Guest Post by Prof. Lefstin: Ariosa v. Sequenom and the Path Ahead for Subject-Matter Eligibility

June 14, 2015 Jason Rantanen

Guest post by Jeffrey A. Lefstin, Professor of Law at the University of California Hastings College of Law. Professor Lefstin's forthcoming article, Inventive Application: a History*, was cited by Judge Linn in his concurrence in* Ariosa.

The Federal Circuit has issued its decision in a closely-watched biotechnology case, *Ariosa Diagnostics v. Sequenom*. The opinion clarifies several aspects of the patent-eligibility inquiry in the wake of *Mayo v. Prometheus*, and has significant long-term implications for patent-eligibility not only in biotechnology, but in other fields where invention is based primarily on discovery.

The invention in the case derived from the inventors' discovery that the cell-free fractions (serum and plasma) of a pregnant woman's blood contain surprisingly large amounts of DNA from the fetus. Based on this discovery, the Sequenom patents claimed methods for prenatal diagnosis of fetal abnormalities, the methods comprising amplifying paternally-inherited sequences from the cell-free fractions of the mother's circulation.

Applying *Mayo*, the Federal Circuit held all the claims in suit ineligible. In step one of the *Mayo* inquiry, the court found that the claims were all directed to a natural phenomenon: the existence of paternally-inherited cell-free fetal DNA (cffDNA) in the maternal bloodstream. In step two, the search for an 'inventive concept,' the court invoked *Parker v. Flook* for the following proposition:

For process claims that encompass natural phenomenon [sic], the process steps are the additional features that must be new and useful.

Because methods of amplifying DNA were well-known at the time of the invention, the court determined that the claims disclosed only well-understood, routine, conventional activity beyond the underlying natural phenomenon. The claims therefore lacked an inventive concept sufficient to transform the natural phenomena into a patent-eligible application. So *Ariosa* makes clear that the test for patent-eligibility is whether a claim represents an 'inventive' application of an underlying natural phenomenon, at the time the invention was made.

Another notable aspect of the case is the court's discussion of preemption. After *Mayo* and *Alice*, some district courts have treated preemption as an operative test for patent-eligibility, while others have regarded preemption as the underlying justification for the doctrine. In *Ariosa*, the Federal Circuit

seemed to adopt the latter view, stating that once claims are determined to disclose only ineligible subject matter under the *Mayo* test, "preemption concerns are fully addressed and made moot." However, the court also wrote that "[w]hile preemption may signal ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility." So the Federal Circuit seems to be suggesting that arguments regarding preemption can be taxed against the patentee in the § 101 inquiry, but not counted in the patentee's favor.

In *Ariosa*, the Federal Circuit has endorsed a highly restrictive interpretation of the test for patent-eligibility, one that was not mandated by *Mayo* itself. A test for 'inventive' application was only one of several possible analytical approaches set forth in *Mayo*. *Mayo* also suggested a test of non-generic application for patent-eligibility: that a claim must do more than state a law of nature or abstract idea, and append an instruction to 'apply it.' That was the aspect of *Mayo* stressed by *Alice*, which emphasized generic application far more than inventive application.

As I argued in a recent paper, under a test of generic application, the claims in *Ariosa* might fare differently than the claims in *Mayo*. The claims in *Mayo* represented generic applications, because they did no more than reveal the results of the underlying relationship between 6-thioguanine levels and therapeutic efficacy. Arguably, at least some of the *Ariosa* claims do more than that: rather than claiming the natural phenomenon (cffDNA in the maternal circulation) itself, they employ the natural phenomenon as a means to a achieve a different end (diagnosing a genetic condition of the fetus).

Moreover, the *Ariosa* opinion appears to endorse dissection of the claim to a degree not only contrary to *Diehr*, but beyond that suggested by *Flook* itself. While *Flook* explained that "the process itself" must be new and useful, *Ariosa* suggests that the individual steps of the process must be new and useful, and identifies the discovery of cffDNA as "[t]he only subject matter new and useful as of the date of the application." Given that most inventions consist of rearrangements of old elements, it is difficult to understand how the court can refrain from addressing the claim steps as an ordered whole, as mandated by *Mayo* itself.

And that highlights what is perhaps the most puzzling (or disturbing) aspect of *Ariosa*. According to Judge Linn's concurrence, the steps of the method *were* new: at the time of the invention, no one was amplifying paternally-inherited sequences from maternal serum or plasma, because no one thought that those fractions contained significant amounts of fetal DNA. That contrasts with *Mayo*, where the acts recited in the method were identical to those performed in the prior art. Yet Judge Linn believed that the Supreme Court's "blanket dismissal of conventional post-solution steps" in *Mayo* left no room to distinguish the *Ariosa* claims on those grounds.

If the step of amplifying paternally inherited DNA from serum or plasma was new, by what analysis could the court could regard it as "well-understood, routine, and conventional activity"? One way would be to sub-dissect that step into the conventional step of obtaining a cell-free fraction, and the conventional step of amplifying a sample containing DNA. That approach seems to lead to the *reductio ad absurdum* that most biotechnology processes are patent-ineligible, because they consist of the conventional steps of transferring drops of fluid from one tube to another.

The alternative way would be to ask if the step of amplifying paternally inherited DNA would be obvious once it was known that there was cffDNA in the maternal bloodstream. In other works, assume the patentee's discovery to be already known, and ask if the invention is obvious once the discovery is assumed away. If that is truly the interpretation of *Mayo* signaled by *Ariosa*, then the case promises to cast a long shadow on the patent-eligibility of inventions based on discovery in the future.

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