

ATHENA DIAGNOSTICS, INC. v. MAYO COLLABORATIVE SERVICES LLC, Appeal No. 2017-2508 (Fed. Cir. February 6, 2019). Before Newman, Lourie, and Stoll. Appealed from D. Mass. (Judge Talwani).

Background:

Athena sued Mayo for patent infringement, which the district court dismissed, finding the claims invalid under §101 as being directed to a law of nature.

Issue/Holding:

Did the district court err in holding that the claims were invalid under §101. No, affirmed.

Discussion:

The claims at issue cover methods for diagnosing myasthenia gravis (a neurological disorder) by detecting antibodies to a protein called muscle-specific tyrosine kinase ("MuSK"), which the inventors discovered was present in about 20% of patients with myasthenia gravis (the presence of MuSK is not associated with any other disease). The previous tests for myasthenia gravis did not detect the presence of myasthenia gravis in these patients. The inventors developed a manmade reaction sequence for detecting MuSK, which the claims are directed to, to diagnose myasthenia gravis in these patients. However, the individual steps performed in the method for detecting MuSK are identified in the Specification as applying conventional techniques.

Majority

In affirming the district court, the majority reasoned that claims that merely recite observing naturally occurring biological correlations with no meaningful non-routine steps in between are directed to a natural law. In particular, the majority reasoned that the additional recited steps in the claims only apply conventional techniques to detect the natural law, and as such, are directed to the natural law.

Newman's Dissent

In dissent, Judge Newman stated "[t]he majority does not distinguish between the question of whether the claimed method as a whole is eligible, and the question of whether the separate steps use conventional procedures. Instead, my colleagues hold that since the separate procedures are conventional, it is irrelevant that the method as a whole is a new method. The majority misconstrues the claims, in holding that claims 7-9 are directed to the 'concept' of 'the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases like MG.' The claimed method determines whether this correlation is present, for diagnostic purposes, but the concept itself is not claimed."

Citing *Diehr*, Judge Newman asserted that it is incorrect to remove steps performed by conventional techniques and their conjunction with all of the other steps from the claims for the purpose of §101 analysis.

Last, Judge Newman reminded the majority that the analysis of the role of steps performed in a conventional manner is under §§102 and 103, not §101.