Publications

Client Alert: The Federal Circuit Affirms Lower Court Ruling Defining Patent Eligibility

Related Services

Intellectual Property

CLIENT ALERT | 2.19.2019

The United States Court of Appeals for the Federal Circuit released a ruling earlier this month that affirmed a District Court decision that certain medical diagnostic claims of U.S. Patent No. 7,267,820 (the '820 patent) were invalid. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC.*, No. 17-2508, 2019 U.S. App. LEXIS 3645 (Fed Cir. Feb. 6, 2019) (Before Newman, Lourie, and Stoll, Circuit Judges). *Athena* is another line drawn in the sand dividing subject matter worthy of patent protection from subject matter free for anyone to exploit. Here, the line does not favor medical diagnostic innovations.

The '820 patent is directed to a novel method of diagnosing Myasthenia gravis (MG), a chronic autoimmune neuromuscular transmission disorder that results in muscle weakness and fatigue. Conventional methods do not work for a minority of afflicted individuals, who may instead be diagnosed by detecting endogenous antibodies to the protein muscle-specific kinase (MuSK).

In light of this novel discovery, the '820 patent covers the method of taking a bodily fluid sample from a patient, contacting it with labelled MuSK, and using conventional techniques to extract any MuSK/antibody complex in order to detect individuals who have an immune response to MuSK, and thus have MG. Mayo challenged this patent, alleging that it was directed to ineligible subject matter.

By statute, any application that claims "a machine, a method, an article of manufacture or a composition of matter" is eligible for a patent. 35 U.S.C. 101. However, the Supreme Court has created additional exceptions to what might be patented, excluding "laws of nature, natural phenomena, and abstract ideas," which are understood to represent fundamental building blocks of science and technology that must be left in the public domain. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). Since the judicial exceptions were created, the courts have continued to shrink the pool of patent eligible subject matter. After a particularly notable case, *Mayo v. Prometheus*, many methods of diagnosing diseases are now patent ineligible, since they are considered to be laws of nature. 566 U.S. 66 (2012).

In *Athena*, the Federal Circuit applied *Mayo*, in combination with another case elucidating the judicial exceptions, to find that the '820 patent was directed to a law of nature. The Court found that once the claims at issue were stripped of everything directed to a law of nature, the remainder did not sufficiently transform the claim so as to make it patentable. Specifically, the Court found that finding an association between MuSK and endogenous antibodies of a patient with MG was "observing naturally occurring biological correlations with no meaningful non-routine steps in between." All steps not directed to the law of nature "only required standard techniques to be applied in a standard way." Judge Newman dissented, finding that the claims were improperly dissected and that the new method produces a tangible and useful result. Judge Newman wrote that the ruling hamstrings the development of diagnostic methods by disincentivizing innovation.

The decision has received attention because it ruled that a method that required a significant amount of work, expense and time to develop was patent ineligible. Yet, the position of the courts is clear: the discovery of many new medical diagnostic and biochemical innovations will not be rewarded with a patent at this time.

PRACTICE NOTE:

This ruling underscores the importance of innovators in the medical space proceeding carefully to ensure any patentable aspects of their efforts are protected. Certain medical diagnostic innovations may still be patentable, if the claims are directed only to patent-eligible aspects of the invention. Inclusion of any non-patent eligible material may lead to a complete loss of patent protection.

On the reverse side, competitors of current patent owners in the space may wish to challenge certain patents covering methods of medical diagnostics to gain the freedom to operate.