

Interim Eligibility Guidance: Life Sciences Example Workshop I

UNITED STATES
PATENT AND TRADEMARK OFFICE



Overview

- This workshop training will demonstrate the application of several key aspects of the Interim Eligibility Guidance including:
 - Understanding how the broadest reasonable interpretation affects the eligibility analysis
 - Identifying judicial exceptions in Step 2A:
 - Abstract ideas and their identification by correspondence to court-identified exceptions
 - Products of nature exceptions and the markedly different characteristics analysis
 - Evaluating additional elements in Step 2B, particularly in combination
 - How to write a rejection that satisfies your burden to make a *prima facie* case of ineligibility



Examples

- In this workshop, you will analyze examples that are taken from the Life Sciences Examples issued in May 2016:
 - Example 29: Diagnosing and Treating Julitis
 - Example 30: Dietary Sweeteners
- Each example should be analyzed under the 2014 Interim Guidance on Patent Subject Matter Eligibility (IEG) and the July 2015 Update
- As the examples are intended to be illustrative only, they should be interpreted based on the fact patterns set forth in the workshop materials. **Other fact patterns may have different eligibility outcomes.**



Worksheets

DO NOT SCAN THIS DOCUMENT INTO IFW
SUBJECT MATTER ELIGIBILITY WORKSHEET

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. 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](#). The use of this worksheet is optional.

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 a judicial exception.

Application/Example No. and claim: _____

I. What did applicant invent?

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

Applicant invented:

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 _____
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

- Each example will step through the analysis using a worksheet and the same set of questions:
 - I. What did applicant invent?
 - II. Does the claimed invention fall within a statutory category (Step 1)?
 - III. Is the claim directed to a judicial exception (Step 2A)?
 - IV. Does the claim as a whole amount to significantly more than the exception (Step 2B)?

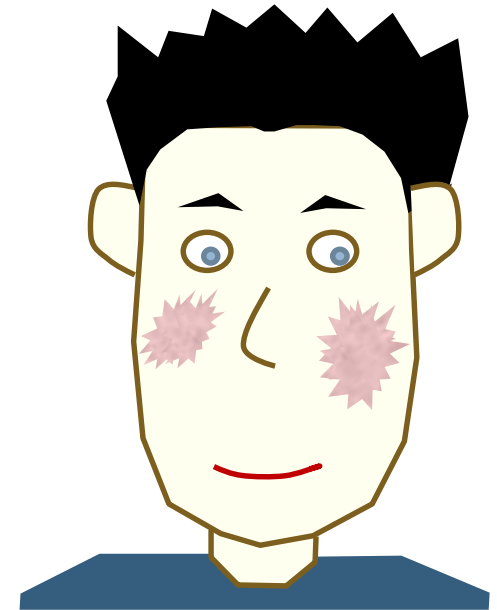
Life Sciences Example 29: Diagnosing & Treating Julitis

- The following slides address three claims from Example 29:
 - Claim 2 (original)
 - Claim 3 (an amended version of claim 2)
 - Claim 6 (a different amended version of claim 2)
- Examiners should use the “generic” worksheet with this example
- Go to page __ of the Workshop Handout for Example 29 to evaluate claim 2

Background of Example 29

“Julitis” is an autoimmune disease that causes chronic inflammation and an itchy and extremely painful rash on the face, hands, and feet.

Conventionally, julitis is diagnosed by a physical examination of the characteristic rash. However, because the rash caused by julitis looks similar to rashes caused by rosacea, doctors often misdiagnosed people as having rosacea when they actually had julitis.



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Background (cont.)

Applicant discovered that the presence of the "JUL-1" protein in a person's plasma is indicative that the person has juitis.

Applicant discloses detecting JUL-1 in plasma by routine and conventional methods, such as immunoassays in which a plasma sample is contacted with an antibody, and then binding between the antibody and the protein is detected using a laboratory technique such as fluoroscopy.

Applicant's immunoassays use human or porcine anti-JUL-1 antibodies. Prior to applicant's invention, and at the time the application was filed, the use of porcine antibodies in veterinary therapeutics was known to most scientists in the field, but these antibodies were not routinely or conventionally used to detect human proteins such as JUL-1.



Background (cont.)

Prior to applicant's invention, and at the time the application was filed, julitis was conventionally treated with anti-tumor necrosis factor (TNF) antibodies. When julitis patients were misdiagnosed as having rosacea, however, the patients would be given rosacea treatments such as antibiotics. These rosacea treatments were not effective to treat julitis.

Applicant's diagnostic methods have improved patient outcomes, by ensuring that patients who have julitis will be accurately diagnosed (due to the detection of JUL-1 in their plasma), and then properly treated with anti-TNF antibodies, as opposed to being misdiagnosed as having rosacea as was previously commonplace.



Claim 2

2. A method of diagnosing julitis in a patient, said method comprising:
 - a. obtaining a plasma sample from a human patient;
 - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
 - c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Worksheet Section I: What Has Applicant Invented?

- Before analyzing for eligibility or any other patentability requirement:
 - Review the detailed disclosure and specific embodiments to understand what the applicant has invented
 - Determine the broadest reasonable interpretation (BRI) of the claims
 - Identify the boundaries of protection sought by applicant
 - Understand how the claims relate to and define what applicant has indicated as the invention

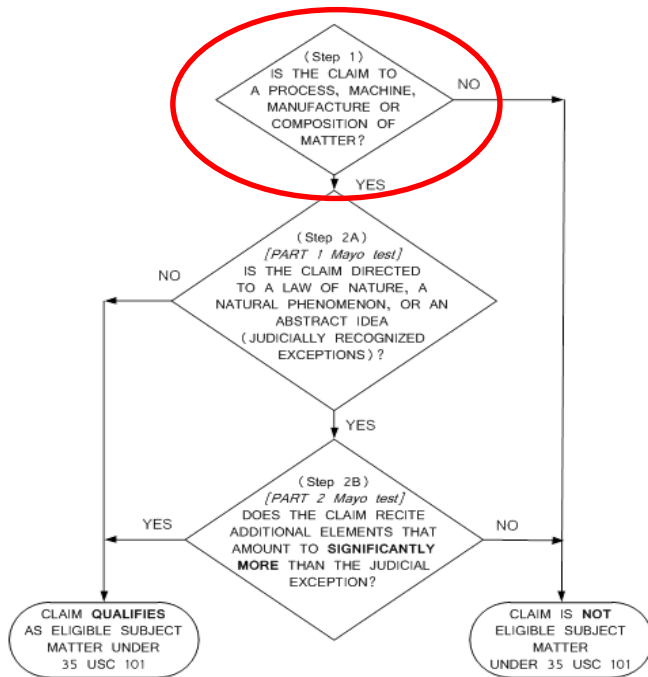
Examiners should fill out Section I of the blank worksheet



