



Greenblum & Bernstein, P.L.C.  
**CLIENT ADVISORY**  
Recent Changes in Rules and Procedures

March 7, 2014

**USPTO issues new Guidance for Analyzing Subject Matter Eligibility of Claims Reciting Laws of Nature/Natural Principles, Natural Phenomena or Natural Products (Guidance)**

Dear Clients:

The USPTO recently issued new guidance, detailing a new procedure relating to subject matter eligibility under 35 U.S.C. § 101, which may increase the number and type of patent-eligibility issues raised in biotechnology and software related patent applications.

The Guidance was issued in view of recent court decisions including *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. \_\_\_, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012).

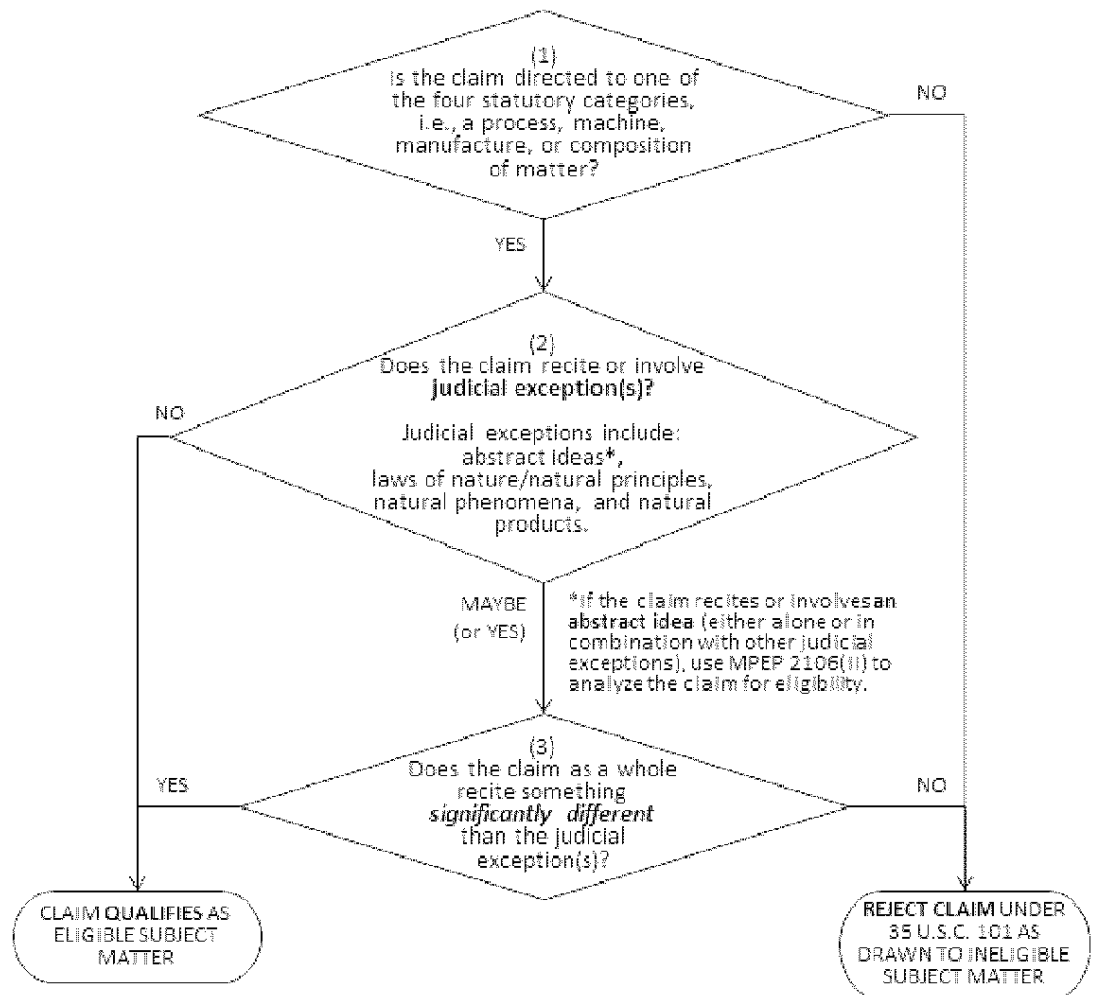
The examination procedure set forth in the *Guidance* is effective as of March 4, 2014 and supersedes the June 13, 2013 memorandum to Examiners titled "Supreme Court Decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*"

Initially, please note that the *Guidance* does not change examination procedures for claims reciting an abstract idea, which should continue to be analyzed for subject matter eligibility using the existing guidance in MPEP § 2106(II).

The *Guidance* directs the Examiner to analyze applications under the following three step inquiry:

1. Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture, or composition of matter?
2. Does the claim recite or involve one or more judicial exceptions?
3. Does the claim as a whole recite something *significantly different* than the judicial exception(s)?

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The *significantly different* analysis in the inquiry may introduce uncertainty in applying the new procedure going forward. For example, the *Guidance* explains that a significant difference can be shown in multiple ways, such as: (1) the claim includes elements or steps in addition to the judicial exception that practically apply the judicial exception in a significant way, e.g., by adding significantly more to the judicial exception; and/or (2) the claim includes features or steps that demonstrate that the claimed subject matter is markedly different from what exists in nature (and thus not a judicial exception).

The *Guidance* also provides several factors and examples that an Examiner should consider in determining subject matter eligibility.

Additionally, the *Guidance* indicates that the examiner’s analysis should carefully consider every relevant factor and related evidence before making a conclusion and that “[t]he determination of eligibility is not a single, simple determination, but is a conclusion reached by weighing the relevant factors, keeping in mind that the weight accorded each factor will vary based upon the facts of the application.” Accordingly, any determination of subject matter eligibility is likely to be very fact specific.

Notably, the *Guidance* states that *Myriad* clarified that not every change to a product will result in a marked (significant) difference, and that the mere recitation

of particular words (e.g., “isolated”) in claims does not automatically confer eligibility. *Id.* at 2119. *See also Mayo*, 132 S. Ct. at 1294 (eligibility does not “depend simply on the draftsman’s art”).

While the holding in *Myriad* relates to naturally occurring nucleic acids, distinguishing, for example, cDNA as patent-eligible, the *Guidance* appears to take a broad view of the case law such that any claim that “recites or involves” natural products, including “chemicals derived from natural sources” such as proteins, peptides, antibiotics, resins, etc., must be analyzed as to whether the claim recites something “significantly different” than the natural product. As a result, patent applicants, particularly in the biotechnology field, may encounter an increase in the number and type of patent-eligibility issues raised in response to claims that recite or involve natural products and/or natural correlations.

If you should have any questions, please do not hesitate to contact us.

Best regards,

GREENBLUM & BERNSTEIN, P.L.C.

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