

DO NOT SCAN THIS DOCUMENT INTO IFW
SUBJECT MATTER ELIGIBILITY WORKSHEET
Nature-Based Products

This worksheet can be used to assist in analyzing a claim for “Subject Matter Eligibility” (SME) under 35 U.S.C. 101 for any judicial exception (law of nature, natural phenomenon, or abstract idea) in accordance with the [2014 Interim Eligibility Guidance](#) and the [July 2015 Update on Subject Matter Eligibility](#). As every claim must be examined individually based on the particular elements recited therein, a separate worksheet should be used to analyze each claim. The use of this worksheet is optional.

This worksheet can be used to analyze any claim, but includes specific information designed to address aspects of the eligibility analysis (such as the markedly different characteristics analysis) that apply only to claims directed to nature-based products. This worksheet will be used to walk through several of the product of nature examples [*Link to Life Sciences examples] published on the website. (A blank generic worksheet is available on the training website.) It is suggested that the worksheet be used with the [2014 Interim Eligibility Guidance Quick Reference Sheet](#), which include an overview of the analysis, along with the flowchart and form paragraphs referenced herein, the [July 2015 Update: Interim Eligibility Guidance Quick Reference Sheet](#) that includes a chart of abstract idea concepts, and the [Subject Matter Eligibility Court Decisions chart](#).

Worksheet Summary: Section I is designed to address the first activity in examination, which is to determine what applicant invented and to construe the claim in accordance with its broadest reasonable interpretation (BRI). Next, referring to the eligibility flowchart reproduced in the *Quick Reference Sheet*, Section II addresses *Step 1* regarding the four statutory categories of invention. Section III addresses *Step 2A* by determining whether the claim is directed to a judicial exception. Section IV addresses *Step 2B* by identifying additional elements to determine if the claim amounts to significantly more than an exception.

Application/Example No. and claim: Example 29, claim 6

I. What did applicant invent?

Review the disclosure to identify what applicant considers as the invention. (MPEP 2103(I))

Applicant invented:

A method of accurately diagnosing and properly treating juitis by detecting JUL-1 protein in a plasma sample from a human patient. The method is based on applicant's discovery of a correlation or relationship between the presence of JUL-1 in a patient's plasma and the presence of juitis in the patient, which allows applicant to distinguish juitis from diseases with similar symptoms (e.g., rosacea). Previously, many patients were misdiagnosed with rosacea and then administered a rosacea treatment that was not effective (because the patients really had juitis). Applicant's method ensures that patients

This can be a brief description and should not merely reproduce the claim. The take away here is that applicant's invention is focused on diagnosing juitis more accurately, so that the proper treatment can be administered.

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SUBJECT MATTER ELIGIBILITY WORKSHEET
Nature-Based Products

with JUL-1 in their plasma are now accurately diagnosed with jultitis, so they can be successfully treated with jultitis therapeutics such as anti-tumor necrosis factor (TNF) antibodies.

Establish the broadest reasonable interpretation (BRI) of the claim.

II. Does the claimed invention fall within one of the four statutory categories of invention (process, machine, manufacture or composition of matter) (Step 1)?

Choose A or B:

A. Yes, the claimed invention is a series of steps or acts, which is a process.

Continue with the SME analysis.

B. No, the claimed invention is not one of the four statutory categories. Make a rejection of the claim as being drawn to non-statutory subject matter. *Use Form Paragraphs 7.05 and 7.05.01 available in Custom OACs.*

If the claim could be amended to fall within one of the statutory categories, it is recommended to **continue with the SME analysis** under that assumption. Make the assumption clear in the record if a rejection is ultimately made under *Step 2*, and consider suggesting a potential amendment to applicant that would result in the claim being drawn to a statutory category.

If no amendment is possible, **conclude the SME analysis** and continue with examination under each of the other patentability requirements.

III. Is the claim directed to a product of nature, a law of nature, a natural phenomenon, or an abstract idea (judicially recognized exceptions) (Step 2A)?

