2014 Interim Eligibility Guidance Quick Reference Sheet

This quick reference sheet provides a summary of the attached guidance document entitled 2014 Interim Guidance on Patent Subject Matter Eligibility (Interim Eligibility Guidance). As explained in detail in the Interim Eligibility Guidance, the attached flowchart illustrates the subject matter eligibility analysis for all claims (*i.e.*, machine, composition of matter, manufacture and process claims). This analysis is to be used during examination for evaluating whether a claim is drawn to patent-eligible subject matter.

<u>Step 1</u> is represented in diamond (1), and determines whether the claim is directed to a process, machine, manufacture, or composition of matter. This step has not changed and is explained in MPEP 2106(I). If the claim is not directed to one of these statutory categories, reject the claim under 35 U.S.C. § 101 as being drawn to non-statutory subject matter, using revised form paragraphs 7.05 and 7.05.01, and continue examination for patentability. If the claim is directed to a statutory category, proceed to **Step 2**.

<u>Step 2</u> is the two-part analysis from *Alice Corp*. (also called the *Mayo* test) for claims directed to laws of nature, natural phenomena, and abstract ideas (the judicially recognized exceptions). This step is represented in diamonds (2A) and (2B) and is the subject of the *Interim Eligibility Guidance*.

In **Step 2A**, determine whether the claim is <u>directed to</u> a law of nature, a natural phenomenon, or an abstract idea (judicial exceptions). If no, the claim is **eligible** and examination should continue for patentability. If yes, proceed to **Step 2B** to analyze whether the claim as a whole amounts to significantly more than the exception.

- "Directed to" means the exception is recited in the claim, *i.e.*, the claim <u>sets forth or describes</u> the exception. See Part I.A.1 of the *Interim Eligibility Guidance*.
- If the claim when viewed as a whole <u>clearly</u> does not seek to "tie up" any judicial exception, use the "streamlined analysis" discussed in Part I.B.3 of the *Interim Eligibility Guidance*.
- Examples of the <u>types of concepts</u> that the courts have found to be laws of nature, natural phenomena, or abstract ideas are provided in Parts I.A.2 and IV of the *Interim Eligibility Guidance*.
- If the claim recites a <u>nature-based product limitation</u>, the markedly different characteristics analysis is used to evaluate whether the claim is directed to a "product of nature" that falls under the law of nature and natural phenomenon exceptions. To determine whether the markedly different characteristics analysis is needed, and how to perform this analysis, see Part I.A.3 of the *Interim Eligibility Guidance*.

In **Step 2B**, determine whether any element, or combination of elements, in the claim is sufficient to ensure that the claim as a whole amounts to **significantly more** than the judicial exception. If no, the claim is **ineligible**, and should be rejected under 35 U.S.C. § 101 as being drawn to ineligible subject matter, using form paragraphs 7.05 [revised] and 7.05.015 [new]. If yes, the claim is **eligible**. In either case, examination should continue for patentability.

- The additional elements should be considered both individually <u>and</u> as an ordered combination. Individual elements when viewed on their own may not appear to add significantly more, but when viewed in combination may amount to significantly more than the exception.
- The Supreme Court has identified a number of <u>considerations</u> for determining whether a claim with additional elements amounts to significantly more than the judicial exception itself. Examples of these considerations, and how they are applied, are provided in Parts I.B.1 and III of the *Interim Eligibility Guidance*.
- Consider each claim separately based on the particular elements recited therein claims <u>do not</u> <u>automatically rise or fall</u> with similar claims in an application.
- If a claim is directed to a <u>plurality of exceptions</u>, conduct the eligibility analysis for one of the exceptions. Additional elements that satisfy **Step 2B** for one exception will likely satisfy **Step 2B** for all exceptions in a claim. On the other hand, if the claim fails under **Step 2B** for one exception, the claim is ineligible, and no further eligibility analysis is needed.

2014 Interim Eligibility Guidance Quick Reference Sheet

Form Paragraphs

7.05 Rejection, 35 U.S.C. 101, -Heading Only- (Utility, Non-Statutory, Inoperative) [REVISED]

Claim [1] rejected under 35 U.S.C. 101 because

Examiner Note: (1) This form paragraph must be preceded by form paragraph 7.04.01 in first actions and final rejections. (2) This form paragraph must be followed by a detailed explanation of the grounds of rejection using one or more of form paragraphs - 7.05.01, 7.05.015, 7.05.02, 7.05.03, or another appropriate reason. (3) See MPEP §§ 706.03(a) and 2105 - 2107.03 for additional guidance.

