



# Greenblum & Bernstein, P.L.C.

## CLIENT ADVISORY

Recent Changes in Rules and Procedures

July 10, 2012

### **USPTO Issues Guidance Regarding Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature in view of *Prometheus***

Dear Clients:

The U.S. Patent and Trademark Office has recently issued a guidance memo entitled "2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature." The guidance memo was issued in view of the recent Supreme Court decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S.Ct. 1289, 101 USPQ2d 1961 (2012) ("*Prometheus*").

The guidance memo is intended for use by USPTO examiners when considering any process claim directed to a law of nature, a natural phenomenon, or a naturally occurring relation or correlation (also referred to in the memo as a "natural principle").

In accordance with the guidance memo, USPTO personnel should conduct three inquiries to determine whether a claim reciting a law of nature is drawn to patent-eligible subject matter:

1. Determine whether the claimed invention is directed to a process (defined as an act, or a series of acts or steps);
2. Determine whether the claim focuses on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation;
3. Ask whether the claim includes 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.

The first inquiry is straightforward. The memo indicates that if the claims are not directed to a process or method, there is no need to proceed further with the instant analysis. However, the guidance does direct USPTO personnel to see the *Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101* issued August 24, 2009 for product claims.

For the second inquiry, the guidance memo indicates that a claim focuses on a natural principle "when the natural principle is a limiting element or step." By way of example, the guidance memo states that a claim reciting a correlation used to make a diagnosis focuses on a natural principle and would require proceeding to the third inquiry.

Once it is determined that a process claim focuses on a natural principle, the guidance memo instructs USPTO personal to proceed to the third inquiry and consider whether such a claim also includes "additional elements or steps to show that the inventor has practically applied, or added something significant to, the natural principle itself."

The guidance memo makes clear that not every recited element or step has to integrate or relate to the natural principle. However, the guidance memo states that there must be at least one additional element or step that applies, relies on

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or uses the natural principle so that the claim amounts to significantly more than the natural principal itself. Recitation of a step directed to recording a diagnosis on a chart, for example, is not enough to render an otherwise patent ineligible diagnosis claim subject matter eligible.

As part of the guidance memo, USPTO personnel are also informed that the additional elements or steps "must narrow the scope of the claim such that others are not foreclosed from using the natural principle...for further innovation." The guidance memo also specifies that elements or steps that are "well-understood, purely conventional, and routinely taken by others in order to apply the natural principle, or that only limit the use to a particular technological environment (field-of-use)" are insufficient in this regard. The examples also indicate that steps such as "obtaining a serum sample from a patient" and "contacting the serum sample with an anti-IgM antibody" would not be sufficient.

The guidance memo also provides USPTO examiners with a list of 9 factors which may be used to analyze whether a process claim directed to a natural principle recites a patent-eligible application of the natural principle. Many of the factors are derived from past eligibility factors such as the "machine-or-transformation test."

Should you have any questions or comments regarding this matter, or should you wish us to forward a copy of the guidance memo to you, please do not hesitate to contact us.

Best regards,

**GREENBLUM & BERNSTEIN, P.L.C.**

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