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A Retrospective on *Myriad Genetics*: What Makes Medical Diagnostics Patent-Eligible 8 Years Later?

The law on whether medical diagnostic methods are patent-eligible can be challenging. Inventors who have heard of cases like *Myriad Genetics* may end up believing that methods of diagnosing disease are per-se ineligible for patent protection under 35 U.S.C. § 101. [1] Judge Moore of the Federal Circuit has remarked that "[s]ince *Mayo*, we have held every single diagnostic claim in every case before us ineligible."[2] Yet the Federal Circuit has hinted that inventions in the medical diagnostic space *may* be eligible for protection when the claims are directed to applications of laws of nature rather than the laws of nature themselves. Recent caselaw highlights the line that divides ineligible and eligible subject matter.

What *Isn't* Eligible?

Applying the familiar *Mayo* framework,[3] the Federal Circuit has indicated that patent claims directed to discovery of a natural law with additional steps only applying conventional techniques to detect that natural law are ineligible for patent protection under 35 U.S.C. § 101. In *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, the Federal Circuit held that a patent drawn to detecting muscle-specific tyrosine kinase (MuSK) was ineligible for protection.[4] The court held the claims failed the first step of the *Mayo* framework because the claimed methods used to detect MuSK involved discovery of a natural law and "the specification describes the claimed concrete steps for observing the natural law as conventional."[5] The court noted that the claims were drafted in a way that made them seem grounded and concrete, but that new biomarkers cannot be patent-eligible simply by virtue of the "specificity of the claimed concrete steps" used to measure them.[6] Under the second step of the *Mayo* framework, the court stated that "appending labeling techniques to a natural law does not provide an inventive concept where, as here, the specification describes labeling as a standard practice in a well-known assay."[7]

Cleveland Clinic Found. v. True Health Diagnostics LLC is similar.[8] The patents at issue in *Cleveland Clinic* disclosed "diagnostic test[s] which can be used to determine whether an individual . . . is at a lower risk or higher risk of developing or having cardiovascular disease."[9] The inventors had discovered that myeloperoxidase was a biomarker for cardiovascular disease and drew claims directed to "comparing levels of myeloperoxidase in a bodily sample from the test subject with levels of myeloperoxidase in comparable bodily samples from control subjects diagnosed as not having the disease."[10] Because the Federal Circuit found that "[t]he claims are not directed to new techniques for performing an immunoassay to detect a patient's blood MPO levels" but rather "only recite applying known methods to detect MPO levels in plasma," the claims were patent-ineligible under § 101.[11]

What *Is* Eligible?

While not directly in the diagnostic space, the Federal Circuit has upheld the patent eligibility of medical measurement patents when the claimed *method of preparing and measuring* a biomarker was itself unconventional. In *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, the patents at issue were directed to measuring newly discovered extracellular fetal DNA that could be found in maternal plasma.[12] Below, the District Court found the claims of these patents to be invalid as patent-ineligible under § 101. The patents identified a problem with applying known methods to measuring the fetal DNA;

> [T]he major proportion (generally >90%) of the extracellular DNA in the maternal circulation is derived from the mother. This vast bulk of maternal circulatory extracellular DNA renders it difficult, if not impossible, to determine fetal genetic alternations [sic] ... from the small amount of circulatory extracellular fetal DNA.[13]

After also noting that fetal DNA is smaller than maternal DNA, the patents then drew claims to an unconventional method of separating out the DNA in maternal plasma on the basis of DNA size.[14] The Federal Circuit explained, "the claims do not cover separated cell-free fetal DNA itself but rather a process for selective removal of non-fetal DNA to enrich a mixture in fetal DNA."[15] It continued, "the Supreme Court's decision in *Myriad* is not on point in this case where the inventors claimed to have conceived and reduced to practice, not the separated DNA, but a method that uses unconventional size parameters to perform the separation."[16] Because the method of filtering DNA by size was unconventional, the Federal Circuit reversed the District Court's finding that the claims were directed to patent-ineligible subject matter under 35 U.S.C. § 101. For support, the court cited back to the Supreme Court's refusal in *Myriad* to "extend its holding to method claims reciting an *innovative process* used to isolate DNA."[17]

Conclusion

Patent claims that measure a new biomarker may be rejected by patent examiners and the courts as directed to a naturally-occurring chemical itself. But claims that measure biomarkers in a new and inventive way may be eligible for patent protection. Medical inventors who discover clinically significant biomarkers may therefore wish to focus on drafting claims to the novel aspects of *how* a biomarker is measured and not *what* the biomarker is. Adding specificity to the steps for measuring a biomarker without adding novelty may cause patent eligibility issues down the line.[18]

As a partner with Finnegan, Daniel Cooley helps companies litigate intellectual property disputes in US district courts, the International Trade Commission (ITC), and the Patent Trial and Appeal Board (PTAB). Mr. Cooley also frequently practices before the US Court of Appeals for the Federal Circuit where he has participated in dozens of appeals and petitions, arguing several as lead counsel.

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1. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).
2. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, LLC, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (Moore, J., dissenting from denial of rehearing en banc).
3. *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc*., 566 U.S. 66, 70 (2012).
4. 915 F.3d 743, 748 (Fed. Cir. 2019).
5. 915 F.3d 743, 748 (Fed. Cir. 2019).
6. *Id.* at 752.
7. *Id*. at 755.
8. 760 F. App'x 1013 (Fed. Cir. 2019).
9. *Id.* at 1014.
10. *Id.*
11. *Id*. at 1018.
12. 967 F.3d 1319, 1325 (Fed. Cir. 2020).
13. *Id.* at 1322 (quoting U.S. Patent No. 9,580,751 1:42–50).
14. *Id.* at 1322–24.
15. *Id.* at 1328.
16. *Id*.
17. *Id.* at 1327–28 (citing *Myriad*, 569 U.S. at 580).
18. *Athena, LLC*, 915 F.3d at 752.

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