Federal Circuit Further Restricts Patentability of Biotechnological Inventions and Other Inventions Involving Discovery

The Federal Circuit's June 12, 2015 decision in a closely-watched biotechnology case, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Appeal No. 2014-1139, 2014-1144. (Fed. Cir. June 12, 2015) ("*Ariosa*"),[1] ostensibly clarifies the patent eligibility analysis established by the Supreme Court in *Mayo Collaborative Services v. Promethius Laboratories, Inc.*, 132 S.Ct. 1289 (2012) ("*Mayo*"). However, this latest case building on the precedent laid down in *Mayo* and in *Myriad* (*Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013)), further restricts the patentability of biotechnological inventions utilizing a restrictive analysis not mandated by Supreme Court precedent. This decision will impact not only molecular diagnostics, but also biotechnology and any field based upon discovery of natural products, processes, or phenomenon.

The invention in *Ariosa* involves the surprising discovery that fetal DNA can be isolated from maternal blood plasma and used in the prenatal diagnosis of a number of genetic abnormalities and in the determination of the sex of the baby. This technique avoids the risks involved with the more invasive forms of diagnostic testing, Chorionic Villus Sampling and Amniocentesis, for example, and is much less expensive. The claims of the patent were directed to methods of detecting fetal cell-free DNA (cffDNA) from the serum of the mother and to methods of prenatal diagnosis using such samples. Representative independent claims 1 and 25 read as follows:

Claim 1: A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises

amplifying a paternally inherited nucleic acid from the serum or plasma sample and

detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

Claim 25: A method for performing a prenatal diagnosis on a maternal blood sample, which method comprises

obtaining a non-cellular fraction of the blood sample

[1] http://www.cafc.uscourts.gov/images/stories/opinions-orders/14-1139.Opinion.6-10-2015.1.PDF

> amplifying a paternally inherited nucleic acid from the non-cellular fraction
>
> and performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal nucleic acid.

Applying the *Mayo* two-part test to the claimed method, the Federal Circuit concluded that the *Ariosa* method started with a natural product (cffDNA), ended with a natural product (isolated paternally-contributed cffDNA), and employed only well-understood, routine and conventional methods of amplification and detection (e.g. PCR and agarose gel electrophoresis). As a result, the claimed methods were deemed directed to ineligible subject matter under 35 U.S.C. § 101. Thus, the *Ariosa* test for patentability for claims involving a natural phenomenon or natural product is whether the claims represent an inventive application of the natural product/phenomenon.

While the court properly quoted the test laid out by *Mayo*, it did not apply that test as stated. In *Mayo*, once a claim is deemed directed to a patent-ineligible concept, the next step is to consider the claim elements both individually and "as an ordered combination" to determine if the additional elements "transform the nature of the claim" into an inventive application of the natural product/phenomenon. However, in *Ariosa*, rather than viewing the claims as directed to the new and novel isolation and amplification of cffDNA from a previously unimagined source, maternal serum, the court determined that the individual steps of isolating serum from blood, PCR amplification, and gel electrophoresis, were all routine and well-known process steps.

In a rather surprising move, Judge Robert Linn took issue in his concurrence with the Supreme Court's test in *Mayo*. Judge Linn writes that the claimed methods in *Ariosa* are new and patentable, but that he joined the court in invalidating the patent "only because I am bound by the sweeping language" set out in *Mayo*. He asserts that the breadth of the *Mayo* test was unnecessary for the holding there and that the *Arioso* case "represents the consequence – perhaps unintended – of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."

So, we are left with a decision that seems to go beyond the guidance provided by the Supreme Court in *Mayo* and one that almost begs for review in the concurrence. In the meantime, broad fields of scientific effort are left without clear guidance as to the ultimate patentability of their inventions.

Please let me know if you wish to discuss further.