Applicant's Invention

- Applicant invented a method of diagnosing julitis, that uses anti-JUL-1 antibodies in an immunoassay to detect JUL-1 protein in a plasma sample from a human patient. The antibodies can be human or porcine.
- The method is based on applicant's discovery that the presence of JUL-1 protein in a person's plasma is indicative that the person has julitis.

Worksheet Section II: Does The Claimed Invention Fall Within A Statutory Category (Step 1)?

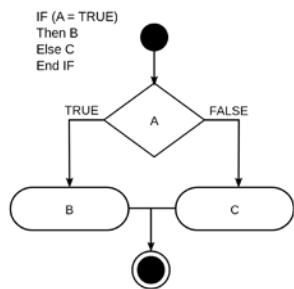


- Claimed inventions that do not fall within the statutory categories are not eligible for patenting
- Identification of one particular category is not necessary for eligibility
- A claim may satisfy the requirements of more than one category



The Statutory Categories

Process



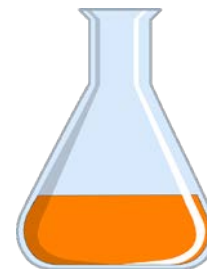
Machine



Manufacture



*Composition
of Matter*

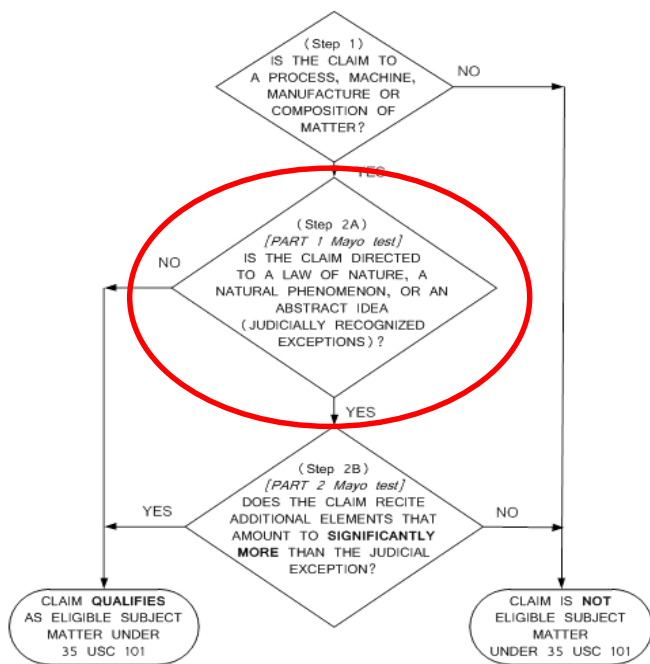


Examiners should fill out Section II of the blank worksheet

The Claimed Invention Falls Within A Statutory Category (Step 1: YES)

- The claim recites a series of steps or acts, including detecting the presence of JUL-1 in a plasma sample. Thus, the claim is directed to a process, which is one of the statutory categories of invention.

Worksheet Section III: Is The Claim Directed To A Judicial Exception (Step 2A)?



- “Directed to” means the exception is recited in the claim, *i.e.*, the claim **sets forth** or **describes** the exception
- Process claims are not directed to products recited therein, except in limited situations (*e.g.*, providing a pomelo fruit)



Examples of Laws of Nature & Natural Phenomena

- The chemical principle underlying the union between fatty elements and water – *Tilghman*
- Electromagnetism to transmit signals – *Morse*
- A correlation that is the consequence of natural processes, e.g., how a certain compound is metabolized by the body – *Mayo*
- An isolated DNA – *Myriad*
- A sheep that “does not possess markedly different characteristics from any farm animals found in nature” – *Roslin*
- Primers having naturally occurring genetic sequence – *Ambry Genetics*



Abstract Ideas

- An abstract idea can be identified by comparison to similar concepts found abstract by the courts.
- The July 2015 Update Quick Reference Sheet (page 2) contains a categorized list of some court-identified abstract ideas.

Concepts relating to the economy and commerce, such as agreements between people in the form of contracts, legal obligations, and business relations

An idea standing alone such as an uninstatiated concept, plan or scheme, as well as a mental process (thinking) that "can be performed in the human mind, or by a human using a pen and paper"

"Fundamental Economic Practices"	"An Idea 'Of Itself'"	
<ul style="list-style-type: none"> • Creating a contractual relationship (<i>buySAFE</i>) • Hedging (<i>Bilski</i>) • Mitigating settlement risk (<i>Alice</i>) 	<ul style="list-style-type: none"> • Comparing information regarding a sample or test subject to a control or target data (<i>Ambry, Myriad CAFC</i>) • Comparing data to determine a risk level (<i>Perkin-Elmer</i>) • Collecting and comparing known information (<i>Classen</i>) 	<ul style="list-style-type: none"> • Diagnosing an abnormal condition by performing clinical tests and thinking about the results (<i>Grams</i>) • Comparing new and stored information and using rules to identify options (<i>SmartGene</i>)
"Certain Methods of Organizing Human Activity"		"Mathematical Relationships/Formulas"
<ul style="list-style-type: none"> • Meal planning (<i>DietGoal</i>) • Generating rule-based tasks for processing an insurance claim (<i>Accenture</i>) 	<ul style="list-style-type: none"> • A mental process that a neurologist should follow when testing a patient for nervous system malfunctions (<i>Meyer</i>) 	<ul style="list-style-type: none"> • A formula for computing an alarm limit (<i>Flook</i>) • Managing a stable value protected life insurance policy by performing calculations and manipulating the results (<i>Bancorp</i>) • An algorithm for calculating parameters indicating an abnormal condition (<i>Grams</i>)

Concepts relating to interpersonal and intrapersonal activities, such as managing relationships or transactions between people, social activities, and human behavior; satisfying or avoiding a legal obligation; advertising, marketing, and sales activities or behaviors; and managing human mental activity

Mathematical concepts such as mathematical algorithms, mathematical relationships, mathematical formulas, and calculations

Which Limitation Is A Judicial Exception?