A claim is “directed” to a product of nature exception when the claim recites (*i.e.*, **sets forth or describes**) a nature-based product limitation that does not exhibit markedly different characteristics from its naturally occurring counterpart in its natural state. Although a nature-based product can be claimed by itself (*e.g.*, “a *Lactobacillus* bacterium”) or as one or more limitations of a claim (*e.g.*, “a probiotic composition comprising a mixture of *Lactobacillus* and milk in a container”), the markedly different characteristics analysis should be applied only to the nature-based product limitations in the claim to determine whether the nature-based products are “product of nature” exceptions. Non-limiting examples of the types of characteristics considered by the courts when determining whether there is a marked difference include: biological or pharmacological functions or activities; chemical and physical properties; phenotype, including functional and structural characteristics; and structure and form, whether chemical, genetic or physical.

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SUBJECT MATTER ELIGIBILITY WORKSHEET
Nature-Based Products

Note that a process claim is not subject to the markedly different analysis for nature-based products used in the process, except in the limited situation where a process claim is drafted in such a way that there is no difference in substance from a product claim (*e.g.*, “a method of providing an apple.”).

Even if a claim is not “directed” to a product of nature, it may be “directed” to a different exception, for example when a law of nature, natural phenomenon, or abstract idea is recited (*i.e.*, **set forth** or **described**) in the claim. For this analysis, it is sufficient to identify that the claimed concept aligns with at least one judicial exception, as there are no bright lines between the types of exceptions. Laws of nature and natural phenomena, as identified by the courts, include naturally occurring principles or substances. Abstract ideas have been identified by the courts by way of example, including fundamental economic practices, certain methods of organizing human activity, ideas themselves (standing alone), or mathematical relationships/formulae.

Assistance in identifying judicial exceptions can be obtained by referring to the case law chart available on the website [insert link] and the court case discussions in the 2014 Interim Eligibility Guidance.

Choose A, B, or C:

- A. No, the claim does not recite a nature-based product limitation, or a concept that is similar to those found by the courts to be an exception. **Conclude SME analysis** and continue with examination under each of the other patentability requirements. If needed, the record can be clarified by providing remarks in the Office action regarding interpretation of the claim (*for example*: the broadest reasonable interpretation of the claim is not directed to an abstract idea or nature-based product.)
- B. Yes, but the streamlined analysis is appropriate as eligibility is self-evident, and a full eligibility analysis is not needed. Applicant’s claimed invention, explained in Section I above, is not focused on an exception, and the claim clearly does not attempt to tie up an exception such that others cannot practice it. (Refer to the [February 2015 Training Slides](#) for information and examples of a streamlined analysis.) **Conclude SME analysis** and continue with examination under each of the other patentability requirements.

C. Yes, the claim is directed to a nature-based product limitation, and/or a concept that is similar to those found by the courts to be an exception. *Proceed to 1 and 2.*

- 1. If the claim is directed to a nature-based product limitation, identify the limitation(s) in the claim that recite(s) the nature-based product and explain whether or not the claimed nature-based product exhibits markedly different characteristics compared to its naturally occurring counterpart in its natural state.

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SUBJECT MATTER ELIGIBILITY WORKSHEET
Nature-Based Products

Complete all of (a), (b) and (c). If the claim is not directed to a nature-based product limitation, proceed to Question 2.

(a) The limitation(s) in the claim that set(s) forth or describe(s) a nature-based product is (are):

(b) The closest naturally occurring counterpart in its natural state is to the claimed nature-based product limitation is:

(c) Compare the claimed nature-based product limitation to its counterpart to determine whether it does or does not exhibit markedly different characteristics as compared to the counterpart in its natural state. Based on the comparison, *choose (i) or (ii)*.

(i) The nature-based product exhibits markedly different characteristics (and thus is not a product of nature exception) because:

(ii) The nature-based product lacks markedly different characteristics (and thus is a product of nature exception) because:

Proceed to Question 2, to determine if the claim is “directed” to another type of exception.

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SUBJECT MATTER ELIGIBILITY WORKSHEET
Nature-Based Products

2. If the claim is directed to an abstract idea, law of nature, and/or natural phenomenon, identify the limitation(s) in the claim that recite(s) the exception and explain why the recited subject matter is an exception.

