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DIAGNOSTIC METHODS: DIRECT CLAIMS TO NON-ROUTINE, NON-CONVENTIONAL ACTIVITY TO INCREASE THE CHANCES OF OBTAINING A VALID PATENT UNDER 35 U.S.C §101

By: Daniel A. Geselowitz, Ph.D.

In *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC* (U.S. Circuit Court, D. Mass., decided on August 25, 2017), plaintiff Athena Diagnostics, Inc. and others ("Athena") had filed a complaint that two diagnostics tests developed by Mayo Collaborative Services ("Mayo") had infringed Athena's U.S. Patent No. 7,267,820 ("the '820 patent"). Mayo had filed a Renewed Motion to Dismiss this complaint, arguing that the patent was invalid under 35 U.S.C. §101 because the claimed method applies routine and conventional techniques to a law of nature, and therefore unpatentable.

Discussed in the patent's specification are, for example, Figures 4 and 5 shown below. Figure 4 is an illustration of the results obtained from tests to confirm the specificity of the test for *Myasthenia gravis* set out in the described examples; and Figure 5 is an illustration of the results obtained from a test to detect MuSK antibodies in mothers of babies with developmental defects.

FIG. 4.

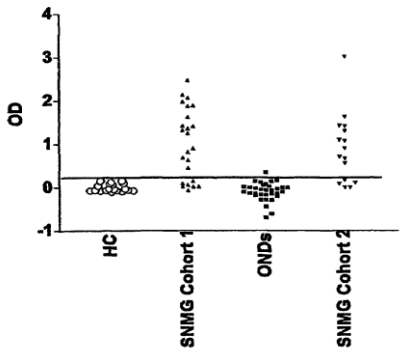
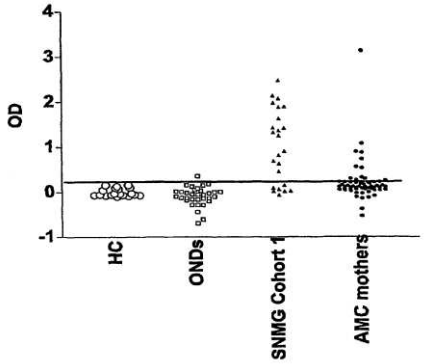


FIG. 5.



Claim 1 of the '820 patent reads as follows:

> A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK).

The dependent claims included claims in which the detection procedure involved the use of ^{125}I-labeled MuSK protein.

Mayo's argument was that the '820 patent seeks to claim a law of nature, that is, that these autoantibodies naturally occur in a mammal, and the claimed detection involves standard techniques in the art. Athena argued that the claims are not directed to a law of nature because the detection requires the use of a non-naturally occurring protein, the ^{125}I-labeled MuSK protein.

Court Decision: The district court applied the two-step analysis set forth in the U.S. Supreme Court cases of *Mayo Collaborative Services v. Prometheus Labs, Inc.* and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* (please also see our firm's Newsletter, Volume XI, No. 4, for additional discussions on this *Mayo/Alice* two-step test). The court determined that claims were directed to diagnostic method claims, and were not directed to the ^{125}I-labeled MuSK protein.

The court determined in regard to the first step of the two-step analysis that the '820 patent was directed to a law of nature: that is, that the bodily fluid of some people with *Myasthenia gravis* have autoantibodies to MuSK. The court also determined that the "desired outcome of the Plaintiff's method is the detection of MuSK autoantibodies" and this method "does not produce something useful beyond this diagnosis."

With regard to the second step of the *Mayo/Alice* two-step test, the court determined that the claimed method did use well-known techniques for identifying the autoantibodies, and that the claims of the '820 patent lack an "inventive concept" and are thus directed to non-patentable subject matter under 35 U.S.C. §101. The district court therefore granted Mayo's Renewed Motion to Dismiss.

Lessons to be Learned: The *Athena* case provides yet a further example of the current issues pertaining to the patenting of diagnostic methods in view of *Mayo Collaborative Services v. Prometheus Labs, Inc.* In a diagnostic method that simply recites detection of a naturally occurring product (i.e., a biological marker) in a patient, the chances of obtaining a valid patent becomes more difficult.

Under 35 U.S.C. §101, the chances of obtaining a valid diagnostic method patent (specially inventions focused on biological markers for disease) may increase if the claims are directed to a non-routine, non-conventional activity.

NOTICE: The U.S. PTO has announced government fee increases effective January 16, 2018. Modest government fee increases involve the search fee ($660) and examination fee ($760) for filing utility patent applications. The government fee for filing a 1st RCE will increase to $1,300, and the government fees for filing 2nd and 3rd RCEs will similarly increase. The government fee for the late filing of a Declaration or an English translation of a specification will increase to $160. For information on all other government patent fee increases, please search on-line the Federal Register, Vol. 82, No. 218, page 52780.

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