2. A method of diagnosing julitis in a patient, said method comprising:
 - a. obtaining a plasma sample from a human patient;
 - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
 - c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Examiners should fill out Section III of the blank worksheet by indicating which limitation of the claim sets forth or describes a judicial exception



Step (c) Recites A Judicial Exception...But Why?

2. A method of diagnosing jultitis in a patient, said method comprising:
 - a. obtaining a plasma sample from a human patient;
 - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
 - c. ***diagnosing the patient with jultitis when the presence of JUL-1 in the plasma sample is detected.***

Court-Identified Exceptions

- A correlation that is the consequence of natural processes, *e.g.*, how a certain compound is metabolized by the body (*Mayo*)
- Mental processes or basic critical thinking that can be performed in the human mind, such as:
 - comparing information regarding a sample or test subject to a control or target data (*Ambry*)
 - diagnosing an abnormal condition by performing clinical tests and thinking about the results (*Grams*)

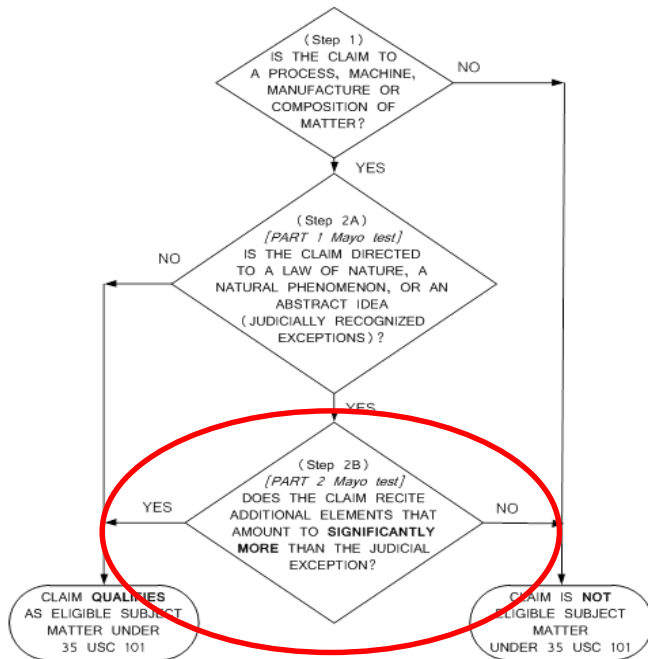
Examiners should fill out Section III of the blank worksheet by indicating the reasons why step (c) is considered a judicial exception

The Claim Is Directed To A Judicial Exception (Step 2A: YES)

- Step c recites diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected, which describes a naturally occurring correlation or relationship between the presence of JUL-1 in a patient's plasma and the presence of julitis in the patient.
- This type of correlation is a judicial exception, which may be termed a law of nature, an abstract idea, or both:
 - The 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*.
 - The diagnosing of step c could be performed by a human using mental steps or basic critical thinking, which 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*).



Worksheet Section IV: Does The Claim As A Whole Amount To Significantly More Than The Exception (Step 2B)?



- Claim is analyzed as a whole
- Consider the additional elements claimed with the exception, both individually and as a combination, to ensure that the claim describes a product or process that applies the exception in a meaningful way



Significantly More Considerations

Considerations that assist in determining whether additional elements provide significantly more than a judicial exception:

May provide “significantly more”

- Improvements to another technology or technical field
- Improvements to the functioning of the computer itself
- Applying the judicial exception with, or by use of, a particular machine
- Effecting a transformation or reduction of a particular article to a different state or thing
- Adding a specific limitation other than what is well-understood, routine and conventional in the field
- Adding unconventional steps that confine the claim to a particular useful application
- Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment

May not provide

- Generic computer performing generic computer function
- Words equivalent to “apply the exception”
- Mere instructions to implement a judicial exception on a computer
- Insignificant extra-solution activity, such as mere data gathering
- Generally linking the use of the judicial exception to a particular technological environment or field of use
- Merely appending well understood, routine, conventional activities previously known to the industry, specified at a high level of generality

Identify The Additional Elements

2. A method of diagnosing julitis in a patient, said method comprising:
 - a. obtaining a plasma sample from a human patient;
 - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
 - c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Examiners should fill out Section IV.A of the blank worksheet by identifying any additional elements (features/limitations/steps) recited in the claim beyond the exception

The Claim Recites Additional Elements

- There are two additional elements besides the law of nature:
 - Obtaining a plasma sample from a human patient (step a)
 - Detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting resultant binding between JUL-1 and the antibody (step b)

Do The Additional Elements Amount To Significantly More?

- It is **vital** that the additional elements be considered both individually **and** as a combination when determining whether the claim as a whole recites eligible subject matter
- When evaluating whether an element represents well-understood, routine, conventional activity previously engaged in by those in the field, keep the following points in mind:
 - Finding the element in the prior art does not necessarily show that it is well-understood, routine or conventional
 - Such an element must have been **widely prevalent** in the field at the time the invention was made and the application was filed

Examiners should fill out Section IV.B of the blank worksheet

The Additional Elements Individually

- Step a: obtaining a sample in order to perform tests is well-understood, routine, conventional activity previously engaged in by scientists in the field of diagnostics, and this step is recited at a high level of generality such that it amounts to insignificant presolution activity, *e.g.*, obtaining samples is a necessary precursor to gather data for using the correlation.
- Step b: detecting whether JUL-1 is present in the plasma sample merely instructs a scientist to use any detection technique with any generic anti-JUL-1 antibody. When recited at this high level of generality, there is no meaningful limitation in this step that distinguishes it from well-understood, routine, conventional data gathering activity previously engaged in by scientists in the field prior to applicant's invention, and at the time the application was filed.



