IP Alert: Recalibrating the Alice/Mayo Test

Recalibrating the Alice/Mayo Test

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Repeated challenges to invalidity holdings of diagnostic method claims under the Alice/Mayo framework at the U.S. Court of Appeals for the Federal Circuit prompt a flurry of questions about appellants' motivations. Does each challenger truly believe its method claims distinct from the methods in Mayo? Are challengers appealing adverse holdings merely to extend patent life in the hope of a legislative or judicial fix? Are patent owners blinded by the non-obviousness of their discovered laws of nature? Are they deluded to think the non-obviousness of the discovery will overcome the exclusion of natural laws from patent eligibility?

The repeated challenges also prompt a flurry of questions about the judge-made exclusions to patentability. Is the Alice/Mayo test overbroad and does it need recalibration? Are patents on diagnostic methods more societally damaging than patents on therapeutic methods or drugs themselves? Does a diagnostic method depend more on a law of nature than a therapeutic method or a drug?

Athena's appeal of the final decision of the U.S. District Court for the District of Massachusetts dismissing Athena's infringement complaint for failure to state a claim under 35 U.S.C. § 101 raises these questions once again. Athena Diagnostics, Inc., v. Mayo Collaborative Services LLC, Appeal No. 2017-2508. The filing of four amicus briefs reinforces the raising of these questions. Not only are patentees reluctant to relinquish their prize properties, but the patent bar is seriously bothered by the state of § 101 jurisprudence.

The litigants participated in oral arguments before a panel of the U.S. Court of Appeals for the Federal Circuit consisting of Judges Newman, Lourie, and Stoll on October 4, 2018.

The Alice/Mayo test has two steps: (1) is the claim directed to a law of nature, a natural phenomenon, or an abstract idea? and (2) Does the claim recite additional elements that

amount to significantly more than the judicial exception? In their briefs, the parties differed at both step 1 and step 2 of the Alice/Mayo analysis. At step 1, appellee Mayo urged that the claims were directed to a law of nature, but appellant Athena urged that the claims were directed to an assay. While Athena's contention has great appeal, because indeed the methods of the claim describe an assay, the court has on many occasions ignored the plain meaning of such claims and sought out an underlying natural law. Athena's asserted claims 7, 8, and 9 recite (along with base claim 1[1]):

1. A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of **detecting** in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK).

7. A method according to claim 1**,** comprising **contacting** MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid, **immunoprecipitating** any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and **monitoring** for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex, wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to muscle specific tyrosine kinase (MuSK).

8. A method according to claim **7** wherein said label is a radioactive label.

9. A method according to claim 8 wherein said label is ^{125}I.

(emphasis added).

The district court identified the underlying patent-ineligible concept of the claims as the naturally occurring interaction of ^{125}I-MuSK and a bodily fluid. Memorandum and Order, Civil Action No. 15-cv-40075-IT, at page 7. The court was not deterred by its recognition that ^{125}I-MuSK is not naturally occurring. Rather, it characterized step 1 as a search for the focus of the claims.

At step 2, Athena urged in its brief that the inventive concept contained in the claimed methods is the use of a novel, laboratory-made, labeled, MuSK complex. Mayo argued in its brief that merely labeling a natural product does not make it an inventive concept. At the oral argument Athena argued that the novel epitopic fragments of MuSK that it identified were inventive, but Mayo pointed out that the claims are not limited to the use of such fragments (reciting "MuSK or an epitope or antigenic determinant").

At oral argument, responding to Judge Lourie's question about distinguishing over the Supreme Court's Mayo holding,[2] Athena urged that the step of administering in the Mayo case was old, but here the claims describe a new assay that employs reagents that are not off-the-shelf.

Appellee Mayo argued that the only novel element in the claims beyond the natural correlation of MuSK auto-antibodies to Myasthenia gravis was the iodination of MuSK or MuSK fragments, and iodination is not novel or inventive. Mayo stated that the law prevents claims to a method to observe a natural law using conventional steps. That, it continued, is what this claim does.

