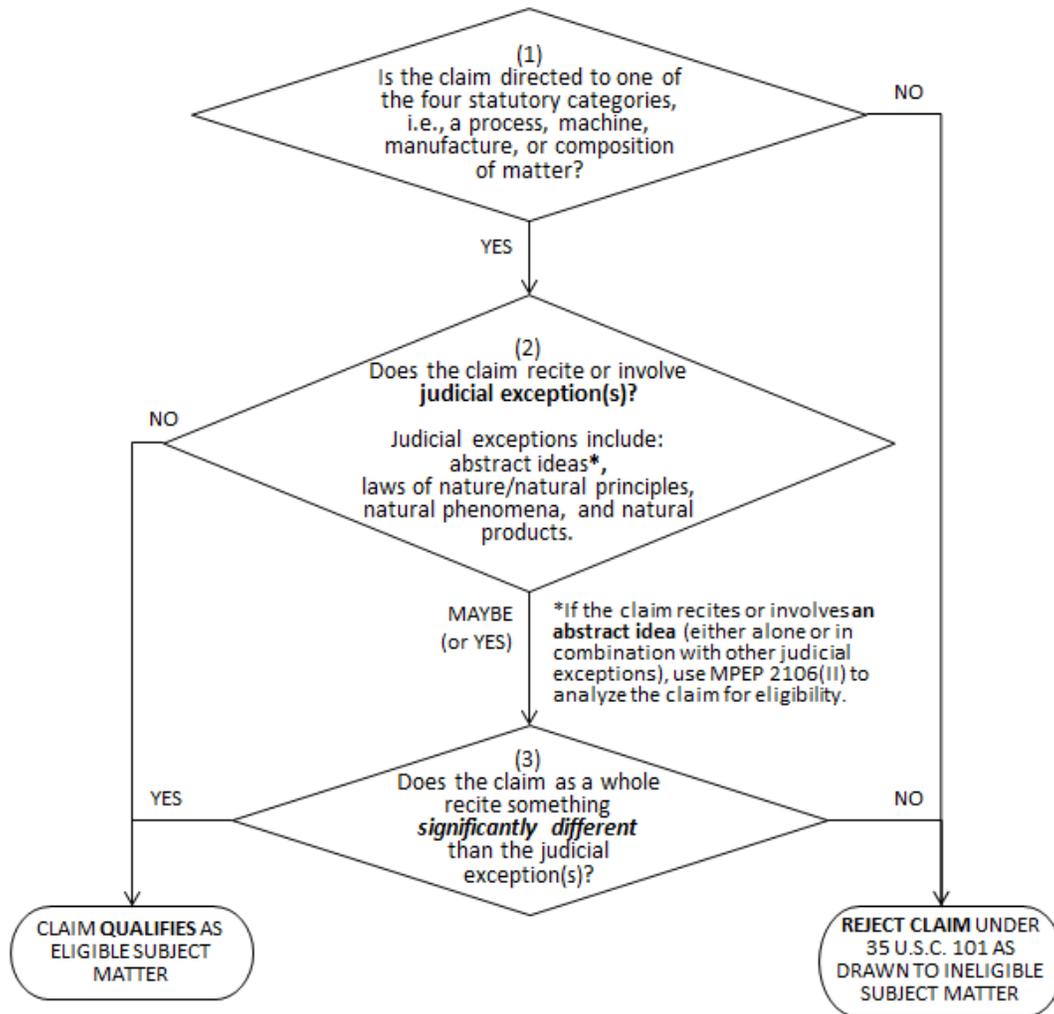


## Eligibility Guidance Quick Reference Sheet

This quick reference sheet provides a summary of the attached guidance memorandum entitled *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (Guidance)* dated March 4, 2014.

As explained in detail in the *Guidance*, the overall process for determining subject matter eligibility of all claims (i.e., machine, composition, manufacture and process claims) reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products<sup>1</sup> is to walk through the three questions in the flowchart below to determine whether the claim is drawn to patent-eligible subject matter. If not, then the claim is prima facie ineligible, and the claim should be rejected using revised form paragraph 7.05.13 (in Part IV of the *Guidance*).



The following factors should be used to analyze the claim to assist in answering Question 3 for claims reciting or involving judicial exceptions other than abstract ideas. On balance, if the totality of the relevant factors weigh toward eligibility, the claim qualifies as eligible subject matter. If the totality of the relevant factors weighs against eligibility, the claim should be rejected. The examiner's analysis should carefully consider every relevant factor and related evidence before making a conclusion. The 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. This factor-based analysis, which requires consideration and subsequent weighing of

<sup>1</sup> The *Guidance* does not change examination of claims reciting an abstract idea, which should continue to be analyzed for subject matter eligibility using the existing guidance in MPEP § 2106(II).

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multiple factors, is similar to the *Wands* factor-based analysis used to evaluate whether undue experimentation is required to make and use a particular claimed invention. *See, e.g.*, MPEP 2164.01(a) for an explanation of the *Wands* analysis. Not every factor will be relevant to every claim and, as such, need not be considered in every analysis.

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-resolution 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.

Factors a) and g) concern the question of whether something that initially appears to be a natural product is in fact non-naturally occurring and markedly different from what exists in nature, i.e., from naturally occurring products. This question can be resolved by first identifying the differences between the recited product and naturally occurring products, and then evaluating whether the identified differences together rise to the level of a **marked** difference in structure. Not all differences rise to the level of marked differences, e.g., merely isolating a nucleic acid changes its structure (by breaking bonds) but that change does not create a marked difference in structure between the isolated nucleic acid and its naturally occurring counterpart. Instead, a marked difference must be a significant difference, i.e., more than an incidental or trivial difference.