

Intellectual Property Alert:

The USPTO Announces New Guidelines for Determining Subject Matter Eligibility Under 35 U.S.C. §101 in View of *Myriad*, *Prometheus* and *Chakrabarty*

By John P. Iwanicki

March 10, 2014 – On March 4, 2014, the United States Patent & Trademark Office issued guidelines for the examination 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” in view of the U.S. Supreme Court decisions in *Myriad*, *Prometheus* and *Chakrabarty*. The goal of the Examiners is to determine “whether a claim reflects a significant difference from what exists in nature and thus is eligible, or whether a claim is effectively drawn to something that is naturally occurring.”

The guidelines emphasize “the Office’s reliance on *Chakrabarty*’s criterion for eligibility of natural products (i.e., whether the claimed product is a non-naturally occurring product of human ingenuity that is markedly different from naturally occurring products)” and that “claims reciting or involving natural products should be examined for a marked difference under *Chakrabarty*.”

THE TEST

The Examiners are instructed to follow the flowchart below to determine whether a claim should be rejected as ineligible subject matter under 35 U.S.C. §101.

The flowchart requires the Examiner to assess whether the claim includes a law of nature/natural principle, natural phenomena or natural product, i.e. a judicial exception. Examples include:

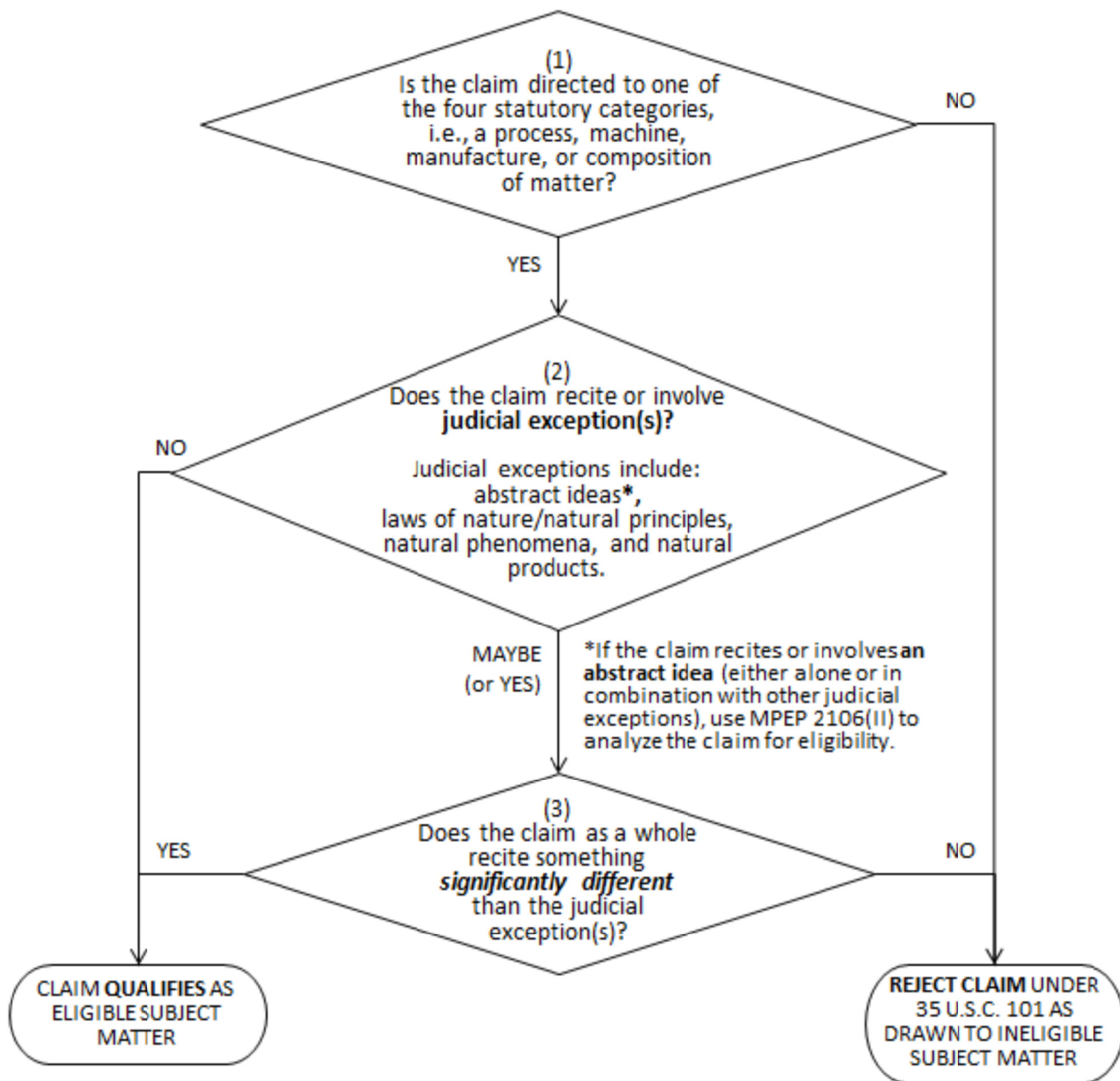
the law of gravity, $F=ma$, sunlight, barometric pressure, etc.;