Judge Lourie asked Mayo how discovery of a correlation could be protected. Mayo said it cannot be protected. Judge Newman questioned Mayo why important advances should not be protectable merely because they involve a natural product. Mayo pointed to both Federal Circuit and Supreme Court precedents that bar such protection, including Mayo, AMP, Arioso, and Cleveland Clinic.[3]

The amicus briefs were not mentioned at the oral arguments, but they provide interesting

comments in support of Athena, although not all are designated as supporting Athena. "Ten Law Professors" argued in their brief that lower courts and the U.S. Patent and Trademark Office have misunderstood the Supreme Court's Alice/Mayo test. The lower tribunals have made the test indeterminate and overly restrictive, the Ten urged. An approach that assessed the "claim as a whole" would solve the problems, they said, in particular the negative effects of the lower tribunals' holdings on the diagnostics industry. The Ten did not demonstrate how their approach would apply to the Athena claims. They may have meant that the second step of the Alice/Mayo test, the so-called search for an inventive concept, should not be limited to exclude the elements of the claim that embody the natural phenomenon or abstract idea. Alternatively, they may have meant that the first step of Alice/Mayo should not exclude elements that do not embody the natural phenomenon or abstract idea.

The Chartered Institute of Patent Attorneys, a body of United Kingdom patent attorneys, agents, and students, submitted an amicus brief. The Institute claimed that the subject of the appeal is of fundamental concern to its members and their clients. The Institute argued that the holding of the district court conflicts with the obligation of the United States under Article 27 and Note 5 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The institute argued that patent rights under the treaty are to be enjoyed without discrimination as to field of technology. The treaty does not exclude natural products or processes involving natural products. The district court's over-expansive interpretation of Mayo, Myriad, and Alice results in a violation of U.S. treaty obligations, the institute concluded.

Five Life Sciences Patent Practitioners' amicus brief also supported the validity of Athena's claims. This brief focused on the lack of pre-emption by the Athena claims and the failure of the district court to recognize a novel reagent that transformed the claimed law of nature into "something more." The Five discussed the negative impact on the diagnostics industry of overly broad interpretations of Alice/Mayo. The analysis of the Five did not require that the claim be considered as a whole, as did the Ten, but agreed with Athena that the recitation of a novel reagent was sufficient to transform the claim into "something more."

The Biotechnology Innovation Organization (BIO) filed an amicus brief in support of neither party. BIO argued that step 1 of the Alice/Mayo test as applied to software should be similarly applied to biological innovations. The analysis should focus on whether the innovation makes a technical advance over the prior art. It also urged that the step 1 analysis (what is the invention directed toward?) is too slippery when applied to biotechnology innovations. Regardless of novel elements, the courts consistently see a law of nature. BIO picked up on a dissent by Judge Linn, who stated that it remains unclear where to "draw the line between properly determining what the claim is directed to and engaging in an overly reductionist exercise" to find the patent-ineligible concept underlying any claim. BIO, like the Ten, suggested that considering the "claim as a whole" would remedy this problem.

BIO criticized the district court's decision for conflating the step 2 inquiry into "routine and conventional" elements with a § 112 (enablement) inquiry. The interrelationship of these statutory requirements, if any, was procedurally and substantively improper, BIO urged.

The amicus briefs seem to be throwing lifelines to the panel, in particular to Judges Lourie

and Newman, who seemed to want to find a way to protect innovations that are indeed meritorious. One common element in the amici's approaches is the need to clarify a test so that it still complies with Supreme Court precedent but does not see a natural law under every rock and does not permit a natural law in a claim to swallow other elements of a claim. We will need to wait to see whether the Federal Circuit can roll back the accretions onto the Alice/Mayo test, or whether these are so firmly affixed that only legislation can provide a reset.

Click here to listen to the oral arguments in Athena Diagnostics, Inc., v. Mayo Collaborative Services LLC.

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[1] Base claim 1 is not asserted against Mayo, but is shown here as it is incorporated into each of asserted claims 7-9.

[2] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012)

[3] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012), Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013, Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), and Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352 (Fed. Cir. 2017).

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