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The USPTO Issues New Patent Eligibility Guidance Under Prometheus v. Mayo

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Practitioners and applicants have been wondering how the USPTO would respond to the July 20, 2012, U.S. Supreme Court decision in ***Mayo Collaborative Services v. Prometheus Laboratories, Inc.***, which held that Prometheus' personalized medicine method claims could not be patented because they were directed to a law of nature, and so excluded from patent-eligibility under 35 USC § 101. Now the USPTO has issued internal guidance to the Examining Corps, in a memorandum entitled *2012 Interim Procedure for Subject Matter Eligibility Analysis 0f Process Claims Involving Laws of Nature***.** The guidelines walk a careful line between following Supreme Court precedent without eviscerating the ability to obtain patents on methods that involve laws of nature, natural phenomena, or naturally occurring correlations.

The Basic Framework

The guidelines outline a three-step inquiry for examining claims that may fall under *Prometheus*:

1. Is the claimed invention directed to a process, defined as an act, or a series of acts or steps?
If no, this analysis is not applicable. For product claims, see the Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 USC § 101 issued August 24, 2009.
If yes, proceed to Inquiry 2.

2. Does the claim focus on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation (collectively referred to as a natural principle herein)? (Is the natural principle a limiting feature of the claim?)
If no, this analysis is complete, and the claim should be analyzed to determine if an abstract idea is claimed (see the **2010 Interim *Bilski* Guidance**).
If yes, proceed to Inquiry 3.

3. Does the claim include additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself? (Is it more than a law of nature + the general instruction to simply "apply it"?)
If no, the claim is not patent-eligible and should be rejected.
If yes, the claim is patent-eligible, and the analysis is complete.

The guidelines include a discussion of this framework and a list of factors that may be helpful in answering Inquiry 3. The guidelines emphasize consideration of the claim as whole, but indicate that "there must be at least one additional element or step that applies, relies on or uses the natural principle so that the claim amounts to significantly more than the natural principle itself."

The guidelines warn that the additional step must not be an "insignificant extra-solution activity," "data-gathering," or "well-understood, routine, [or] conventional." At the same time, the guidelines make clear that the step need ***not*** be novel and non-obvious to carry the claim across the patent-eligibility threshold.

The guidelines indicate that the following subject matter does ***not*** require such close scrutiny:

Claims that do not include a natural principle as a limitation do not raise issues of subject matter eligibility under the law of nature exception. For example, a claim directed to simply administering a man-made drug that does not recite other steps or elements directed to use of a natural principle, such as a naturally occurring correlation, would be directed to eligible subject matter. Further, a claim that recites a novel drug or a new use of an existing drug, in combination with a natural principle, would be sufficiently specific to be eligible because the claim would amount to significantly more than the natural principle itself.

The guidelines include examples of claims sets with some claims that are not, and some claims that are, patent-eligible under this framework. In each example, claims that are patent-eligibile include at least one step that is not well-understood, routine or conventional without regard to the novelty of the natural principle.

Patenting After Prometheus

In view of these guidelines, applicants seeking to patent methods that relate to "natural principles" may want to consider whether their methods can be described in terms of the use of a new drug or in terms of a new use of an existing drug (in conjunction with the natural principle). Moving forward, applicants may be able to set the stage in their patent applications to support patent-eligibility by highlighting any and all non-conventional steps that ***apply*** the natural principle in order to satisfy § 101, while also demonstrating the novelty and non-obviousness of their methods as a whole in order to satisfy § 102 and § 103. Patent holders who have concerns about the validity of granted method claims may want to consider whether pursuing a reissue application is appropriate or whether they might want to avail themselves of the new **Supplemental Examination** proceedings that will become available September 16, 2012.

The Myriad Piece Of The Puzzle

Inventions that are tied to both a "natural principle" and a compound that may be isolated from nature (such as DNA, proteins, or antibodies) may have another hurdle to clear. Applying only the *Prometheus* guidance, it is possible that the patent-eligibility of a method could rest on the novelty of a genetic marker recited in the claims. However, the viability of such a rationale may be impacted by the resolution of *Association for Molecular Pathology v. Myriad Genetics, Inc.* (the ACLU "gene patenting"/BRCA1 case). The Federal Circuit is scheduled to hear oral arguments in that case on July 20, 2012. (Please see these articles on PharmaPatentsBlog.com for a review of the party and amicus briefs filed at the Federal Circuit.) Because this case is likely to make its way to the Supreme Court again, we may not see final resolution of this issue until 2013 or 2014.

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