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Patent Eligibility in the Life Sciences: Supreme Court Declines Review of *Ariosa Diagnostics v. Sequenom*

By Jeffrey Schmidt*, Karen Potter, and James J. Mullen, III

On June 27, 2016, the U.S. Supreme Court denied *certiorari* in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,¹ thereby letting stand the Federal Circuit's June 2015 ruling that Sequenom's diagnostic test for prenatal DNA is not patent eligible. In *Ariosa*, the Federal Circuit found that the claims, which were recognized to be directed to a groundbreaking discovery, are not entitled to patent protection because the presence of prenatal DNA in a maternal sample is a natural phenomenon.

The decision to decline review of patent eligible subject matter in the diagnostic and life science areas may reinforce the courts' increased scrutiny of life science claims after recent Supreme Court decisions including *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).

As a result, this decision represents a welcomed victory for defendants seeking to challenge method claims asserted against them as being patent ineligible. For companies seeking patent claims to diagnostic methods, biomarker detection, and other life science-based technologies, however, the decision may lead to continuing uncertainties regarding the validity or patentability of numerous patents or applications in this area. While this uncertainty may be concerning to these companies, dicta by the Supreme Court in its *Mayo* decision and recent guidelines issued by the United States Patent and Trademark Office (USPTO)² offer some hope that certain subject matter may remain patent eligible in this area.

BACKGROUND

Subject matter eligibility is governed by 35 U.S.C. §101 and extends patent protection to "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." There are, however, judicially created exceptions, including laws of nature, natural phenomena, or abstract ideas, which are not eligible for patent protection.³ Nonetheless, the bar for patent eligibility has, historically, been relatively low. That is, until the past few years.

The scope of what constitutes patent ineligible subject matter has increased following the Supreme Court's decision in *Mayo*, which held that a method of correlating effectiveness of treatment to a natural metabolite of an administered drug is a law of nature, and, therefore, not patent eligible.

¹ 788 F.3d 1371 (Fed. Cir. 2015).

² May 2016 Subject Matter Eligibility Update, 88 Fed. Reg. 27381 (May 6, 2016).

³ See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

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Mayo provided a two-part framework for determining whether an invention is patent eligible subject matter.⁴ The framework first assesses the claims to determine if they are directed to a patent ineligible concept (*i.e.*, a law of nature, natural phenomena, or abstract idea). If they are, then the claims are not patent eligible unless the claim as a whole is directed to “significantly more” than the law of nature, natural phenomena, or abstract idea itself.

As technologies are now being evaluated, or reevaluated, in the post-*Mayo* world, a new question arises: “Is this *still* patent eligible subject matter under the *Mayo* framework?” Some claims that would have been patent eligible just a few years ago may no longer be eligible for patent protection today in view of the more stringent standards for patent eligibility in *Mayo* and other court decisions.

THE *ARIOSA* OPINION

Sequenom was granted a patent to a method of non-invasively measuring cell-free fetal DNA (cffDNA) in maternal plasma and serum. The inventors discovered that cffDNA, which originated with the fetus but circulates freely in mother’s bloodstream, could be isolated, amplified, and detected as an alternative to the more invasive prenatal diagnostic techniques.⁵ After being sued for infringement by Sequenom, Ariosa challenged the patent as being invalid for being directed to a patent ineligible natural phenomenon.

The district court applied the *Mayo* two-part test and concluded that the diagnostic methods were patent ineligible, since the claims were directed to a natural phenomenon, the cffDNA, and the remaining steps were “well-understood, routine, and conventional” in the field.

On appeal to the Federal Circuit, Sequenom argued that “the claimed methods are patent eligible *applications* of a natural phenomenon, specifically a method for detecting paternally inherited cffDNA.”⁶ In support of patent eligibility, Sequenom argued that “before the ‘540 patent, *no one* was using the plasma or serum of pregnant mothers to amplify and detect paternally-inherited cffDNA.”⁷ Nonetheless, the Federal Circuit reasoned that, in view of the “sweeping language”⁸ of *Mayo*, it was obligated to affirm the district court’s ruling that the claimed methods were not eligible for patent protection.⁹ Under the guidelines of *Mayo*, the court found that the cffDNA constituted a “natural phenomenon” (*Mayo* step 1) and the remaining steps of amplifying and detecting the cffDNA were “well-understood, routine, and conventional activity” (*Mayo* step 2).¹⁰

The court held that “[w]here claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art.”¹¹

⁴ *Mayo*, 132 S. Ct. at 1293—94.

⁵ *Id.*

⁶ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Nos. 2014-1139, 2014-1144, slip op. at *11 (Fed. Cir. 2015) (emphasis added).

⁷ *Id.* at *15 (citing Appellants’ Br. 49).

⁸ *Id.* at *4 (Linn, J., concurring).

⁹ *Id.* at *16 (majority).

¹⁰ *Id.* at *13.

¹¹ *Id.*

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Judge Linn authored a concurring opinion that evinced the reluctance of at least some judges of the Federal Circuit to invalidate Sequenom's claims as being patent ineligible. Judge Linn noted, "[t]his case represents the consequence—perhaps unintended—of that broad language [in *Mayo*] in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."¹² This criticism of the potential reach of the *Mayo* decision offered hope that the issue was ripe for review by the Supreme Court. Unfortunately, by declining *certiorari*, the Supreme Court may be reinforcing the broad-sweeping impact of the *Mayo* framework.

THE FUTURE OF METHOD CLAIMS IN THE LIFE SCIENCES

Because the Supreme Court has declined to review the issue of patent eligibility at this time, the *Mayo* framework will likely be the test for patent eligibility for the foreseeable future. So far, courts have provided little guidance in the life sciences arena as to what additional elements must be present for a claim to be directed to "significantly more" than the judicial exception. Nevertheless, there is no categorical exclusion of subject matter eligibility in this area, since even the Supreme Court in *Mayo* stated that "too broad an interpretation of this exclusionary principle could eviscerate patent law"¹³ and that "an application of a law of nature...to a known structure or process may well be deserving of patent protection."¹⁴

Without further guidance from the Supreme Court, the lower courts will likely continue to invalidate certain patent claims. For example, on April 8, 2016, the Federal Circuit in *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016) struck down claims directed to "methods of detecting a coding region allele by amplifying and analyzing any linked non-coding region" for failing to satisfy patent eligibility under *Mayo*. As in *Ariosa*, the court concluded that the exception at issue (here, a "law of nature") was applied using only the conventional and routine steps of amplifying and detecting the DNA.

CONCLUSION

The impact that the Supreme Court's denial of *certiorari* in *Ariosa* will have is unclear. While the Court decided not to revisit the *Mayo* framework at this time, it does not foreclose the possibility that the Court will revisit it in the future. Nonetheless, it appears that, at least for now, the lower courts will continue to invalidate life sciences-related method claims. If the Court does not take up this issue in the future, the current test for patent eligibility under *Mayo* will remain the law unless Congress steps in—An event that seems unlikely to occur soon.

In the meantime, clients pursuing intellectual property protection for certain method claims in the life sciences will want to work closely with their patent counsel to address the impact of these recent decisions on their businesses and patent estates, while defendants in cases may want to consider how these cases might apply to claims asserted against them.

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¹² *Id.* at *2 (Linn, J., concurring).

¹³ *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1293 (2012).

¹⁴ *Id.* at 1293-94 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)).

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