The Additional Elements In Combination

- Consideration of the additional elements as a combination adds no other meaningful limitations not already present when the elements are considered separately.
- Unlike the eligible claim in *Diehr* in which the elements limiting the exception are individually conventional, but taken together act in concert to improve a technical field, the claim here does not invoke any of the considerations that courts have identified as providing significantly more than an exception. Even when viewed as a combination, the additional elements fail to transform the exception into a patent-eligible application of that exception.



What Should The Rejection Include?

- *Prima facie* case of ineligibility requires clear articulation of the reason(s) why the claimed invention is not eligible:
 - Identify judicial exception, and explain why it is an exception
 - Identify additional elements (if any), and explain why they do not amount to significantly more
- Sample rejections satisfying this burden are in prior training:
 - Phase I Training slides 37 (*Mayo* claim 1) and 41-42 (*Alice Corp.* claim 26)
 - Abstract Idea Workshop Materials: worksheets for examples 5-8, 21 and 23 (posted on the web)

Examiners should fill out the rejection portion of the blank worksheet

Sample Rejection Summary

- A rejection of claim 2 should identify step c as an exception by pointing to it in the claim and explaining why it is an exception, *e.g.*, that the recited correlation is a law of nature because it is a consequence of a natural process in the body, and/or that the critical thinking step is an abstract idea similar to those found by the courts to be an exception.
- The rejection should also identify the additional elements in the claim and explain why they do not amount to significantly more, in this case, because they merely add data gathering and well-understood, routine and conventional activities that do not impose meaningful limits on the law of nature.



Can The Claim Be Amended To Achieve Eligibility?

- Are there elements in the disclosure that could be added to the claim that may amount to significantly more (*i.e.*, provide an inventive concept) and make it eligible?
- To answer this question, it will be helpful to review the background of the example while keeping the significantly more considerations in mind

Examiners should fill out the suggestion portion of the blank worksheet

Claim Amendments

- The following slides walk through two different ways in which claim 2 could be amended in response to the rejection under § 101
 - For purposes of consistency, the following claims are numbered the same as in the published examples
 - Differences in language between the following claims and rejected claim 2 are shown as if the claims had been amended
- Examiners should use a new “generic” worksheet with each claim

Claim 3

3. A method of diagnosing julitis in a patient, said method comprising:
 - a. obtaining a plasma sample from a human patient;
 - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with **[[an]] a porcine** anti-JUL-1 antibody and detecting binding between JUL-1 and the **porcine** antibody; and
 - c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Note: Claim 3 is marked-up as if it were an amended version of claim 2.



Worksheet Sections I and II

- Review the claim “amendments”, and perform the following analysis:
 - Determine whether the amended claim has the same or a different broadest reasonable interpretation (BRI) as original claim 2
 - Determine whether the amended claim still falls within the same statutory category as original claim 2 (Step 1)

Examiners should fill out Sections I & II of the blank worksheet

Applicant's Invention Is Still Claimed Within A Statutory Category (Step 1: YES)

- The amended claim is still to a method of diagnosing julitis using anti-JUL-1 antibodies, however the claim is now limited to using porcine antibodies in the immunoassay.
- The amended claim is still to a process.

Worksheet Section III

- Review the claim amendments, and evaluate whether the amendments have affected the Step 2A analysis
 - Does the amended claim recite the same judicial exception as original claim 2?
 - Does the amended claim recite additional judicial exceptions that were not in original claim 2?

Examiners should fill out Section III of the blank worksheet by indicating which limitation of the claim sets forth or describes a judicial exception, and why that limitation is considered a judicial exception

The Amended Claim Is Directed To A Judicial Exception (Step 2A: YES)

- The amended claim recites the same correlation and critical thinking step (step c) as claim 2, which as explained above is a law of nature and/or an abstract idea.
- Thus, the amended claim is still directed to a judicial exception.

Worksheet Section IV: Identify The Additional Elements

3. A method of diagnosing julitis in a patient, said method comprising:
 - a. obtaining a plasma sample from a human patient;
 - b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with **[[an]] a porcine** anti-JUL-1 antibody and detecting binding between JUL-1 and the **porcine** antibody; and
 - c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Examiners should fill out Section IV.A of the blank worksheet by identifying any additional elements (features/limitations/steps) recited in the claim beyond the exception

Do The Additional Elements Amount To Significantly More?

- The amended claim recites two additional elements:
 - obtaining a plasma sample from a human patient (step a)
 - detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a **porcine** anti-JUL-1 antibody and detecting resultant binding between JUL-1 and the **porcine** antibody (step b)
- Do the additional elements in the amended claim amount to significantly more, either individually or in combination?

Examiners should fill out Section IV.B of the blank worksheet

The Amended Claim As A Whole Amounts To Significantly More (Step 2B: YES)

- Step a does not add significantly more, for the reasons discussed above for claim 2.
- Step b, however, requires detecting using a **porcine** anti-JUL-1 antibody.
 - Prior to applicant's invention, and at the time the application was filed, porcine antibodies were not routinely or conventionally used to detect human proteins such as JUL-1. Thus, detecting JUL-1 using a porcine antibody is an unconventional step that is more than a mere instruction to "apply" the correlation and critical thinking step (the exception) using well-understood, routine, conventional activity previously engaged in by scientists in the field.
 - Whether taken alone or in combination with step a, step b yields a claim as a whole that amounts to significantly more than the exception itself.

Claim 6

6. A method of diagnosing **and treating** julitis in a patient, said method comprising:
- a. obtaining a plasma sample from a human patient;
 - b. detecting whether JUL-1 is present in the plasma sample ~~by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody;~~ and
 - c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected; **and**
 - d. **administering an effective amount of anti-tumor necrosis factor (TNF) antibodies to the diagnosed patient.**

Note: Claim 6 is marked-up as if it were an amended version of claim 2.



