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3 Takeaways From The Latest Ax Of A Diagnostic Patent

By **Ryan Davis**

Law360 (February 12, 2019, 8:26 PM EST) -- The Federal Circuit's latest invalidation of a medical diagnostic test patent for claiming a natural law could motivate lawmakers pursuing legislation to curb such decisions, and also provides guidance on how patentees can avoid a similar fate. Here are some lessons from the decision.

The Outcome Vexed the Court, but Congress Could Act

Though it affirmed a lower court's ruling invalidating an Athena Diagnostics Inc. patent asserted against the Mayo Clinic on a test for diagnosing an autoimmune disease, the Federal Circuit seemed reluctant and said it was bound by U.S. Supreme Court precedent. The outcome could become a rallying cry for proponents of a legislative overhaul to expand what is patent-eligible.

"This decision is, I think, being offered as a vehicle to spur action in Congress, where there has been increasing interest in looking for a legislative fix of the seemingly intractable problem of protecting these types of inventions" on methods of diagnosing diseases, said Pauline Pelletier of Sterne Kessler Goldstein & Fox PLLC.

In a 2-1 decision last week, the appeals court said Athena's patent was invalid under the high court's 2012 Mayo v. Prometheus decision, which held that inventions directed to laws of nature are not patent-eligible unless they contain an additional inventive concept.

Athena's patent is based on the discovery that the 20 percent of people with myasthenia gravis, a chronic disorder causing waning muscle strength, who cannot be diagnosed by traditional means can be diagnosed using the presence of certain antibodies. The Federal Circuit said such a natural correlation can't be patented and since Athena's test uses only conventional methods, its patent is invalid.

However, U.S. Circuit Judge Alan Lourie said in a footnote that allowing patents on such diagnostic methods "would promote the progress of science and useful arts," but high court precedent "leaves no room for a different outcome here." In a dissent, U.S. Circuit Judge Pauline Newman said invalidating the patent will "exacerbate the judge-made disincentives to development of new diagnostic methods, with no public benefit."

Athena could always appeal, but an en banc rehearing seems unlikely if the other Federal Circuit judges also feel their hands are tied by the Supreme Court, and the justices themselves may not be inclined to

revisit their unanimous ruling from seven years ago. Change would likely have to come from Capitol Hill, where there may be some appetite for rewriting eligibility law.

“I think if it's going to get fixed, it's going to have to get fixed by Congress,” said Joseph O'Malley of Paul Hastings LLP, who noted that “you almost see some frustration bleeding through for Federal Circuit judges."

There has recently been some movement toward legislation to make more inventions patent-eligible, since Sens. Chris Coons, D-Del., and Thom Tillis, R-N.C., convened a meeting late last year to begin a discussion on rewriting the patent-eligibility provision of the Patent Act.

Both senators have expressed concern about limits on what is patent-eligible and were just named leaders of a new intellectual property subcommittee of the Senate Judiciary Committee. Tillis said last week that "confusion ... about what is even patentable" threatens the U.S. economy, and IP groups have proposed legislative changes.

"I think their ask to Congress would be to reverse course from what the Supreme Court has done under Mayo and offer some form of patent protection for those types of inventions,” Pelletier said.

In its 2012 decision, the Supreme Court left the door open for changes to expand patent-eligibility beyond the limits it set. It wrote that "we must recognize the role of Congress in crafting more finely tailored rules where necessary, [so] we need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable."

"They're saying, 'Congress, go ahead,'" said Thomas Hedemann of Axinn Veltrop & Harkrider LLP.

There are Clues to How Similar Patents Can Survive

Methods of diagnosing disease can be important medical advances that help patients and are lucrative for life sciences companies. The Athena decision is the latest to suggest that many such inventions may not be patent-eligible absent new laws, but it provides some hints on what inventors can do to help their patents pass muster.

The "broad, sweeping language" used by the Supreme Court "is now killing some pretty interesting diagnostic techniques just because they happen to be related to naturally occurring biologic relationships," O'Malley said.

The decision doesn't offer much comfort for those who own patents that predate the 2012 Mayo decision — Athena's was issued in 2007 — but applicants going forward can look to the new ruling to give their patents a better chance of survival.

"There are important lessons that can be applied prospectively in how you draft patent applications and claim diagnostic inventions," Pelletier said.

For one, Athena stressed in the patent that its invention was the discovery of the relationship between the antibodies and the disease, detected using conventional techniques, but that is clearly now a bad idea.

"One of the flaws the court highlighted in this case was that the invention was admitted to be the

naturally occurring correlation," Pelletier said. "You don't want to identify the invention as being the natural law."

Instead, it would be better if possible to focus on any newly devised method for detecting the correlation, which the court said would be patent-eligible. Creating a new testing method is generally not the top priority of those developing diagnostic patents, but doing so seems to confer patent-eligibility.

"Diagnostic method claims are going to be held invalid unless the patent holder is able to point to some unconventionality, something new, in the method of detection," Hedemann said. "It seems pretty clear that the court will look favorably on any such claims."

Athena did not devise any new lab techniques and mentioned in the patent that its invention used conventional methods, so "what I glean from this decision most forcefully is that an admission in the specification of a patent about what is well-known and conventional tends to be the kiss of death," Pelletier said.

Another way patents could survive eligibility challenges would be to incorporate some method of treating the disease beyond just detecting it. The Federal Circuit held last year that most treatment method inventions are patent-eligible, and reiterated that last week to stress that Athena's invention has no treatment aspect.

The appeals court "suggests that if your claim has any kind of treatment element to it, it's going to survive," Hedemann said, adding that "I would imagine that many people will try to put a treatment element into the claim language, and that shouldn't be too hard to do."

The Court Showed How to Delay Invalidity Rulings

One troubling aspect of ineligibility decisions for patentees is that they can come very early in litigation on a motion to dismiss, as was the case for Athena. The Federal Circuit affirmed the lower court's dismissal, but gave a hint on how patent owners can delay such rulings.

The appeals court ruled last year that deciding patent eligibility on a motion to dismiss may not be appropriate if there are factual issues in dispute. In opposing dismissal, Athena said there was such a dispute over whether the technique used in its invention was conventional and submitted an expert declaration to that effect, but the Federal Circuit said the judge didn't have to consider it.

That's because on a motion to dismiss, judges can only consider facts in the complaint, and Athena's "complaint does not reference [the declaration] or otherwise depend on it," the court said. Future patent plaintiffs in this situation should therefore consider incorporating expert opinions into their complaint to have a better shot at fending off dismissal.

"Patentees will want to think about the extent to which you want to bolster your complaint with factual allegations about the unconventionality of the techniques employed," Hedemann said, adding, "If you believe that you may be vulnerable to an eligibility challenge at the motion to dismiss stage, you may not really have an alternative."

The court's explanation on that point is helpful guidance on how eligibility issues should be litigated, Pelletier said.

"The Federal Circuit is trying to provide parties with more procedural clarity about how to litigate these disputes properly, things that were not clear at all a year ago," she said.

The case is Athena Diagnostics Inc. et al. v. Mayo Collaborative Services LLC, case number 2017-2508, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Kelly Duncan and Aaron Pelc.