Impact of Federal Circuit's Opinion in 'Athena' on Medical Diagnosis Patents

The Legal Intelligencer

March 30, 2020

Michael Piscitelli & Nicholas Rogillio

Is a new method of diagnosing a disease patentable? Can it survive a motion to dismiss? And, irrespective of the current precedent, should a new method of diagnosing a disease be patentable?

Is a new method of diagnosing a disease patentable? Can it survive a motion to dismiss? And, irrespective of the current precedent, should a new method of diagnosing a disease be patentable? These are questions the U.S. Court of Appeals for the Federal Circuit, the solicitor general and medical diagnosis patent holders are struggling with.

Last year, in *Athena Diagnostics v. Mayo Collaborative Servivces,* the Federal Circuit held diagnostic claims ineligible under 35 U.S.C. Section 101, upholding, and perhaps expanding, the U.S. Supreme Court's holding of the 2012 case, *Mayo Collaborative Services v. Prometheus Laboratories.* What's more, on Jan. 20 the Supreme Court denied certiorari in *Athena* against the backdrop of pleas for clarification from the Federal Circuit, the solicitor general, and multiple amici briefs, including one from the former chief judge of the Federal Circuit. So, without additional clarification in sight, medical diagnosis patent holders, researchers and practitioners are left to make do with the current landscape.

The result of *Athena* is disconcerting to diagnostic patent drafters and holders alike. Going forward, patents issued prior to *Mayo* and *Athena* may be less valuable due to the risk of invalidation, and patent drafters will need to take extra care to ensure that their applications both issue and are valuable. *Athena* teaches another lesson—when a patent may be at risk of invalidation, supporting a complaint with expert testimony may help a case survive a motion to dismiss by placing sufficient factual issues in play.

As background, Athena asserted claims 6-9 of U.S. Patent 7,260,820 against Mayo. The patent claims consist of new methods for diagnosing Myasthenia gravis, a neurological disorder, by detecting autoantibodies that bind to a membrane protein, MuSK, epitope. The diagnosis method is accomplished by various means, such as enzyme-linked immunosorbent assay (ELISA), iodination and immunoprecipitation.

Procedurally, *Athena* rose to the Federal Circuit on appeal from a renewed motion to dismiss, where the district court granted Mayo's motion to dismiss Athena's complaint under 12(b)(6), holding the asserted claims invalid. Mayo first filed a motion to dismiss, which the court denied. In denying Mayo's motion, the court went through steps one and two of the *Mayo* analysis, finding at step one that the claims at issue were directed to patent-ineligible concepts, but finding insufficient evidence to decide that Athena's claims failed to satisfy the inventive concept requirement of step two of *Mayo*. However, the district court granted

Mayo's renewed motion to dismiss, this time finding that the specification's characterization of "iodination and immunoprecipitation" as "standard techniques in the art" constituted a sufficient basis to determine that the claims failed step two of the *Mayo* analysis.

After the district court granted Mayo's renewed motion to dismiss, Athena appealed to the Federal Circuit, where the district court's ruling was reluctantly upheld in light of the Supreme Court's noteworthy decision in *Mayo*. And to say "reluctantly" might be an understatement. The judges implored the Supreme Court to interject, with comments such as: "This is not a problem that we can solve. As an inferior appellate court, we are bound by the Supreme Court," "Had the Supreme Court not disregarded Congress' wishes for a second time, perhaps the outcome in this case would be different," and, "If I could write on a clean slate … I would not exclude uses or detection of natural laws … But we do not write here on a clean slate; we are bound by Supreme Court precedent."

But to no avail—even against this backdrop, the S30upreme Court denied certiorari, evincing the court's disinclination to revisit or revise its holding in *Mayo*. Suffice it to say, *Athena* stands for the premise that the Federal Circuit is upholding stare decisis in spite of the judges' personal opinions on the soundness of the precedent. And, the Supreme Court is not interested in providing any clarification at this time. Thus, *Mayo*, and now *Athena*, are here to stay, at least for the time being.