The limitation(s) in the claim that set(s) forth or describe(s) the law of nature, natural phenomenon, or abstract idea is (are):

step c, which recites diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected. This claim language describes a correlation or relationship between the presence of JUL-1 in a patient's plasma and the presence of julitis in the patient. Additionally, step c could be performed by a human using mental steps or basic critical thinking.

Although the claim recites several natural-based product limitations (e.g., plasma, JUL-1, and the anti-TNF antibodies) the focus of the claim is directed to a process and not a product *per se*. Thus, there is no need to perform the markedly different characteristics analysis on the recited nature-based product limitations.

The reason(s) that the limitation(s) are considered a judicial exception is (are):

Judicial exceptions need not be old or long-prevalent.

this type of correlation is a consequence of natural processes, similar to the naturally occurring correlation found to be a law of nature by the Supreme Court in *Mayo*. Also, mental steps or basic critical thinking are types of activities that have been found by the courts to represent abstract ideas (e.g., the mental comparison in *Ambry Genetics*, or the diagnosing an abnormal condition by performing clinical tests and thinking about the results in *Grams*).

If the results of Questions 1 and 2 is that the claim is not directed to any judicial exception, conclude SME analysis and continue with examination under each of the other patentability requirements. If needed, the record can be clarified by providing remarks in the Office action regarding interpretation of the claim (*for example*: the broadest reasonable interpretation of the claim is directed to a nature-based product that exhibits markedly different characteristics from its natural counterparts).

Otherwise, the claim is directed to at least one judicial exception. Continue with the SME analysis.

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SUBJECT MATTER ELIGIBILITY WORKSHEET
Nature-Based Products

IV. Does the claim as a whole amount to significantly more than the judicial exception, i.e., the product of nature, law of nature, natural phenomenon, or abstract idea (Step 2B)?

- A. Are there any additional elements (features/limitations/step) recited in the claim beyond the exception(s) identified above? Note that if the claim is directed to a product of nature comprising a combination of component elements that do not occur together in nature as claimed, each component element should be considered as an additional element to the other components to determine whether their combination results in significantly more.

Choose 1 or 2:

1. No, there are no other elements in the claim in addition to the exception. **Conclude SME analysis** by making a § 101 rejection and continue with examination under each of the other patentability requirements. *Use Form Paragraphs 7.05 and 7.05.015 available in Custom OACs.*

Are there elements in the disclosure that could be added to the claim that may make it eligible? Identify those elements and consider suggesting them to applicant:

2. Yes, the claim elements (features/limitations/steps) in addition to the exception are:
the additional steps of obtaining a plasma sample from a human patient (step a), detecting whether JUL-1 is present in the plasma sample (step b), and administering an effective amount of anti-TNF antibodies to the diagnosed patient (step d).

Continue with the SME analysis.

- B. Evaluate the significance of the additional elements. Identifying additional elements and evaluating their significance involves the search for an “inventive concept” in the claim. It can be helpful to keep in mind what applicant invented (identified in Section I above) and how that relates to the additional elements to evaluate their significance.

Consider the identified additional elements individually and in combination to determine whether the claim as a whole amounts to significantly more than the exception(s) identified above. Reasons supporting the significance of the additional elements can include one or more of the following:

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SUBJECT MATTER ELIGIBILITY WORKSHEET
Nature-Based Products

The additional elements must show an "inventive concept." Many of these considerations overlap, and more than one can often be applied to describe an element. It is not important how the elements are characterized or how many considerations apply from this list. It is important to evaluate the significance of the additional elements relative to applicant's invention.

