

Ariosa V. Sequenom Signals Trouble Ahead For Life Sciences

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The Federal Circuit's recent decision in *Ariosa Diagnostics Inc. v. Sequenom Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), represents yet another example of the expanding impact of patent eligibility challenges in the wake of the U.S. Supreme Court's *Myriad* and *Prometheus* decisions. By this decision, the Federal Circuit appears to be more directly conflating patentability standards like obviousness with patent eligibility in order to strike down inventions that, on their face, appear to cover more than ineligible "natural phenomena." This trend is particularly troubling for the life sciences industry, where innovation necessarily is built on the study of biological properties and interactions that exist in nature. Historically, the prospect of real and enforceable patent protection has incentivized companies to develop life-saving treatments based on the discovery of new ways to impact the biological pathways involved in diseases. However, these incentives are steadily being eroded by the narrowing of patent eligible subject matter.



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Decisions like *Ariosa* potentially place at risk patents directed to diagnostic methods, vaccine technology, gene therapy, personalized medicine techniques, and other areas that carry real therapeutic potential and that have been the subject of significant research and development investment in recent years. How this trend continues in the courts could shape the direction of innovation in the biotech industry for years to come.

The Federal Circuit's decision in *Ariosa* sets an ominous precedent for future courts considering Section 101 challenges to life sciences patents. For purposes of assessing patent eligibility (as distinct from patentability), the Federal Circuit focused on whether the individual steps used in practicing the claimed method were obvious or conventional, notwithstanding the acknowledged novelty of the use of the natural phenomenon at issue. In so doing, the new test announced in *Ariosa* appears to conflate the test for patent eligibility with the test for obviousness and, thereby, expands the scope of the Supreme Court's test for patent eligible subject matter.

Taken to its logical extreme, courts applying the holding in *Ariosa* will be more likely to invalidate any life sciences method patents where the claimed method utilizes a newly discovered biological property in a way that has never been done before, but by using processes that are "routine or conventional." Given that standard laboratory techniques are necessary to perform most method patents in the life sciences, *Ariosa's* emphasis on the routine nature of the steps used to practice a method patent threatens to render patent ineligible a broad swath of valuable, pioneering inventions in the life sciences industry.

Ariosa's Method Claims

The patent claims at issue in *Ariosa Diagnostics v. Sequenom* were directed to a method for detecting cell-free paternally inherited DNA of fetal origin from a plasma or blood sample of a pregnant woman by amplifying a paternally inherited nucleic acid from the blood or serum sample and performing tests or analysis to detect paternally inherited nucleic acid. Other claims in the patent were directed to methods for performing prenatal diagnosis using the claimed method for detecting paternally inherited nucleic acid. Notably, the patent did not claim the cell-free paternally inherited fetal DNA used in the method claim. 788 F.3d at 1373.

As the Federal Circuit acknowledged, the patented method represented a novel alternative for prenatal diagnosis of fetal DNA, in contrast to the pre-existing diagnostic techniques — such as amniocentesis — which required risky procedures involving sampling cells from the fetus or the placenta. *Id.* Prior to the inventors, no one else had thought to sample blood and plasma of a pregnant woman for fetal DNA to use in genetic diagnosis of the fetus and, in fact, discarded plasma and blood samples from the mother. *Id.* Thus, the claims were directed to true innovation of the type the patent system should be designed to protect.

The Ariosa Court Conflates Obviousness and Patentability

The Federal Circuit considered the patent eligibility of the method claims at issue under the framework articulated by the Supreme Court in *Mayo v. Prometheus*, 112 S. Ct. 1289 (2012). The two-part *Prometheus* test instructs courts to first determine whether the claims are directed to patent ineligible phenomena of nature or abstract ideas. If they are, courts must then determine whether the patent contains other elements that are “sufficient to ensure that patent in practice amounts to significantly more than a patent” on a natural phenomenon. *Id.* at 1294. In *Ariosa*, the Federal Circuit first determined that the claimed method was directed to ineligible subject matter because the method “begins and ends with a naturally occurring phenomenon” — cell-free fetal paternally inherited DNA taken from a plasma or blood sample. 788 F.3d at 1376.

