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New USPTO Patent Subject Matter Eligibility Guidelines Raise More Questions Than They Answer

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The USPTO has issued new [Guidance For Determining Subject Matter Eligibility](#) to help examiners apply the principles of [Myriad](#) and [Prometheus](#) to any claim “reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products.” The guidelines focus on a “significantly different” test, and include lists of factors that weigh towards and against patent eligibility. The guidelines also include several examples applying the new analytical framework to sample claims. The guidelines do not apply to claims that raise “abstract idea” issues, which are still to be examined under [MPEP 2106\(II\)](#).

This article delves into the details of the guidelines, and you can read about the five things all practitioners should know about them [here](#).

Three Questions for Determining Patent Subject Matter Eligibility Under 35 USC § 101

The first section of the guidelines outlines the “overall process” for making a subject matter eligibility determination, that includes a [three question flowchart](#).

Question 1: Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture, or composition of matter?

If no, the claim is not eligible for patent protection and should be rejected under § 101.

If yes, proceed to Question 2.

Question 2: Does the claim recite or involve one or more judicial exceptions?

If no, the claim is patent-eligible, and the analysis is complete.

If yes, or if it is unclear whether the claim recites or involves a judicial exception, proceed to Question 3.

Question 3: Does the claim as a whole recite something significantly different than the judicial exception(s)?[Unless the claim recites an abstract idea], answer this Question using the factor-based analysis of “significantly different” that is discussed below in Part II.

If the answer is no ... the claim is not patent-eligible and should be rejected under § 101.

The “Significantly Different” Test

The guidelines mandate a multi-factored analysis for assessing whether a claim recites something

“significantly different” from non-eligible subject matter. The guidelines emphasize consideration of the claimed subject matter as a whole, in view of “every relevant factor and related evidence,” similar to the *Wands* analysis used to evaluate enablement. The guidelines emphasize that not every factor will apply to every claim, and that the analysis may change because “developing case law may generate additional factors over time.”

Factors that weigh toward eligibility (significantly different):

- a) Claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products.
- b) Claim recites elements/steps in addition to the judicial exception(s) that impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s).
- c) Claim recites elements/steps in addition to the judicial exception(s) that relate to the judicial exception in a significant way, i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception(s).
- d) Claim recites elements/steps in addition to the judicial exception(s) that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).
- e) Claim recites elements/steps in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application. (See MPEP 2106(II)(B)(1) for an explanation of the machine or transformation factors).
- f) Claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field.

Factors that weigh against eligibility (not significantly different):

- g) Claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products.
- h) Claim recites elements/steps in addition to the judicial exception(s) at a high level of generality such that substantially all practical applications of the judicial exception(s) are covered.
- i) Claim recites elements/steps in addition to the judicial exception(s) that must be used/taken by others to apply the judicial exception(s).
- j) Claim recites elements/steps in addition to the judicial exception(s) that are well-understood, purely conventional or routine in the relevant field.
- k) Claim recites elements/steps in addition to the judicial exception(s) that are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).
- l) Claim recites elements/steps in addition to the judicial exception(s) that amount to nothing more than a mere field of use.

The Broad Reach of the New USPTO Patent Subject Matter Eligibility Guidelines

Although the Supreme Court *Myriad* decision was limited to human DNA sequences and its *Prometheus* decision was limited to a personalized medicine method, the new guidelines appear to embrace everything under the sun, whether or not made by man.

The guidelines include the following list of subject matter that would trigger a “yes” answer to Question 2:

chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature.

Practitioners and stakeholders in the pharmaceutical industry should consider the issues raised in [this article](#).

Learning More About The New USPTO Patent Subject Matter Eligibility Guidelines

The guidelines themselves note that they “implement a new procedure” for examining claims to a broad range of subject matter under 35 USC § 101. I invite you to join me in discussing the new guidelines during the IPO Chat Channel webinar, ***Myriad and Mayo: New USPTO Examination Guidelines***, scheduled for Thursday, March 20, 2014, at 2:00 PM EST. I am honored to be speaking on a panel with Raul Tamayo of the USPTO, and Duane Marks of Roche Diagnostics Operations, Inc. (You can [register for the webinar here](#).)

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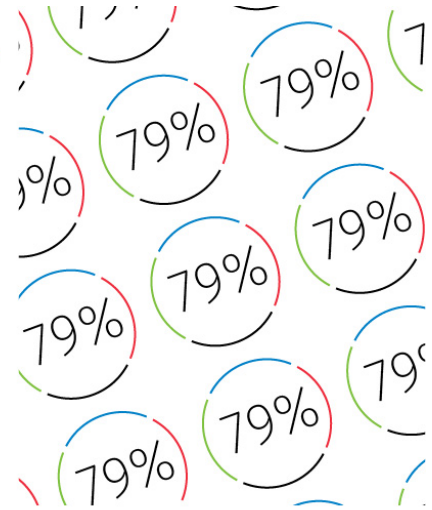
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