

Claims Covering DNA Are Not Patent-Eligible but a Process for Isolating It Can Be

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Illumina, Inc. v. Ariosa Diagnostics, Inc., No. 2019-1419 (Fed. Cir. Mar. 17, 2020)

The patentee appealed a lower court ruling finding claims of two patents related to fetal DNA invalid under 35 U.S.C. § 101. The Federal Circuit reversed and remanded.

The patents explained that while it was known that cell-free fetal DNA existed in a mother's bloodstream, there was no known way of distinguishing this tiny amount of fetal DNA from a much larger proportion of maternal DNA in the bloodstream. In attempting to solve this problem, the inventors discovered a natural phenomenon—that extracellular fetal DNA has a relatively small size of 500 base pairs or less, whereas most maternal DNA in maternal plasma has a size greater than 500 base pairs. This finding formed the basis of the invention in the two patents at issue.

The patents at issue claimed methods of preparing and manipulating the DNA to isolate and detect the fetal DNA. While the methods were based on the natural phenomenon that cell-free fetal DNA tends to be shorter than cell-free maternal DNA in a mother's bloodstream, the claims themselves were not directed to this natural phenomenon itself. Rather, the Federal Circuit found that the claims were directed to a patent-eligible method that utilizes that information.

The Federal Circuit explained that the claims are directed to methods for preparing a fraction of cell-free DNA that is enriched in fetal DNA. The methods include “specific process steps—size discriminating and selectively removing DNA fragments that are above a specific size threshold—to increase the relative amount of fetal DNA as compared to maternal DNA in the sample.” The process steps therefore change the composition of the mixture, resulting in a DNA fraction that is different from what is naturally occurring in the mother's blood. Thus, the Federal Circuit reasoned that the claimed method does not simply observe the natural phenomenon (that fetal DNA is shorter than maternal DNA).

In distinguishing related case law where claims involved observing or detecting DNA were found to be patent-ineligible, the court observed the claims involve removing some DNA from the mother's blood to prepare a fraction of cell-free DNA enriched in fetal DNA. In other words, because the claimed methods relate to a process of manipulating and isolating the DNA rather than the DNA itself, the court found the claims were valid under 35 U.S.C. § 101.

A copy of the opinion can be found [here](#).

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