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Intellectual Property

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Federal Circuit Finds Revolutionary Non-Invasive Fetal DNA Test Method Unpatentable Under *Mayo*

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On June 12, 2015, in *Ariosa Diagnostics, Inc. et. al. v. Sequenom, Inc. et. al.*, the Court of Appeals for the Federal Circuit invalidated claims in U.S. Patent 6,258,540 directed to methods for detecting paternally inherited cell-free fetal DNA (cffDNA) in a mother's blood, holding that the claims were not directed to patent-eligible subject matter under 35 U.S.C. § 101. To starkly summarize *Ariosa*, applying known methods – even to a pioneering discovery of a natural phenomenon – does not pass muster under § 101.

Despite repeatedly acknowledging that the discovery of cffDNA in maternal blood made a significant contribution to prenatal care, Judge Reyna, writing for the panel that included Judges Linn and Wallach, held that "even such valuable contributions can fall short of patentable subject matter." Judge Linn concurred, stating that the sweeping language in the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* was binding on him. "But for" that language, Judge Linn saw no reason in policy or statute that Sequenom's "breakthrough invention" should not be deemed patent eligible. It remains to be seen whether this view, perhaps as endorsed en banc by the Federal Circuit, will prompt the Supreme Court to take the case given what is likely an inevitable petition for writ of certiorari.

The claims at issue stem from the inventors' discovery of cffDNA in maternal blood samples. Previously, those samples had been discarded as medical waste. Based on their discovery, the inventors employed methods by which the paternally inherited cffDNA was amplified using well-known techniques, such as polymerase chain reaction (PCR), and then detected. The paternally inherited cffDNA was used to diagnose various fetal characteristics, such as gender and genetic disorders. Before the development of the methods claimed in the '540 patent, such testing was invasive and exposed mothers and fetuses to risk.

In holding that the claimed methods of the '540 patent fell short of reciting patent-eligible subject matter, the Court applied *Mayo*'s two-step test for patent eligibility: determining (1) "whether the claims at issue are directed to a patent-ineligible concept" and, if so, (2) whether the additional claim elements "transform the nature of the claim into a patent-eligible application" of the concept.

The Court concluded the claims at issue satisfied *Mayo*'s first step: "the claimed method begins and ends with a naturally occurring phenomenon," cffDNA. The Court noted that "Sequenom does not contend that [the inventors] created or altered any genetic information in the cffDNA, and it is undisputed that the location of the nucleic acids existed in nature before [the inventors] found them."

Applying *Mayo*'s second step, the Court found that none of the additional claim elements was sufficiently inventive to "transform" the claims into patent-eligible applications of a natural phenomenon. For process claims that encompass a natural phenomenon to satisfy *Mayo*'s second step, the Court explained, "the process steps are the additional features that must be new and useful." The claims at issue, however, recited steps of preparing, amplifying, and detecting cffDNA, which the Court determined were all well known at the time of invention. The Court concluded, therefore, that "appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, [were] not enough to supply an inventive concept."

The Court also rejected Sequenom's argument that the claims were patentable because they are narrow and specific, and, thus, did not preempt all uses of cffDNA. The Court explained that "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patentability." Where claims are directed only to ineligible subject matter under the *Mayo* test, the issue of preemption is moot.

The Court also cast aside Sequenom's argument "that before the '540 patent, no one was using plasma or serum of pregnant mothers to amplify and detect paternally-inherited cffDNA." The Court noted that Sequenom's argument implied that the inventive concept lay in the discovery of cffDNA in maternal blood. That was not, however, the claimed invention. In reaching its conclusion, the Court relied on the Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, which held that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."

In his concurring opinion, Judge Linn lamented that he was obligated to join the Court's decision solely because he was "bound by the sweeping language in the test set out in *Mayo*." Judge Linn observed that in articulating step two of the *Mayo* test, the Supreme Court had dismissed, seemingly without qualification, any "[p]ost-solution activity that is purely conventional or obvious." That blanket dismissal, Judge Linn explained, "leaves no room to distinguish *Mayo* from this case." In his view, it was unnecessary for the Supreme Court to have used such sweeping language based on the facts in *Mayo*: doctors were already performing in combination all of the claimed steps at issue. Here, in contrast, no one was detecting paternally inherited cffDNA or using it to diagnose fetal characteristics. *Ariosa* is the consequence – perhaps unintended – of *Mayo*'s overbroad language, Judge Linn explained.

Judge Linn found it "hard to deny that Sequenom's invention is truly meritorious." He described it as "groundbreaking" and noted that the Royal Society praised the discovery of cffDNA as "a paradigm shift in non-invasive prenatal diagnosis." Absent the Supreme Court's language in *Mayo*, Judge Linn would have found that the '540 patent satisfied § 101:

> But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why [Sequenom's] breakthrough invention should be deemed patent ineligible.

Judge Linn's concurrence may serve as the catalyst for the Federal Circuit to rehear *Ariosa* en banc. While there may be support among other active Federal Circuit judges to rein in *Mayo*, they may believe, like Senior Judge Linn, that they are constrained by *Mayo*. If that is the case, curtailing *Mayo*'s scope will require Congressional or Supreme Court intervention. In recent years, the Supreme Court has weighed in on § 101 issues repeatedly, deciding *Bilski v. Kappos* in 2010, *Mayo* in 2012, *Myriad* in 2013, and *Alice Corp. v. CLS Bank International* in 2014. Will *Ariosa* be next?

Ariosa leaves open the question of what "new and useful" process steps would be sufficient to confer patentability under step two of *Mayo*. While the Court held that the application of well-known techniques for amplifying and detecting DNA stated at a high level of generality is insufficient, it is unclear if limitations directed to detecting a specific cffDNA sequence related to a specific genetic disorder would be sufficient. Certainly, generic sequence probes, a specific locus, and a generic phenotype – all of which were identified in the dependent claims at issue in *Ariosa* – were not enough for patentability. By contrast to those generalities, it is unclear whether the specific markers and/or their relationship to the disease or condition would also have to be independently novel and inventive. *See, e.g., Myriad Genetics, Inc. v. Ambry Genetics Corp.*, 774 F.3d 755, 765 (Fed. Cir. 2014) (stating in *dicta* that method claims directed to detecting "particular mutations the inventors discovered" were "qualitatively different" than claims held to be directed to patent-ineligible subject matter); *see* also 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618, 74,624 and n.38 (Dec. 16, 2014). These open questions will have to be addressed by future courts.

A copy of the Federal Circuit's *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* decision is available here. To further discuss the potential impact of Ariosa, or other decisions related to patentable subject matter under § 101, please contact your usual Ropes & Gray attorney or one of the Ropes & Gray attorneys listed above.