7.05.01 Rejection, 35 U.S.C. 101, Non-Statutory (Not One of the Four Statutory Categories) [REVISED]

the claimed invention is directed to non-statutory subject matter. The claim(s) does not fall within at least one of the four categories of patent eligible subject matter because [1]

Examiner Note: (1) This form paragraph should be preceded by form paragraph 7.05. (2) In bracket 1, explain why the claimed invention is not patent eligible subject matter by identifying what the claim(s) is/are directed to and explain why it does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter), e.g., the claim(s) is/are directed to a signal per se, mere information in the form of data, a contract between two parties, or a human being (see MPEP § 2106, subsection I). (3) For a claim that is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) and is non-statutory, use form paragraph 7.05.015.

7.05.015 Rejection, 35 U.S.C. 101, Non-Statutory (Directed to a Judicial Exception without Significantly More) [NEW]

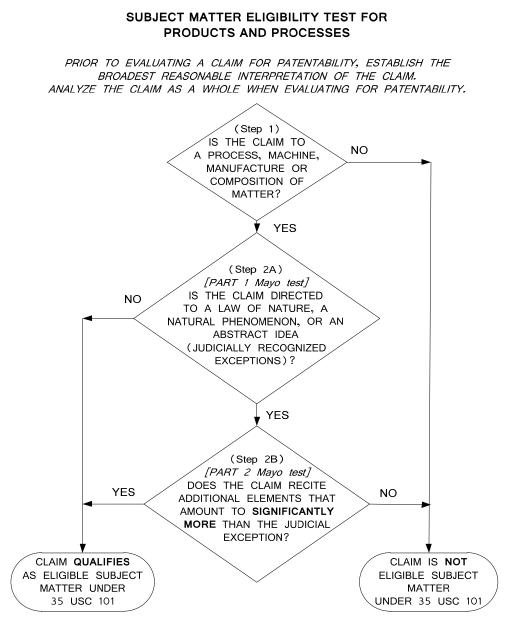
the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. Claim(s) [1] is/are directed to [2]. The claim(s) does/do not include additional elements that are sufficient to amount to significantly more than the judicial exception because [3].

Examiner Note: (1) This form paragraph should be preceded by form paragraph 7.05. (2) This form paragraph is for use with all claims, including product (machine, manufacture, and composition of matter) and process claims, and for any type of judicial exception.

(3) In bracket 1, identify the claim or claims that recite the judicial exception.

(4) In bracket 2, identify the exception by referring to how it is recited (set forth or described) in the claim and explain why it is considered an exception. For example, "the Arrhenius equation, which is a law of nature in the form of a mathematical algorithm" or "the series of steps instructing how to hedge risk, which is a fundamental economic practice and thus an abstract idea." For products of nature, explain how the characteristics are not markedly different from the product's naturally occurring counterpart in its natural state. For example, "the naturally occurring DNA segment, which is not markedly different from its naturally occurring counterpart because it conveys the same genetic information." Provide additional explanation regarding the exception and how it has been identified when appropriate.

(5) In bracket 3, identify the additional elements and explain why, when considered separately and in combination, they do not add significantly more to the exception. For example, if the claim is directed to an abstract idea with additional generic computer elements explain that the generically recited computer elements do not add a meaningful limitation to the abstract idea because they would be routine in any computer implementation, or if the claim is directed to a method of using a naturally occurring correlation explain that steps for routine data gathering in order to test for the correlation do not add a meaningful limitation to the method as they would be routinely used by those of ordinary skill in the art in order to apply the correlation.



IN ACCORDANCE WITH COMPACT PROSECUTION, ALONG WITH DETERMINING ELIGIBILITY, ALL CLAIMS ARE TO BE FULLY EXAMINED UNDER EACH OF THE OTHER PATENTABILITY REQUIREMENTS: 35 USC §§ 102, 103, 112, and 101 (UTILITY, INVENTORSHIP, DOUBLE PATENTING) AND NON-STATUTORY DOUBLE PATENTING.

Notable changes from prior guidance:

• All claims (product and process) with a judicial exception (any type) are subject to the same steps. • Claims including a nature-based product are analyzed in Step 2A to identify whether the claim is directed to (recites) a "product of nature" exception. This analysis compares the nature-based product in the claim to its naturally occurring counterpart to identify markedly different characteristics based on structure, function, and/or properties. The analysis proceeds to Step 2B only when the claim is directed to an exception (when no markedly different characteristics are shown).

Nature-Based Products

The following examples should be used in conjunction with the 2014 Interim Eligibility Guidance. They replace the examples issued with the March 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products and related training. As the examples are intended to be illustrative only, they should be interpreted based on fact patterns set forth below. Other fact patterns may have different eligibility outcomes.

1. Gunpowder and Fireworks: Product Claims That Are Not Directed To An Exception

This example illustrates the application of the markedly different characteristics analysis to a naturebased product produced by combining multiple components (claim 1), and also provides a sample of a claimed product that when viewed as a whole is not nature-based, and thus is not subjected to the markedly different characteristics analysis in order to determine that the claim is not directed to an exception (claim 2).

