

From: Tom Brody [e-mail address redacted]

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To: 2014_interim_guidance

Subject: Subject matter eligibility conferred by recitation in claim of an algorithm or of a statistical formula

Honorable Commissioner,

In autumn of 2014, I reviewed the file histories of about 100 patent applications, where the claims (as issued) included the term "diagnosing." In reviewing these file histories, I only used those where the Examiner had rejected a claim under 101, and where the Examiner referred to *Prometheus*.

From this review, I determined various techniques for overcoming 101-rejections where the Examiner cited *Prometheus*. I will only discuss one of these techniques. The technique is to amend the claim to require an **algorithm or to require a statistical formula**.

This technique succeeded in winning allowance claims to the following patents (see below). The claim elements, added by way of amendment, are also disclosed below:

U.S. Pat. No. 8,715,943. "when said IBD sample has an ANCA level greater than a quartile score of 3"

U.S. Pat. No. 8,735,080. "statistical correlation"

U.S. Pat. No. 8,741,575. "generating a senescence score"

U.S. Pat. No. 8,771,963. "wherein the diagnosis has a sensitivity of 3.7% and a specificity of 95.9%"

U.S. Pat. No. 8,685,739. "using multivariate statistical analysis"

In my opinion, the Patent Office should comment on the use of **algorithms and statistical formulas** for conferring patentability to diagnostics claims.

I think that it is good idea, that including a claim element requiring an algorithm or statistical formula, should confer patentability to a claim to a diagnostics method. The Patent Office should comment on this, and should include an example in its list of examples, in future publications that provide guidance.

Best regards, *Tom Brody, Ph.D.*, Reg. No. 46,433

P.S. I am the author of eleven 60-page articles on patent law. A few of these have appeared in JPTOS.