Worksheet Sections I and II

- Review the claim “amendments”, and perform the following analysis:
 - Determine whether the amended claim has the same or a different broadest reasonable interpretation (BRI) as original claim 2
 - Determine whether the amended claim still falls within the same statutory category as original claim 2 (Step 1)

Examiners should fill out Sections I & II of the blank worksheet

Applicant's Invention Is Still Claimed Within A Statutory Category (Step 1: YES)

- The amended claim is still to a method of diagnosing julitis based on the detection of JUL-1, but now has an altered BRI:
 - the BRI is no longer limited to detection methods using anti-JUL-1 antibodies (step b); and
 - the BRI now encompasses a step of administering an effective amount of anti-TNF antibodies to the diagnosed patient (step d).
- The amended claim is still to a process.

Worksheet Section III

- Review the claim amendments, and evaluate whether the amendments have affected the Step 2A analysis
 - Does the amended claim recite the same judicial exception as original claim 2?
 - Does the amended claim recite additional judicial exceptions that were not in original claim 2?

Examiners should fill out Section III of the blank worksheet by indicating which limitation of the claim sets forth or describes a judicial exception, and why that limitation is considered a judicial exception

The Amended Claim Is Directed To A Judicial Exception (Step 2A: YES)

- The amended claim recites the same correlation and critical thinking step (step c) as claim 2, which as explained above is a law of nature and/or an abstract idea.
- Thus, the amended claim is still directed to a judicial exception.

Worksheet Section IV: Identify The Additional Elements

6. A method of diagnosing **and treating** juitis in a patient, said method comprising:
- a. obtaining a plasma sample from a human patient;
 - b. detecting whether JUL-1 is present in the plasma sample ~~by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and~~
 - c. diagnosing the patient with juitis when the presence of JUL-1 in the plasma sample is detected; **and**
 - d. **administering an effective amount of anti-tumor necrosis factor (TNF) antibodies to the diagnosed patient.**

Examiners should fill out Section IV.A of the blank worksheet by identifying any additional elements (features/limitations/steps) recited in the claim beyond the exception

Do The Additional Elements Amount To Significantly More?

- The amended claim recites three additional elements:
 - obtaining a plasma sample from a human patient (step a)
 - detecting whether JUL-1 is present in the plasma sample (step b)
 - administering an effective amount of anti-TNF antibodies to the diagnosed patient (step d)
- Do the additional elements in the amended claim amount to significantly more, either individually or in combination?

Examiners should fill out Section IV.B of the blank worksheet

The Additional Elements Individually

- Step a does not add significantly more, for the reasons discussed above for claim 2.
- Step b does not add significantly more, for the reasons discussed above for claim 2. *E.g.*, step b in this claim is recited at an even higher level of generality than in claim 2, because it encompasses any protein detection method, whether or not it uses antibodies.
- Step d does not add significantly more, because administering these antibodies to treat a patient diagnosed with julitis was well-understood, routine, conventional activity previously engaged in by doctors in the field prior to applicant's invention, and at the time the application was filed.



The Additional Elements In Combination Amount To Significantly More (Step 2B: YES)

- The combination of the additional elements (steps a, b and d) adds meaningful limits on the use of the exception (the correlation and critical thinking step) and thus amounts to significantly more than the exception itself.
- In combination, the steps add meaningful limits because:
 - Treatment step d is integrated into the claim as a whole (which ensures that patients with julitis will be accurately diagnosed and properly treated with anti-TNF antibodies, as opposed to being misdiagnosed as having rosacea and given the wrong treatment as was previously commonplace) and thus is more than insignificant post-solution activity;
 - The claimed steps and particularly recitation of a particular treatment (administration of an effective amount of anti-TNF antibodies) in step d amounts to more than merely diagnosing a patient with julitis and instructing a doctor to generically “treat it”; and
 - The combination of additional elements was not well-understood, routine, conventional activity previously engaged in by those in the field.



Summary of Example 29

- The claim “amendments” demonstrate two different ways to make a claim directed to a judicial exception eligible
 - Claim 3 demonstrates how an unconventional reagent (the porcine antibodies) can provide eligibility
 - Claim 6 demonstrates how a combination of additional elements including a particular treatment can provide eligibility
- For more information about the eligibility analysis of these claims, consult the published example set
- A sample rejection of claim 2 is presented in the worksheet answer key



Life Sciences Example 30: Dietary Sweeteners

- The following slides address three claims from Example 30:
 - Claim 2 (original)
 - Claim 3 (an amended version of claim 2)
 - Claim 6 (a different amended version of claim 2)
- Examiners should use the “**nature-based products**” worksheet with this example
- Go to page __ of the Workshop Handout for Example 30 to evaluate claim 2

Background of Example 30



The “Texas mint” plant has a thin liquid sap containing about 10% texiol (a newly discovered glycoside), water, and other nutrients. Texiol is lower in calories and tastes sweeter than table sugar, but it has a bitter aftertaste.

Applicant discloses a dietary sweetener comprising texiol mixed with other components such as water to form a heterogeneous or homogenous mixture.

Applicant discloses that trained sensory panels reviewed formulations having varying concentrations of texiol in water, and preferred a dietary sweetener comprising 1-5% texiol and at least 90% water. This preferred sweetener retains the naturally occurring texiol’s sweetness and bitter aftertaste.



Background (cont.)

Applicant also discloses a dietary sweetener comprising texiol mixed with water and Compound N (a natural flavor excreted from mushrooms and having a mild umami taste). When combined with texiol in particular amounts, Compound N neutralizes the bitter aftertaste of texiol, even though it does not chemically react with texiol.

The same sensory panel tasted mixtures having various concentrations of Compound N and texiol, and found that a formulation comprising 1-5% texiol, 1-2% Compound N, and the balance water produced the most palatable results for a dietary sweetener with no bitter aftertaste. When Compound N is added in the specified amount, the changed taste perception occurs whether or not the texiol is fully dissolved, *e.g.*, even when large crystals of texiol are used.



Background (cont.)

Applicant discloses that the same sensory panel, upon tasting naturally occurring texiol, reported perceiving an immediate burst of sweetness that rapidly dissipated. Because prolonged sweetening is desirable for some sweetened products such as chewing gum, applicant discloses dietary sweeteners comprising texiol in a controlled release formulation.

