THE
NATIONAL LAW REVIEW

Federal Circuit Digs Deeper Hole For Diagnostic Methods

Tuesday, February 12, 2019

In *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, the Federal Circuit once again held diagnostic method claims invalid under 35 USC § 101. Footnote 4 of the majority decision blames the Supreme Court for this outcome, but Judge Newman's dissent outlines her views on how the court could have followed all relevant Supreme Court precedent and reached a different conclusion by heeding Supreme Court guidance that patent claims must be considered as a whole.

Article By
Courtenay C. Brinckerhoff
Foley & Lardner LLPPharmaPatents

Intellectual Property
Litigation / Trial Practice
Federal Circuit / U.S. Court of Spec. Jurisdiction

The Patent At Issue

The patent at issue was U.S. Patent 7,267,820, described in the decision as being directed to "a method of detecting antibodies to a protein called muscle-specific tyrosine kinase (MuSK)" which is associated with neurological disorders such as myasthenia gravis ("MG"). As discussed in the decision, 80% of MG patients produce acetylcholine receptor autoantibodies and can be diagnosed on that basis, but 20% do not. Many of those previously undiagnosable 20% produce autoantibodies to MuSK, and so can be diagnosed by the method of the '820 patent.

This Washington Post article published a few days before the decision highlights the agony of suffering from undiagnosed MG.

The court focused on claim 7, which depends from claim 1:

1. A method for diagnosing neurotransmission or developmental disorders related to [MuSK] in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of [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 [MuSK].

The patent stems from an application filed in 2001, and was granted in 2007–five years before the Supreme Court decision in *Mayo v. Prometheus*.

The Federal Circuit Decision

The Federal Circuit decision was authored by Judge Lourie and joined by Judge Stoll. As noted above, Judge Newman dissented. According to the majority:

> The claims at issue here involve both the discovery of a natural law and certain concrete steps to observe its operation.

The majority applied the *Mayo/Alice* two-step analysis as follows:

1. The claims are directed to the natural law of "the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases like MG."
2. The additional steps "only require standard techniques to be applied in a standard way."

The majority justified its conclusion at step one because the only "innovation" reflected in the claims is the "discovery of the natural law." The majority acknowledged that the claims did not preempt the "natural law" at issue, but held that lack of preemption is not sufficient to satisfy § 101:

> Preemption is sufficient to render a claim ineligible under § 101, but it is not necessary.

Responding to arguments that that "the claimed steps were unconventional because they had not been applied to detect MuSK autoantibodies prior to Athena's discovery of the correlation between MuSK autoantibodies and MG," the majority stated:

> We cannot hold that performing standard techniques in a standard way to observe a newly discovered natural law provides an inventive concept.

The court therefore affirmed the judgment of the district court that detect held the claims invalid under § 101.

Footnote 4

The majority responded to some of the issues raised in the dissent in footnote 4:

> The dissent states much that one can agree with from the standpoint of policy, and history, including that "the public interest is poorly served by adding disincentive to the development of new diagnostic methods." Dissent at 12. We would add further that, in our view, providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts. But, whether or not we as individual judges might agree or not that these claims only recite a natural law, *cf. Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, J., concurring in the denial of rehearing *en banc*) (discussing traditional laws of nature such as "Ohm's Law, Boyle's Law, [and] the equivalence of matter and energy"), the Supreme Court has effectively told us in *Mayo* that correlations between the presence of a biological material and a disease are laws of nature, *see* 566 U.S. at 77, and "[p]urely 'conventional or obvious' '[pre]-solution activity' is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law," *id.* at 79 (second alteration in original) (quoting *Flook*, 437 U.S. at 590). We have since confirmed that applying somewhat specific yet conventional techniques (such as the polymerase chain reaction) to detect a newly discovered natural law does not confer eligibility under § 101. *Ariosa*, 788 F.3d at 1377; see also *Cleveland Clinic,* 859 F.3d at 1356, 1362 (addressing other conventional techniques such as flow cytometry). Our precedent leaves no room for a different outcome here.

Judge Newman's Dissent

Judge Newman's dissent outlines legal and policy reasons why she believes the majority decision is wrong.

Legally, Judge Newman finds that "[t]he claims are for a multi-step method of diagnosis, not a law of nature."

> The '820 inventors did not patent their scientific discovery of MuSK autoantibodies. Rather, they applied this discovery to create a new method of diagnosis, for a previously undiagnosable neurological condition.

She also criticizes the majority's analysis for failing to consider the claims as a whole, and reminds the majority that the Supreme Court itself held in *Diamond v. Diehr* that "[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." She also explains that this guidance from *Diehr* is not changed by *Mayo* or *Alice*.

Turning to policy, Judge Newman considers the positions of various *amici*, and concludes that sound policy favors patent eligibility:

> [F]or procedures that require extensive development and federal approval, unpredictability of patent support is a disincentive to development of new diagnostic methods. The loser is the afflicted

public, for diagnostic methods that are not developed benefit no one.

Digging A Deeper Hole

Although footnote 4 of the majority decision cites the Supreme Court decision in *Mayo v. Prometheus*, much of the court's own analysis refers to post-*Mayo* Federal Circuit decisions, including *Ariosa* and *Cleveland Clinic*. Thus, when the majority states "***Our*** precedent leaves no room for a different outcome here," the court must acknowledge its own role in declining to draw a line between the problematic claims invalidated in *Mayo v. Prometheus* and more specific claims with more concrete method steps. At this point, it may be that only Congress can fill the hole in patent eligibility that grows with every decision invalidating diagnostic method claims.