Next, the Federal Circuit determined that the claimed method did not sufficiently transform the subject matter and, therefore, the claims were directed to patent ineligible natural phenomena. The court reasoned that the steps used to practice the claimed method of amplifying and detecting the fetal DNA — including polymerase chain reaction and the use of genetic probes — were “well-understood, conventional, and routine” at the time the inventors began experimenting and therefore did not add any “inventive concept” to the claimed law of nature. *Id.* at 1377-78.

Although the court acknowledged that the patented method “combined and utilized man-made tools of biotechnology that revolutionized prenatal care,” the court nevertheless held that even “valuable contributions” to the medical field, like the patent at issue, can still fall short of the Section 101 threshold. *Id.* at 1379-80. In a concurring opinion, Judge Richard Linn expressed concern about the consequences of the *Ariosa* court’s unnecessarily broad interpretation of the *Prometheus* test which, in this case, excluded a “meritorious invention from the patent protection it deserves and should have been entitled to retain.” *Id.* at 1380.

In holding that the claims in *Ariosa* lacked an “inventive concept,” the Federal Circuit superimposed an obviousness-type inquiry onto the “transformation” prong of the *Prometheus* test. In determining whether a claimed invention would be obvious to one skilled in the art under Section 103, courts

consider, among other things, whether a patent merely combines known prior art elements according to known methods to yield predictable results or applies known techniques to a known method to yield predictable results. MPEP Section 2141; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). According to the Federal Circuit's reasoning in *Ariosa*, the mere fact that the claimed method requires obvious, routine, or conventional techniques to practice the method — even where the results are unpredictable, as in *Ariosa* — renders the claim patent ineligible, not merely unpatentable. The *Ariosa* court's focus on the individual steps used to practice the method, as opposed to the method as a whole, is more properly placed in an obviousness inquiry. In considering whether the patent is unpatentable for obviousness, a court would consider whether the known and conventional steps were combined in such a way that would not have been expected. The method claims in *Ariosa* would likely have survived such a test, as no one had previously thought to search for cell-free fetal DNA or use it to test for fetal genetic characteristics.

What is more, the *Ariosa* court's holding greatly widens the scope of the *Prometheus* test and arguably conflicts with precedential decisions. As courts have previously held, the patent eligibility test of Section 101, in contrast to the obviousness inquiry, requires courts to consider the combined elements of the claim as a whole — not the individual steps used to practice the claimed method. In *Diamond v. Diehr*, for instance, the techniques used to practice the method — a method of curing rubber — were all well-known and routine; yet the combination of those techniques in that particular application had never been performed. 450 U.S. 175 (1981). In contrast, the patent at issue in *Prometheus* merely recited an entire method — i.e., all of the steps in combination — that had already been practiced in the field for years. As Judge Linn noted in concurrence in *Ariosa*, the claims at issue in *Ariosa* fundamentally resembled those of *Diehr* more so than those of *Prometheus*, and, accordingly should have been held to be patent eligible.

Danger Ahead in Life Sciences

Ariosa portends ominous consequences for patents on methods and diagnostics in the life sciences. According to the logic of the *Ariosa* decision, any patent whose steps involve applying standard scientific techniques to previously undiscovered biological phenomena could be held patent ineligible. This standard puts at risk such inventions as immunodiagnostics, molecular diagnostics, and method patents directed to therapeutic uses of antibodies, vaccines, gene therapy, and biologics and biosimilars — all of which depend upon the natural characteristics and propensities of biological phenomena for their claimed therapeutic use.

Take, as an illustrative example of *Ariosa*'s ramifications, monoclonal antibodies used in cancer immunotherapy. Such antibodies “begin and end” with biological phenomena — namely, antibodies — thereby satisfying part one of the *Prometheus* test. And, to the extent any interim steps used to identify the antigen to which an antibody will bind or to administer the antibody are “well-known, routine, or conventional,” the *Ariosa* ruling could theoretically expose such patents to challenge on Section 101 grounds.

Such a blunt tool for determining patent eligibility threatens to eradicate patent protection for thousands of pioneering, innovative and useful inventions in the life sciences field. In place of a scalpel, the *Ariosa* ruling uses a machete to mow down a field of inventions worthy of patent protection.

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