Claims:

- 1. Gunpowder comprising: an intimate finely-ground mixture of 75% potassium nitrate, 15% charcoal and 10% sulfur.
- 2. A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) the gunpowder of claim 1, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder, and (e) a plastic ignition fuse having one end extending into the second compartment and the other end extending out of the cardboard body.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Both claims are directed to a statutory category, *e.g.*, a composition of matter or manufacture (*Step 1: YES*).

<u>Claim 1: Eligible</u>. Because the claim is a nature-based product, *i.e.*, a combination of three naturally occurring substances (potassium nitrate, charcoal and sulfur), the nature-based product (the combination) is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. In this case, there is no naturally occurring counterpart to the claimed combination (the components do not occur together in nature), so the combination is compared to the individual components as they occur in nature. None of the three claimed substances are explosive in nature. When the substances are finely-ground and intimately mixed in the claimed ratio, however, the claimed combination is explosive upon ignition. This explosive property of the claimed combination is markedly different from the non-explosive properties of the substances by themselves in nature. Accordingly, the claimed combination has markedly different characteristics, and is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

<u>Claim 2: Eligible</u>. Although the claim recites two nature-based products (calcium chloride and gunpowder), analysis of the claim as a whole indicates that the claim is focused on the assembly of components that together form the firework, and not the nature-based products. Thus, it is not necessary to apply the markedly different characteristics analysis in order to conclude that the claim is not directed to an exception (*Step 2A: NO*). The claim qualifies as eligible subject matter.

2. Pomelo Juice: Process Claim That Is Directed To An Exception And Product Claim That Is Not Directed To An Exception

This example illustrates the eligibility analysis of a process (claim 1) that focuses on a nature-based product and a product (claim 2) that is nature-based but is not directed to an exception because it has markedly different characteristics from its naturally occurring counterpart.

Nature-Based Products

<u>Background</u>: The pomelo tree (*Citrus maxima*) is a naturally occurring tree that is native to South and Southeast Asia. Pomelo fruit is often eaten raw or juiced, and has a mild grapefruit-like flavor. Naturally occurring pomelo juice spoils over the course of a few days even when refrigerated, due to the growth of bacteria that are naturally present in the juice. The specification indicates that suitable preservatives for fruit juices are known in the art, and include naturally occurring preservatives such as vitamin E, and nonnaturally occurring preservatives such as preservative X. The specification defines an "effective amount" of these preservatives as an amount sufficient to prevent juice from spoiling for at least three weeks, *e.g.*, by retarding the growth of bacteria in the juice.

Claims:

- 1. A method comprising providing a pomelo fruit.
- 2. A beverage composition comprising pomelo juice and an effective amount of an added preservative.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. All of the claims are directed to a statutory category, *e.g.*, a process or composition of matter (*Step 1: YES*).

<u>Claim 1: Ineligible</u>. Although the claim is a process claim, it has been drafted such that there is no difference in substance from a product claim to the pomelo fruit itself. Accordingly, this process claim is focused on the pomelo fruit *per se* (a nature-based product), and must be analyzed for markedly different characteristics, to determine whether the claimed pomelo fruit is a "product of nature" exception. There is no indication in the specification that the claimed fruit has any characteristics (structural, functional, or otherwise) that are different from the naturally occurring fruit provided by pomelo trees. Thus, the claimed fruit does not have markedly different characteristics from what occurs in nature, and is a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

<u>Claim 2: Eligible</u>. Because the claim is a nature-based product, *i.e.*, a combination of a naturally occurring substance (pomelo juice) with an added preservative, the nature-based combination is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. In this case, there is no naturally occurring counterpart to the claimed combination, so the combination is compared to the individual components as they occur in nature. The specification indicates that the preservative can be natural or non-natural in origin, but that regardless of its origin, when an effective amount of preservative is mixed with the pomelo juice, the preservative affects the juice so that it spoils much more slowly (spoils in a few weeks) than the naturally occurring juice by itself (spoils in a few days). This property (slower spoiling) of the claimed combination is markedly different from properties of the juice by itself in nature. Accordingly, the claimed combination has markedly different characteristics, and is not a "product of nature" exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

3. Amazonic Acid, Pharmaceutical Compositions, & Methods of Treatment

This example illustrates the application of the markedly different characteristics analysis to singleelement product claims (claims 1, 2 and 3) and to a product-by-process claim (claim 4). It also demonstrates that changes in chemical structure (claims 2 and 3), physical form (claim 5), or chemical/physical properties (claim 6), as compared to a product's natural counterpart can demonstrate markedly different characteristics. Additionally, this example provides samples of claimed processes that when viewed as a whole are not directed to a nature-based product, and thus are not subjected to the markedly different characteristics analysis in order to determine that the claim is not directed to an exception (claims 7 and 8).