Applicant's formulations achieve controlled release (*e.g.*, release of specific amounts of texiol from the formulation at specific time intervals, or over a prolonged period of time) by mixing the texiol with other substances such as polymers and/or changing the form of the texiol so that a controlled perception of sweetness is achieved. For example, in one such formulation, texiol particles are encapsulated in a polymer-emulsifier mixture that delays release of the texiol as compared to unencapsulated (*e.g.*, naturally occurring) texiol particles. These controlled release formulations alter the time over which texiol's sweetness is perceived.



Claim 2

2. A dietary sweetener comprising:
1-5 percent texiol; and
at least 90 percent water.

Worksheet Section I: What Is Applicant's Invention & The BRI?

- Before analyzing for eligibility or any other patentability requirement:
 - Understand what applicant has invented
 - Establish the BRI of the claim
- BRI is particularly crucial for claims reciting nature-based products, because it assists in identifying appropriate naturally occurring counterparts

Examiners should fill out Section I of the blank worksheet



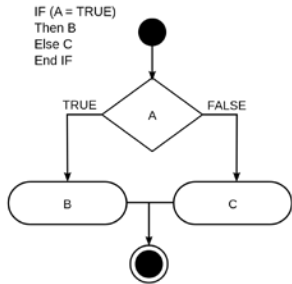
Applicant's Invention & The BRI

- Applicant invented a dietary sweetener comprising texiol mixed with water.
- Based on the specification's definition of "dietary sweetener", the BRI of the claim is a mixture of texiol and water in the specified amounts (1-5% texiol and at least 90% water).
- The BRI does not encompass the naturally occurring sap of the Texas mint plant, which contains a different amount of texiol (10%).



Worksheet Section II: Does The Claimed Invention Fall Within A Statutory Category (Step 1)?

Process



Machine



Manufacture



*Composition
of Matter*

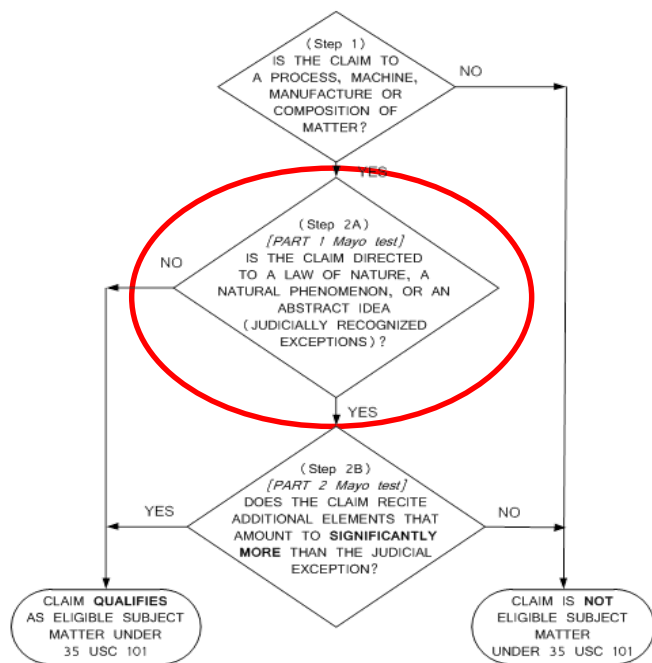


Examiners should fill out Section II of the blank worksheet

The Claimed Invention Falls Within A Statutory Category (Step 1: YES)

- Because texiol and water are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter.

Worksheet Section III: Is The Claim Directed To A Judicial Exception (Step 2A)?



- “Directed to” means the exception is recited in the claim, *i.e.*, the claim **sets forth** or **describes** the exception
- The **Markedly Different Characteristics (MDC)** analysis is used to determine if a nature-based product is a product of nature exception



Products of Nature

- Nature-based products that are ***naturally occurring***
 - “a new mineral discovered in the earth or a new plant found in the wild”
- *Chakrabarty*
 - “naturally occurring things” – *Myriad*
 - “any existing organism” - *Roslin*
- Nature-based products that are not naturally occurring but ***do not have markedly different characteristics*** from any naturally occurring counterpart
 - An isolated DNA – *Myriad*
 - A cloned sheep that “does not possess markedly different characteristics from any farm animals found in nature” – *Roslin*
 - Primers having naturally occurring genetic sequence – *Ambry Genetics*

How To Perform The MDC Analysis

- Using the “product of nature” worksheet, you will walk through the three parts of the MDC analysis
 1. Identify the nature-based product limitation in the claim;
 2. Identify the appropriate naturally occurring counterpart to the nature-based product limitation; and
 3. Compare the nature-based product limitation to its counterpart, to determine whether it exhibits MDC
- The MDC analysis is laid out in Section III.C of the “product of nature” worksheet



MDC Analysis Part One: Which Limitation Is A Nature-Based Product?

2. A dietary sweetener comprising:
1-5 percent texiol; and
at least 90 percent water.

Examiners should fill out Section III.C of the blank worksheet by indicating in part 1(a) which limitation of the claim sets forth or describes a nature-based product

The Nature-Based Product

- The claimed mixture of texiol and water is a nature-based product. This mixture must be analyzed for MDC, in order to determine if it is a product of nature exception.

MDC Analysis Part Two: What Is The Naturally Occurring Counterpart?

Consider what the courts have used as counterparts

<u>Case</u>	<u>Nature-Based Product</u>	<u>Counterpart</u>
<i>Funk Brothers</i>	Mixture of bacterial species	Each naturally occurring species by itself
<i>Chakrabarty</i>	Genetically modified <i>Pseudomonas</i> bacterium	Unmodified <i>Pseudomonas</i> bacterium
<i>Myriad</i>	Isolated DNA segment	Same DNA segment as part of chromosome
<i>Roslin</i>	Cloned sheep	Parent sheep; naturally occurring sheep

Examiners should fill out Section III.C of the blank worksheet by indicating in part 1(b) an appropriate naturally occurring counterpart

The Naturally Occurring Counterpart

- The closest naturally occurring counterpart in its natural state to the claimed nature-based product limitation is the naturally occurring texiol-water mixture in the sap of the Texas mint plant.

