



## ***Illustrina v. Ariosa: En Banc Rehearing Denied, Illustrina***

### **Patents Again Upheld on Rehearing**

*By Rebecca Tapscott / August 4, 2020*

***“The CAFC explained that the 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.’”***

On August 3, the United States Court of Appeals for the Federal Circuit (CAFC) denied a petition for rehearing en banc and issued a modified opinion, following a petition for rehearing filed by Ariosa in *Illustrina, Inc. v. Ariosa Diagnostics, Inc.* Sticking closely to the reasoning of its March opinion, the CAFC reversed a decision by the United States District Court for the Northern District of California that claims of U.S. Patent Nos. 9,580,751 (the ‘751 patent) and 9,738,931 (the ‘931 patent) belonging to Sequenom and Illustrina (Illustrina) were invalid under 35 U.S.C. § 101 as being directed to an ineligible natural phenomenon.

The ‘751 and ‘931 patents were directed to methods of preparing a fraction of cell-free DNA enriched in fetal DNA including size discrimination of the DNA. Illustrina filed suit against Ariosa Diagnostics, Inc., Roche Sequencing Solutions, Inc., and Roche Molecular Systems, Inc. (collectively, Roche) in the district court alleging infringement of the patents and Roche moved for summary judgment alleging invalidity of the asserted claims under 35 U.S.C. § 101. The district court granted the motion for summary judgment and entered judgment in favor of Roche. Illustrina appealed to the CAFC.

### **Modified Opinion**

Reviewing the grant of summary judgment *de novo*, the CAFC again explained that this was not a diagnostic case or a method of treatment case, but rather it was a method of preparation case. Explaining that diagnostic claims have consistently been held ineligible under *Athena Diagnostics, Inc. v. Mayo* and method of treatment claims have been held eligible, the CAFC noted that the claims of this case do not fall under either category and commenced consideration under the *Alice/Mayo* test.

The CAFC stated that the focus of the dispute in this case was “whether the claims of the ’751 and ’931 patents [were] ‘directed to’ the natural phenomenon, *i.e.*, whether they claim the discovered natural phenomenon itself versus eligible subject matter that exploits the discovery of the natural phenomenon.” The majority adopted Illumina’s identification of the natural phenomenon, *i.e.* “that cell-free fetal DNA tends to be shorter than cell-free maternal DNA in a mother’s bloodstream,” and explained that the claims included specific process steps of size discrimination and selectively removing DNA fragments having a size greater than a predetermined size, 500 base pairs in the ’751 patent and 300 base pairs in the ’931 patent, in order to increase the relative amount of fetal DNA as compared to maternal DNA in the fraction. The Court explained that the claimed size thresholds are “human-engineered parameters that optimize the amount of maternal DNA that is removed from the mixture and the amount of fetal DNA that remains in the mixture” and further the claimed methods included more than a simple observation of the natural phenomenon that a fetal DNA is shorter than a mother’s DNA. Rather, the CAFC explained, the 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.”

The CAFC then distinguished the present claims from the claims in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, wherein the patent claims were directed to a method of starting with a sample that contains cell-free fetal DNA and observing that that the cell-free fetal DNA exists, by explaining that the claims of the patents-

in-suit were directed to more than a correlation between DNA fragment size and whether it is fetal or maternal. The CAFC explained that the patents-in-suit claimed methods of exploiting a natural size distribution during sample preparation for the purpose of removing some maternal DNA from the mother's blood, rather than simply detecting or observing a property of a previously-prepared sample.

The Court also distinguished Association for Molecular Pathology v. Myriad Genetics, Inc., which held that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated”, explaining that the claims of the patents-in-suit are not directed to the cell-free fetal DNA itself and, therefore, the holding in *Myraid* was not on point. The CAFC noted that, in this case, “the inventors claimed to have conceived and reduced to practice, not the separated DNA, but a method that uses unconventional size parameters to perform the separation.” Concluding that the claims were “directed to” more than merely the natural phenomenon that the inventors discovered, the CAFC held that the claims were directed to patent-eligible subject matter under 35 U.S.C. § 101 and reversed the district court's grant of summary judgment.

### **Judge Reyna Dissents**

In dissenting from the majority, as before, Judge Reyna opined that the asserted claims are directed to a natural phenomenon, the patents-in-suits' “sole claimed advance is the discovery of that natural phenomenon, and the application of the natural phenomenon utilizes routine steps and conventional procedures that are well known in the art.” Reyna noted that, similar to Alice Corp. Pty. Ltd. v. CLS Bank Intern, the claims of the patents-in-suit were “directed to a natural phenomenon because they *involve* a fundamental natural phenomenon, that cff-DNA tends to be shorter than cell-free maternal DNA in a mother's blood, to produce a ‘mixture’ of naturally-occurring substances.”

After determining that the claims did not survive step 1 of the *Alice/Mayo* inquiry, Reyna continued to assert they further would not survive an analysis of step 2. In particular, Reyna noted, the fact that “the size discrimination and selective removal method steps were applied for the first time to the newly discovered natural phenomenon does not render those steps transformative, new and useful, under the *Alice/Mayo* step-two inquiry.”

In conclusion, Reyna noted that, while there may be other cases where process claims directed to a natural phenomenon may be patent eligible, this was not such a case.