a citrus fruit, uranium metal, nucleic acid, protein etc.;

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 minerals (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found or derived from nature.

If the claim includes a law of nature/natural principle, natural phenomena or natural product, then the Examiner is required to determine whether the claim as a whole recites something ***significantly different*** than the law of nature/natural principle, natural phenomena or natural product. According to the guidelines, a significant difference can be shown in multiple ways. For example:

(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).



GUIDING FACTORS

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.

EXAMPLES

For product or composition claims, the Examiners are provided with examples for determining eligibility of subject matter under 35 U.S.C. §101 that focus on whether the claimed subject matter is markedly different in structure from a natural product. The guidelines note that the structural changes to nucleic acids resulting from their isolation are not markedly different from naturally occurring nucleic acids. “[A] marked difference must be a significant difference, i.e., more than an incidental or trivial difference.”

cDNA, hybrid plants and genetically modified bacteria are given as examples of being markedly different in structure from naturally occurring DNA or naturally occurring plants even though the methods of making such cDNA or hybrid plants may be considered routine manipulation of natural processes.

An isolated compound from a natural source is not markedly different from the natural product. However, a synthetic derivative of the compound that has a different property from the natural product may be markedly different from the natural compound. Also, a use of the product in its isolated form according to a dosage amount and regimen to treat a particular disease that otherwise could not be treated by the compound in its natural form may be markedly different subject matter.

Articles of manufacture including naturally occurring substances are considered statutory subject matter where the article includes “something significantly different from the natural products themselves.” The example given is a firework including a cardboard body, sparking composition, and ignition fuse in addition to the naturally occurring calcium chloride and gunpowder formulations. This amounts to a specific practical application of the natural products.

Compositions of multiple natural products may not be statutory subject matter where the combination does not result in properties markedly different from what exists in nature. For example, where different species of naturally occurring bacteria are combined and each species is unaffected in its properties by the other species, then the composition may not be markedly different from the individual naturally occurring bacteria.

A claim to primers of specific sequences is not statutory subject matter where the sequences are naturally occurring sequences found on a human chromosome. However, a claim to the use of the primers to amplify target DNA using a template, a polymerase, nucleotides and reaction conditions may be statutory subject matter because the claim amounts to a practical application of the natural product primers.

A method claim to diagnosing whether an individual has a degenerative disease may not be statutory subject matter where a natural principle, i.e., a mere correlation between a degenerative disease and the presence of a metabolite, is all that is required by the claims. However, when the claimed method uses an antibody that does not exist in nature and is not purely conventional or routine in the art, i.e., it was created by the inventors, then the method may be statutory subject matter because the claim recites something significantly different from the natural principle and amounts to a practical application of the natural principle.

A method claim to treating an individual by subjecting the individual to natural principle or natural phenomena without more may not be statutory subject matter. The guidelines present an example where an individual is treated with sunlight to alter neuronal activity, which leads to mitigation of a mood disorder. It is known that white light changes neuronal activity and affects a person’s mood and that sunlight is a natural source of white light. Therefore, the use of sunlight is purely conventional and routine in the art of treating mood disorders. Even if the source of white light is synthetic and not natural, the use of a synthetic source is not significantly different from the natural principle itself and does not amount to a practical application of the natural principle. However, where conditions such as filtering ultraviolet rays from a white light source, positioning a patient a distance from the white light source and other treatment conditions are recited in a claim, the claim may recite something significantly different from the natural principle such that the claim is a practical application of the natural principle.

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