MDC Analysis Part Three: Are There Markedly Different Characteristics?

- Compare the nature-based product limitation to its counterpart, to determine whether it exhibits MDC
 - Consider whether any of the following characteristics were changed:
 - biological and pharmacological functions or activities
 - structure or form
 - phenotype
 - chemical or physical properties
 - To show a marked difference, the characteristic(s) must be changed as compared to nature, and the change must be “marked” (significant)

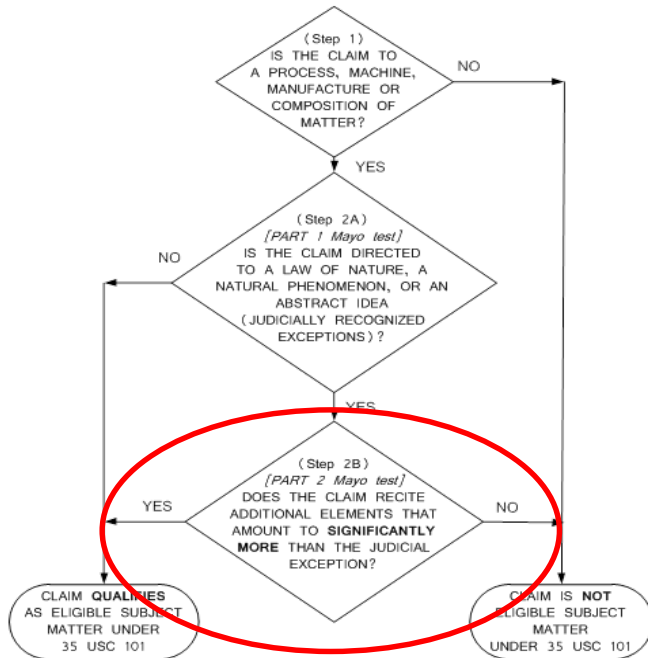
Examiners should fill out Section III.C of the blank worksheet by indicating the results of the comparison in part 1(c)

The Claim Is Directed To A Product of Nature (Step 2A: YES)

- Although the combination as claimed is novel and does not occur in nature, there is no indication that mixing 1-5 percent texiol with at least 90 percent water changes the structure, function, or other properties of the texiol or water in any marked way.
- The texiol in the claimed mixture retains its naturally occurring structure and properties (*e.g.*, its sweetness and bitter aftertaste), and is merely located in water, which also retains its naturally occurring structure and properties (*e.g.*, its liquid form at room temperature).
- These characteristics are also the same as the naturally occurring texiol and water in the sap, which is also a sweet liquid at room temperature. Thus, the claimed mixture as a whole does not display markedly different characteristics compared to the closest naturally occurring counterpart.
- There are no other exceptions in the claim.

Worksheet Section IV:

Does The Claim As A Whole Amount To Significantly More Than The Exception (Step 2B)?



- Claim is analyzed as a whole
- Consider the additional elements claimed with the exception, both individually and as a combination, to ensure that the claim describes a product or process that applies the exception in a meaningful way



Significantly More Considerations

Considerations that assist in determining whether additional elements provide significantly more than a judicial exception:

May provide “significantly more”

- Improvements to another technology or technical field
- Improvements to the functioning of the computer itself
- Applying the judicial exception with, or by use of, a particular machine
- Effecting a transformation or reduction of a particular article to a different state or thing
- Adding a specific limitation other than what is well-understood, routine and conventional in the field
- Adding unconventional steps that confine the claim to a particular useful application
- Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment

May not provide

- Generic computer performing generic computer function
- Words equivalent to “apply the exception”
- Mere instructions to implement a judicial exception on a computer
- Insignificant extra-solution activity, such as mere data gathering
- Generally linking the use of the judicial exception to a particular technological environment or field of use
- Merely appending well understood, routine, conventional activities previously known to the industry, specified at a high level of generality

Do The Additional Elements Amount To Significantly More?

- Unique treatment of “additional elements” is available for combination products of nature like the texiol-water mixture here
 - Because the component elements (texiol and water) do not occur together in nature as claimed (*i.e.*, in the recited amounts), each component element is considered as an additional element to the other components
 - This unique treatment provides an opportunity to explore whether the combination of products of nature results in significantly more

Examiners should fill out Section IV.B of the blank worksheet, indicating whether the texiol and water, individually or in a combination, amount to significantly more than the products of nature

The Claim As A Whole Does Not Amount To Significantly More (Step 2B: NO)

- On their own, each component continues to have the same properties in the mixture as it had alone.
- Mixing sweeteners with water was well-understood, routine, conventional activity engaged in by those in the field prior to applicant's invention and at the time of filing the application. The widespread prevalence of such mixtures is evidenced by, *e.g.*, the ubiquity of simple syrup and stevia-based liquid sweeteners.
- Mixing specific amounts of sweeteners with water (or vice-versa) was also well-understood, routine, conventional activity at the time, *e.g.*, to achieve commercially acceptable sweetness levels and provide sweeteners for different purposes.
- Thus, the mixing of texiol and water, when recited at this high level of generality, does not meaningfully limit the claim, and the claim as a whole does not amount to significantly more than each "product of nature" by itself.



What Should The Rejection Include?

- *Prima facie* case of ineligibility requires clear articulation of the reason(s) why the claimed invention is not eligible:
 - Identify judicial exception, and explain why it is an exception
 - Identify additional elements (if any), and explain why they do not amount to significantly more
- Sample rejections satisfying this burden are in prior training:
 - Phase I Training slides 37 (*Mayo* claim 1) and 41-42 (*Alice Corp.* claim 26)
 - Abstract Idea Workshop Materials: worksheets for examples 5-8, 21 and 23 (posted on the web)

Examiners should fill out the rejection portion of the blank worksheet

Sample Rejection Summary

- A rejection of claim 2 should identify the exceptions by pointing to the nature-based product limitations in the claim (texiol and water) and explaining why they lack markedly different characteristics from their naturally occurring counterparts, *e.g.*, because there are no marked changes in structure, function or other characteristics.
- The rejection also should explain that mixing texiol and water does not amount to significantly more than the exceptions, because mixtures of sweeteners and water are well-understood, routine and conventional in the field.