- improves another technology or technical field
- improves the functioning of a computer itself
- applies the exception with, or by use of, a particular machine
 - *not* a generic computer performing generic computer functions
 - *not* adding the words "apply it" or words equivalent to "apply the exception"
 - *not* mere instructions to implement an abstract idea on a computer
- effects a transformation or reduction of a particular article to a different state or thing
- adds a specific limitation other than what is well-understood, routine and conventional in the field
 - *not* appending well-understood, routine, and conventional activities previously known to the industry, specified at a high level of generality
 - *not* a generic computer performing generic computer functions
- adds unconventional steps that confine the claim to a particular useful application
 - *not* adding insignificant extrasolution activity, such as mere data gathering
- adds meaningful limitations that amount to more than generally linking the use of the exception to a particular technological environment

Complete (1) or (2) below:

1. Yes, the additional elements, taken individually or as a combination, result in the claim amounting to significantly more than the exception(s) because

The step of obtaining a plasma sample from a human patient (step a) does not by itself add significantly more, because obtaining a sample in order to perform tests is well-understood, routine and conventional activity for those in the field

of diagnostics. Further, the step is recited at a high level of generality such that it amounts to insignificant pre-solution activity, e.g., a mere data gathering step necessary to use the correlation. The step of detecting the presence of JUL-1 in the sample (step b) merely instructs a scientist to use any protein detection technique. When recited at this high level

An explanation of why the claim is eligible is not necessary in the Office action unless there would be a question as to the reasoning such that the record would benefit from clarification.

Note that the presence of some well-understood, routine and conventional elements (i.e., steps a and b) does not alone confer or preclude eligibility.

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SUBJECT MATTER ELIGIBILITY WORKSHEET
Nature-Based Products

of generality, there is no meaningful limitation, such as a particular or unconventional machine or a transformation of a particular article, in this step that distinguishes it from well-understood, routine, and conventional data gathering activity engaged in by scientists prior to applicant's invention, and at the time the application was filed, e.g., the routine and conventional techniques of detecting proteins. In addition, the step of administering an effective amount of anti-TNF antibodies to the diagnosed patient (step d) was well-understood, routine and conventional activity engaged in by doctors in the field prior to applicant's invention, and at the time the application was filed. Thus, when considered individually, steps (a), (b) and (d) do not by themselves add significantly more to the exception.

When the additional elements are viewed as a combination, however, the additional elements (steps a, b and d) amount to a claim as a whole that adds meaningful limits on the use of the exception (the correlation and critical thinking step). The totality of these steps including the recitation of a particular treatment (administration of an effective amount of anti-TNF antibodies) in step d integrate the exception into the diagnostic and treatment process, and amount to more than merely diagnosing a patient with jultitis and instructing a doctor to generically "treat it." Further, the combination of steps, which is not routine and conventional, ensures that patients who have jultitis will be accurately diagnosed (due to the detection of JUL-1 in their plasma) and properly treated with anti-TNF antibodies, as opposed to being misdiagnosed as having rosacea as was previously commonplace. See *Diamond v. Diehr*, 450 U.S. 175, 188 (1981) ("a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made"). Thus, the administration of anti-TNF antibodies, when considered as a combination with the other additional elements, yields a claim as a whole that amounts to significantly more than the exception itself. The claim is eligible.

If any elements, individually or as a combination, amount to the claim reciting significantly more than the exception, **conclude SME analysis** and continue with examination under each of the other patentability requirements.

DO NOT SCAN THIS DOCUMENT INTO IFW
SUBJECT MATTER ELIGIBILITY WORKSHEET
Nature-Based Products

If any elements, individually or as a combination, amount to the claim reciting significantly more than the exception(s), **conclude SME analysis** and continue with examination under each of the other patentability requirements. If needed, the record can be clarified by providing remarks in the Office action regarding interpretation of the claim (*for example*: the claim recites the product of nature “x”, but amounts to significantly more than the product of nature itself with the additional element “y” because “abc”.)

2. No, the additional elements, taken individually and as a combination, do not result in the claim amounting to significantly more than the exception(s) because

If no elements, taken individually and as a combination, amount to the claim reciting significantly more than the exception(s), **conclude the SME analysis** by making a § 101 rejection and continue with examination under each of the other patentability requirements. *Use Form Paragraphs 7.05 and 7.05.015 available in Custom OACs.*

Are there elements in the disclosure that could be added to the claim that may make it eligible? Identify those elements and consider suggesting them to applicant:

Sample Rejection:

Use Form Paragraphs 7.05 and 7.05.015

Claim __ is rejected under 35 U.S.C. 101 because 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 __ is directed to

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Nature-Based Products

The claim does not include additional elements that are sufficient to amount to significantly more than the judicial exception because
