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Federal Circuit Report

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Federal Circuit Strikes Down Diagnostic Patent in Latest § 101 Decision

On February 6, 2019, the Federal Circuit issued its latest opinion on patentable subject matter in the life sciences under 35 U.S.C. § 101 in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, No. 2017-2508, slip. Op. (Fed. Cir. Feb. 6, 2019). Judge Lourie wrote for the majority in this split decision, expressing some regret but affirming an order invalidating a diagnostic patent involving proteins. Judge Newman dissented, voicing a concern that § 101 jurisprudence has become counterproductive to the goals of patent law. Though unsurprising, the decision further narrows an already shrinking space for patents to diagnostic methods. It is unclear from this decision what diagnostic methods, if any, are safe from future § 101 challenges.

The patent claimed methods of diagnosing conditions relating to a protein called muscle-specific tyrosine kinase (MuSK) by contacting MuSK with a patient's bodily fluids and performing immunoprecipitation or enzyme-linked immunosorbent assay (ELISA) to detect autoantibodies to MuSK in the bodily fluids. The premise of the patent was that artificially labeled MuSK protein would form complexes with any autoantibodies to MuSK in a sample of bodily fluids, thus allowing scientists to detect the autoantibodies, which are found in some patients with *myasthenia gravis*. *Myasthenia gravis* is a neurological disorder characterized by muscle weakness and symptoms such as drooping eyelids, double vision, and slurred speech.

Athena, the exclusive licensee, sued Mayo for infringing the patent in the District of Massachusetts. Mayo moved to dismiss the complaint under Rule 12(b)(6), arguing that the asserted claims were invalid under § 101. The district court granted the motion, ruling that the asserted claims were invalid under the two-part test for § 101 established in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012).

A majority of the Federal Circuit panel affirmed in an opinion by Judge Lourie. Applying step one of the Supreme Court's two-part test, the court first determined that the claims were directed to a patent-ineligible concept, a natural law: the correlation between the presence of naturally occurring MuSK autoantibodies in bodily fluid and MuSK-related diseases like *myasthenia gravis*. Citing *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017), and *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015), the court held that a claim is directed to a natural law where, as here, the claimed advance was only in the discovery of a natural law, and the additional steps only applied conventional techniques to detect or observe the natural law.

The court was unmoved by Athena's argument that the claims were not directed to a natural law because they required labeling MuSK with a man-made substance. Analogizing to the facts in *Mayo* and *Ariosa*, the court agreed with Mayo that use of a man-made molecule (the labeled MuSK) is not decisive where, as here, it is a routine step in a conventional method for detecting a natural law.

In step two of the *Mayo* test, the court held that, setting aside the patent-ineligible natural law in the claims, there were no additional elements to the claims that transformed them into patent-eligible applications of such a law. The parties did not dispute that labeling proteins and immunoprecipitation were generally conventional techniques in the prior art. The only dispute was whether these steps were unconventional here because these techniques had not previously been applied to detect MuSK autoantibodies in particular. The court answered in the negative, stating that "we cannot hold that performing standard techniques in a standard way to observe a newly discovered natural law provides an inventive concept." *Athena*, slip op. at 17.

The court showed some reluctance in reaching its holding in a footnote but stated that "[o]ur precedent leaves no room for a different outcome here." *Id.* at 15 n.4.

In a sharp dissent, Judge Newman argued that the panel majority improperly expanded § 101 to the detriment of patentees and the public alike. Judge Newman asserted that the court wrongly stripped

away the steps of the claims in assessing whether the claims were directed to a natural law. According to the dissent, the majority ignored the actual subject matter of the claims—a new, multi-step diagnostic method—and instead focused on what the inventors discovered, but did not claim, their scientific discovery of MuSK autoantibodies. In so doing, Judge Newman argued, the majority departed from a long line of precedent requiring the claims to be considered as a whole.

Judge Newman also warned that the court's current § 101 jurisprudence and its focus on whether additional claim elements are "conventional" far exceeds the original bounds set forth by the statute. She pointed to the Supreme Court's holding in *Diamond v. Diehr*, 450 U.S. 175 (1981), where the Court held that the novelty of any element of a process or even the process itself is of no relevance to determining whether the subject matter is patentable under § 101. According to Judge Newman, "[t]he appropriate analysis of the role of conventional process steps in claims to a new method is under Sections 102 and 103, not Section 101." *Id.* (Newman, J., dissenting) at 11.

Finally, Judge Newman voiced her concern that the court's recent § 101 jurisprudence disincentivizes important innovation in the area of diagnostic methods and that the ultimate "loser is the afflicted public." *Id.* at 14.

Given the direction of § 101 case law in the past several years and the trifecta formed by *Mayo*, *Ariosa*, and *Cleveland Clinic*, the Federal Circuit's decision in *Athena* is not particularly surprising. Judge Newman's vigorous dissent, the patent community's strong reaction to the decision, and the panel majority's own apparent reluctance to rule as it did, however, reflect growing dissatisfaction with the current state of affairs. As the Supreme Court, the driver of these decisions, is unlikely to overrule its relatively recent § 101 decisions in the near future, change, if any, will likely need to come from Congress.

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