Can The Claim Be Amended To Achieve Eligibility?

- Are there elements in the disclosure that could be added to the claim that may make it eligible? Note for products of nature, amending the claim may:
 - Result in MDC, *e.g.*, because an added limitation affects the characteristics of the claimed product
 - Amount to significantly more, *e.g.*, because an added limitation adds an inventive concept to the claimed product
- To answer this question, it will be helpful to review the background of the example

Examiners should fill out the suggestion portion of the blank worksheet

Claim Amendments

- The following slides walk through two different ways in which claim 2 could be amended in response to the rejection under § 101
 - For purposes of consistency, the following claims are numbered the same as in the published examples
 - Differences in language between the following claims and rejected claim 2 are shown as if the claims had been amended
- Examiners should use a new “product of nature” worksheet with each claim

Claim 3

3. A dietary sweetener comprising:
1-5 percent texiol; ~~and~~
at least 90 percent water; and
1-2 percent Compound N.

Note: Claim 3 is marked-up as if it were an amended version of claim 2.

Worksheet Sections I and II

- Review the claim “amendments”, and perform the following analysis:
 - Determine whether the amended claim has the same or a different broadest reasonable interpretation (BRI) as original claim 2
 - Determine whether the amended claim still falls within the same statutory category as original claim 2 (Step 1)

Examiners should fill out Sections I & II of the blank worksheet

The Amended Claim Has An Altered BRI, But Still Falls Within A Statutory Category (Step 1: YES)

- The amended claim is still to a dietary sweetener, but the BRI is now limited to a mixture of texiol, water and Compound N in the specified amounts (1-5% texiol, 1-2% Compound N and at least 90% water).
- The amended claim is still to a composition of matter.

Worksheet Section III

- Review the claim amendments, and evaluate whether the amendments have affected the Step 2A analysis
 - Does the amended claim recite the same nature-based product as original claim 2?
 - Does the amended nature-based product have the same naturally occurring counterpart as original claim 2?
 - Does the amended nature-based product exhibit MDC when compared to its counterpart?

Examiners should fill out Section III.C of the blank worksheet to reflect their MDC analysis of the amended claim



The Amended Claim Is Not Directed To A Judicial Exception (Step 2A: NO)

- When the claimed mixture is compared to its counterparts (the texiol-water mixture in the sap, and Compound N), there are no chemical or structural changes. However, the mixture has a changed organoleptic property (*e.g.*, taste), because its flavor profile (sweet and lacking bitterness) is different than the mere sum of the flavors of the individual components, *e.g.*, texiol's sweetness and bitter aftertaste, and Compound N's mild umami flavor.
- This altered property is a marked difference in characteristics, because it results in the claimed mixture being distinct from its natural counterparts in a way that is relevant to the nature of the invention as a dietary sweetener, *e.g.*, because the taster no longer perceives the bitter aftertaste of naturally occurring texiol. Thus, the claimed dietary sweetener has markedly different characteristics as compared to its natural counterparts, and is not a "product of nature" exception.
- There are no other judicial exceptions in the claim.



Claim 6

6. A dietary sweetener comprising:
~~1-5 percent~~ texiol; and
~~at least 90 percent water~~ **in a controlled release formulation.**

Note: Claim 6 is marked-up as if it were an amended version of claim 2.

Worksheet Sections I and II

- Review the claim “amendments”, and perform the following analysis:
 - Determine whether the amended claim has the same or a different broadest reasonable interpretation (BRI) as original claim 2
 - Determine whether the amended claim still falls within the same statutory category as original claim 2 (Step 1)

Examiners should fill out Sections I & II of the blank worksheet

The Amended Claim Has An Altered BRI, But Still Falls Within A Statutory Category (Step 1: YES)

- The amended claim is still to a dietary sweetener, but the BRI has changed. The BRI of the amended claim encompasses a texiol formulation that has altered time release properties so that its sweetness is now released in a controlled manner over time due to (a) a change in form or structure or (b) being mixed with other substances (*e.g.*, by being encapsulated in a polymer-emulsifier mixture).
- The amended claim is still to a composition of matter.

Worksheet Section III

- Review the claim amendments, and evaluate whether the amendments have affected the Step 2A analysis
 - Does the amended claim recite the same nature-based product as original claim 2?
 - Does the amended nature-based product have the same naturally occurring counterpart as original claim 2?
 - Does the amended nature-based product exhibit MDC when compared to its counterpart?

Examiners should fill out Section III.C of the blank worksheet to reflect their MDC analysis of the amended claim

The Amended Claim Is Not Directed To A Judicial Exception (Step 2A: NO)

- When the claimed formulation is compared to its counterpart (naturally occurring texiol in its natural state), the formulation has altered time release properties, in that it releases the sweetness of texiol in a controlled manner over time, as opposed to the naturally occurring texiol, which releases all of its sweetness at one point in time.
- These altered time release properties are a marked difference in characteristics, because they result in the claimed formulation being distinct from its natural counterpart in a way (release of sweetness over time) that is relevant to the nature of the invention as a dietary sweetener. *E.g.*, the claimed dietary sweetener prolongs enjoyment of a texiol-sweetened product such as chewing gum, by altering the time over which texiol's sweetness is perceived.
- Because it has markedly different characteristics as compared to its natural counterpart, the claimed formulation is not a "product of nature" exception.
- There are no other judicial exceptions in the claim.



Summary of Example 30

- The claim “amendments” demonstrate how to make a claim reciting a nature-based product eligible
 - Claim 3 demonstrates how altering the organoleptic characteristics of the product can provide eligibility
 - Claim 6 demonstrates how altering the time release characteristics of the product can provide eligibility
- For more information about the eligibility analysis of these claims, consult the published example set
- A sample rejection of claim 2 is presented in the worksheet answer key



Questions and Comments?

Please see your SPE for questions or comments.
Your SPE can direct you to TC subject matter
eligibility points of contact (POCs) if needed.

Training Time Code: