is different from the naturally occurring fraction in the mother's blood."[5][4] Ariosa also argued that the claimed DNA removal method is conventional and well-known, but the Federal Circuit countered that "conventional separation technologies can be used in unconventional ways,"[6][5] and the defendant had not demonstrated that using 300 base pairs and 500 base pairs as thresholds represents a conventional way to separate cell-free DNA fragments.

The Federal Circuit's reissued decision is good news for those seeking patent protection, as it expands the potential for patent eligibility in the natural phenomena space of Section 101. It makes clear that a claim may relate to a naturally occurring phenomenon and still remain patent-eligible, so long as it does not effectively claim the phenomenon itself.

[1] *Illumina, Inc. v. Ariosa Diagnostics, Inc.* (Fed. Cir. 2020)opinion at page 3.

[2] *Id*. at 4.

[3] *Id*. at 8.

[4] *Id.* at 10.

[5] *Id.* at 11.

[6] *Id.* at 15.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Anne Elise Herold Li
Partner – New York
Phone: +1 212.895.4279
Email: ali@crowell.com

Siri Rao
Associate – Washington, D.C.
Phone: +1 202.624.2602
Email: srao@crowell.com

Suzanne Trivette
Associate – New York
Phone: +1 212.895.4312
Email: strivette@crowell.com