Athena also emphasizes that in a post-*Mayo* world, pre-*Mayo* medical diagnosis patents may be at risk. Patents drafted and issued prior to *Mayo* and *Athena* will not have had the benefit of being drafted in light of these decisions nor incorporating their lessons. As such, the language used in both the claims and the specification of such patents may be deficient to the point of invalidity, as was seen here with *Athena*. This is an important consideration when, among others, valuing one's own portfolios, evaluating the risk associated with others' patents being asserted, deciding on terms in a licensing agreement and in deciding on how to proceed as either defendants or plaintiffs involved in litigation. The risks are especially crucial in families that have issued out. For instance, some of the risks associated with pre-*Athena* patents may be mitigable through proper claim drafting, while families that have issued out are stuck with their existing structure and language. That said, issues stemming from a deficient or poorly drafted specification will remain uncurable in both situations. Despite the new increase in risk factors, the evaluation of *Athena*'s impact will still be on a case-by-case basis, as not every medical diagnosis patent will fall prey to the shortcomings elucidated by this case.

Going forward, care will need to be taken to incorporate the lessons taught by *Athena*. First, the court's application of *Mayo* and its progeny concluded that Athena's claims were "directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law." Had the claimed advance recited nonstandard techniques to detect that natural law or "harnessed a natural law to produce a technological improvement," the court may have decided differently. For instance, the inclusion of a treatment step might transform an unpatentable method of diagnosis, i.e., a natural law, into a patentable method of treatment, i.e., a specific and practical application of the natural law. The court also indicated that had the claims recited a new composition of matter that was not a natural product, they would not have been invalidated. In other words, if the diagnosis requires at any point the creation of a man-made composition of matter, then it would behoove a drafter to capture that in a claim as well. Additionally, the court discussed Athena's

unconsidered expert declaration, saying, "None of these details are recited in the claims of the 820 patent: no claim requires breaking MuSK into fragments as opposed to using the entire MuSK protein; no claim is limited to a particular MuSK binding site; and no claim recites any detail with respect to immunoprecipitation."

This is telling in that had more details of the process been included, the claims would most likely have been better situated to at least survive a motion to dismiss.

Second, and further to that point, had Athena pleaded with more factual specificity, perhaps supplementing their complaint with expert testimony, Athena may have been able to survive a motion to dismiss by putting sufficient factual issues in contention.

Third, in addition to including greater specificity when claiming, greater specificity and disclosure in the specification will help as well. Of course, to be claimed, there must be sufficient disclosure as support, but further than that, the specification must be thought of as part of the whole, allowing the court to see the technological complexity and improvement provided by an invention. That notion is starkly contrasted with Athena's statements that "iodination, immunoprecipitation, and the overall radioimmunoassay" are "standard techniques." Athena's expert testimony attempted to expound on the complexities and difficulties that would render the diagnosis method patentable, but by then it was "too little, too late." Any actual technological challenges that were overcome, or any uncertain results, were left behind by these over-broad statements that precluded the potential novelty of their diagnosis method from being presented in court.

So, the primary takeaways are that the devil is in the details, disclose sufficiently and avoid characterizing techniques in combination with a natural observation as standard if you wish to claim it. *Athena* affirmed many medical diagnosis patent holders and researchers' worst fears, but not all hope is lost. Pre-*Athena* patents may be less valuable, but through careful attention to drafting, future medical diagnosis patents can be as strong as ever.

Michael Piscitelli *is a shareholder at Flaster Greenberg who concentrates his practice in the fields of intellectual property law, worldwide patent procurement and patent portfolio development. He can be reached at mike.piscitelli@flastergreenberg.com.*

Nicholas Rogillio *is a member of Flaster Greenberg's intellectual property department and patent practice group. His experience lies in patent preparation and prosecution as well as patent litigation support. He can be reached at nick.rogillio@flastergreenberg.com.*

ATTORNEYS MENTIONED

Michael Piscitelli