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Laurie Axford on

**Are Diagnostic Method Claims Patentable?:
New Rulings Raise Old Questions**

2010 Emerging Issues 5134

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Overview. One of the fundamental principles of patent law is that only certain identified subject matter is statutorily patentable under [35 U.S.C. §101](#)¹. Diagnostic method claims fall under the category of patentable “processes” under this code section, but they are still susceptible to patentability challenges if they fall within a recognized exclusion to patentability, such as mathematical algorithms, mental steps and natural phenomena. These exclusions from patentability have therefore been at the heart of many recent controversies surrounding the patentability of diagnostic method claims, which are the cornerstone of intellectual property value in the *in vitro* diagnostic industry.

One of the first challenges to the validity of diagnostic method claims was the case of *Kaiser v. BPMG*². In this case, Kaiser, along with many other diagnostic labs, received a letter demanding that they cease infringing BPMG’s diagnostic method patent³, or license the patent to avoid a lawsuit. Kaiser responded by filing suit against BPMG alleging that the patent was invalid. This case was settled before the issue of patentability was addressed. However, most commentators have assumed that the legal challenge would have been made on the basis that the claims recited only a mathematical relationship, and were therefore excluded from patentability.

In the landmark case of *In re Bilski*⁴, the Federal Circuit specifically addressed the breadth of patentability exclusions. The court held that a process is not excluded from patentability if 1) “it is tied to a particular machine or apparatus,” or 2) “it transforms a particular article into a different state or thing.” This case established the current “machine-or-transformation” test, which is presently applied to process claims, including diagnostic method claims. However, even after *Bilski*, it appears the courts are still strug-

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1. [35 U.S.C. §101](#) recites that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor...”
 2. *Kaiser Foundation Health Plan, Inc. v. Biomedical Patent Mangement Corp.*, U.S. District Court, Northern District of California, August 28, 1997.
 3. U.S. Patent No. 4,874,693 to Mark Bogart.
 4. *In re Bilski*, [545 F.3d 943](#) (Fed. Cir. 2008)

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gling with these same issues. Indeed, they may struggle for quite some time until the *Bilski* decision is reviewed by the Supreme Court later this year.

Prometheus v. Mayo. In the case of *Prometheus v. Mayo*⁵, the claims at issue recited a method for determining levels of drug metabolites, and comparing such levels to threshold values to identify the need to change the drug dosage. The District Court found the claims to be unpatentable under [35 U.S.C. §101](#), which excludes patenting of a natural phenomena resulting from physiological processes. Stated differently, it failed the “transformation” prong of the “machine-or-transformation” test. The court concluded that the inventors did not actually invent the correlation.

On appeal, the Federal Circuit concluded that, even though the claims may be drawn to a naturally occurring correlation, they are still patentable, because the claimed method includes the step of administering the drug, which causes it to be transformed into its metabolites. They also held the “determining” step to be transformative, since the metabolites could not be detected by mere inspection – they had to be “transformed” into a detectable form. This decision may be subject to further scrutiny by the Supreme Court if they decide to review the holding, as requested by *Mayo*⁶.

Although the claims in the *Prometheus* case were focused on a therapeutic method (*i.e.*, they included the step of administering a drug), the Federal Circuit opinion is extremely important to the diagnostic industry, since the step of determining the level of the drug metabolites was found to satisfy the “machine-or-transformation” test. In most every diagnostic method, the analyte being detected cannot be “determined by mere inspection” - it must first be labeled and thereafter detected. It is this determination or detection step that, according to *Prometheus*, made the claims patentable.

The other important holding in *Prometheus* is that merely reciting a purpose of the method that, by itself, would be unpatentable does not render the claim as a whole unpatentable. Accordingly, the addition of a “wherein” clause to *Prometheus*’ claim that recited “wherein result X indicates Y,” which by itself is an unpatentable mental step, does not render the claim, as a whole, unpatentable.

5. *Prometheus Labs, Inc. v. Mayo Collaborative Servs.*, [581 F.3d 1336](#) (Fed. Cir. 2009)

6. *Mayo Collaborative Services et al v. Prometheus Laboratories, Inc.*, No. 09-490 (US October 22, 2009)

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Myriad Genetics. Myriad Genetics, a company focused on genetic testing, co-owns patents to genes associated with breast cancer and their diagnostic use. In a recent decision by the Federal Court in a lawsuit brought by the American Civil Liberties Union on behalf of several organizations and patients against Myriad and the USPTO⁷, the Court held that Myriad's patents were invalid. Regarding the claims to the genes themselves, the judge found the claims to be unpatentable, because they involved a "law of nature," and did not embody a patentable "transformation" of the DNA.

In addition to the gene claims, the other issue in this case was whether the claims to a diagnostic "analysis" or "comparison" of a patient's gene sequences to normal, "wild type" genes was patentable. Myriad argued that, according to the *Prometheus* decision, you could not analyze or compare the genes unless you "transformed" them in some way to make them comparable. They asserted that the claims required the isolation and sequencing of DNA, and that this "transformed" the DNA.

However, the judge disagreed. In distinguishing *Prometheus*, the judge stated that the claims required the step of "determining metabolite levels", which inherently required extraction and measurement of metabolite concentration. In contrast, Myriad's claims, which simply required "analysis" and "comparison" steps, were characterized as mere "data gathering" and were therefore not patentable.

In arriving at this conclusion, the Court cited *In re Grams*⁸. The patent at issue in this case claimed a method of diagnosing an abnormal condition which consisted of two steps: 1) performing a clinical laboratory test to obtain data, and 2) analyzing the data to determine the existence of the abnormal condition. The Court held that the sole physical process, i.e. laboratory testing, was merely data-gathering and hence constituted an unpatentable mathematical algorithm. The Judge in the Myriad case held that, just as in *Grams*, the isolation and sequencing of DNA represents nothing more than data gathering to perform the claimed comparison or analysis. Because of this, the claims constituted nothing more than unpatentable abstract mental processes.

In summary, the patentability of diagnostic method claims is still up in the air. Along with *Mayo*, several third parties (AARP, the Public Patent Foundation, American College of

7. *Association for Molecular Pathology [AMP] v. USPTO, Myriad Genetics*, [2010 U.S. Dist. LEXIS 30629](#) (S.D.N.Y., March 29, 2010).

8. *In re Grams*, [888 F.2d 835](#) (Fed. Cir. 1989)

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Medical Genetics and Quest Laboratories) have also filed briefs with the Supreme Court urging reconsideration of the *Prometheus* decision. Many of these parties are asserting that the *Prometheus* opinion undermines the advancement of science, and puts too fine a point on *Bilski's* machine-or-transformation test. For the present, drafters of patent claims for diagnostic methods would be well served by focusing attention on each method step, and making sure that one or more of the steps constitutes a true “transformation” of the substance or substances being analyzed.

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