

# Evaluating Subject Matter Eligibility Under 35 USC § 101: March 2014 Update



United States Patent and Trademark Office

March 19, 2014



# Overview of Guidance



# Existing Guidance

- Current PTO examination guidance directed to three recent Supreme Court decisions:
  - Process claims involving Abstract Ideas  
(2010 *Bilski* Guidance; MPEP 2106)
  - Process claims involving Laws of Nature  
(2012 *Mayo* Guidance; MPEP 2106.01)
  - Product claims reciting nucleic acids  
(6/13/2013 *Myriad* preliminary memo)

Replaced by  
New  
Guidance



# Scope of New Guidance

- Applies to all types of claims (i.e., machine, composition, manufacture and process claims) that recite or involve:
  - Laws of nature/natural principles,
  - Natural phenomena, and/or
  - Natural products.



# What About Abstract Ideas?

- No change to examination of claims reciting abstract ideas.
  - Continue to analyze claims reciting abstract ideas for subject matter eligibility using only the existing guidance in MPEP § 2106(II), even if claim also recites other judicial exceptions.
- Why?
  - Law is unsettled.
  - Supreme Court is scheduled to hear at least one case in 2014 (*Alice v. CLS Bank*) involving the abstract idea judicial exception.

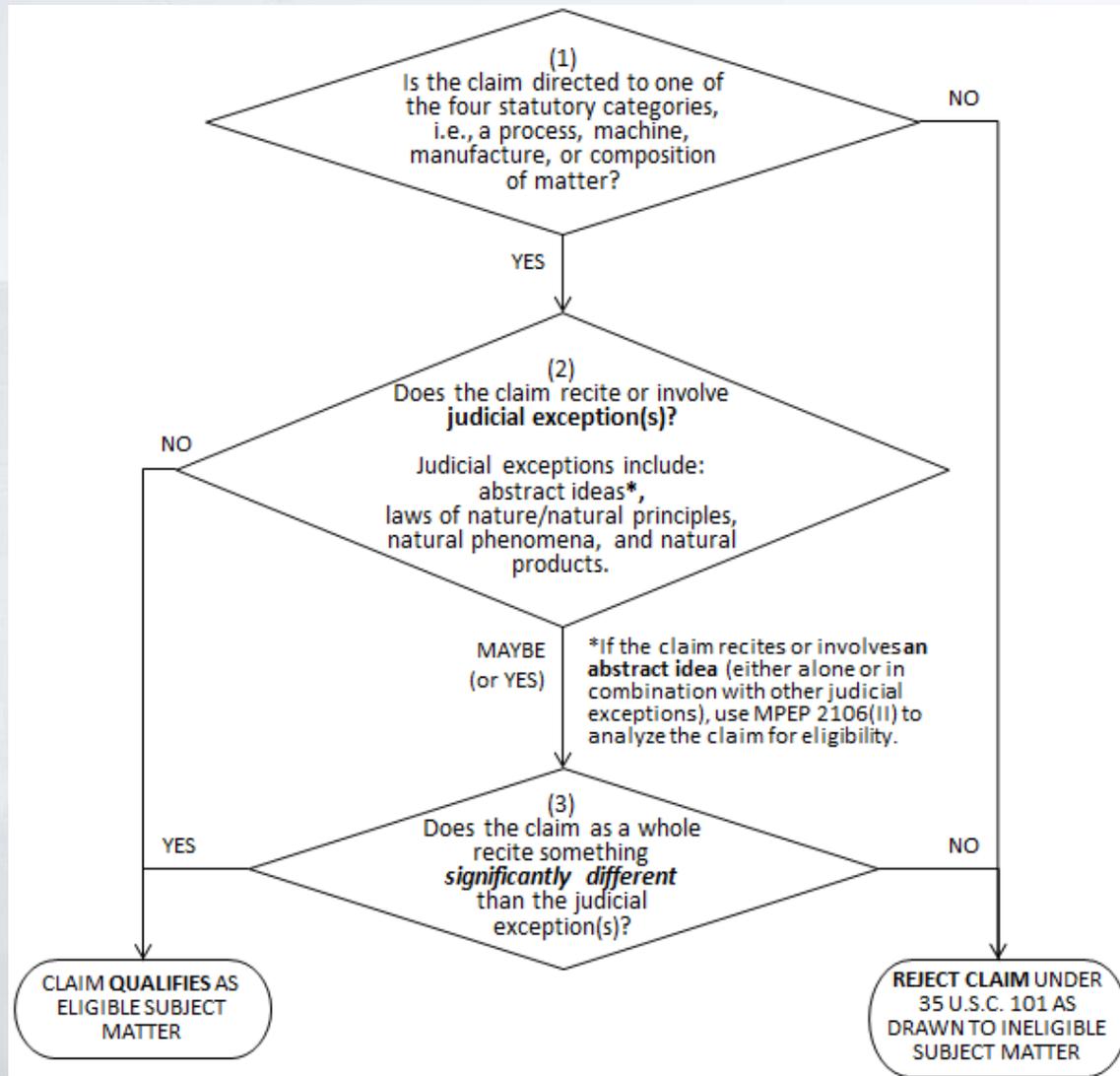


# Limited To Utility Patent Applications

- Guidance applies only to utility patent applications.
  - Because guidance concerns subject matter eligibility under 35 U.S.C. § 101.
- No effect on design or plant patent applications, because their eligibility is determined by different statutory sections.



# Overall Process: Flowchart





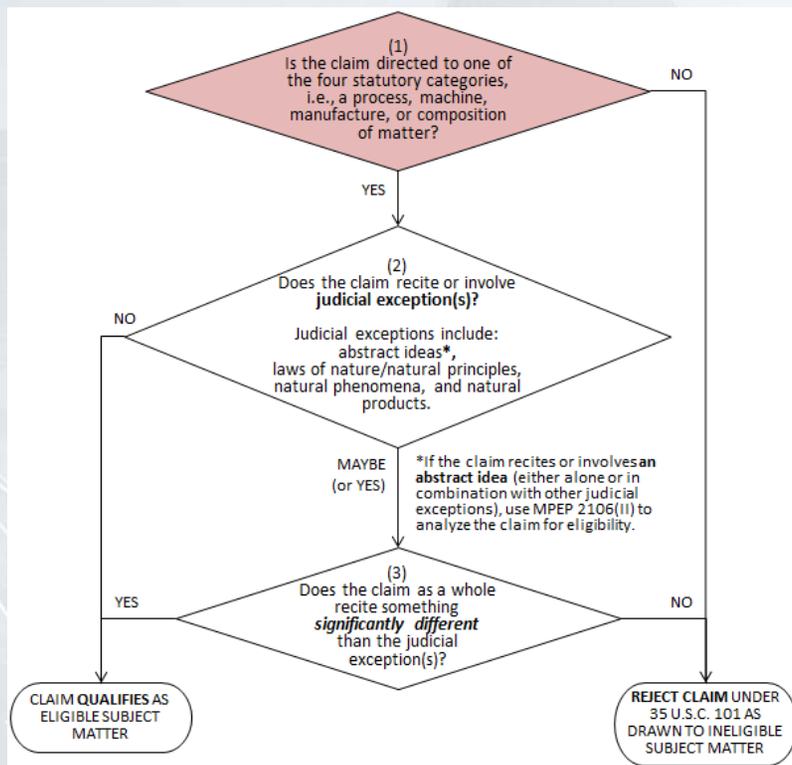
# Overall Process: Summary

- New guidance uses the same essential approach to eligibility as the existing guidance:
  - The claim as a whole is given its **broadest reasonable interpretation** (BRI)
  - Using the BRI, the claim is evaluated to determine whether it falls within at least one of the **statutory categories** of invention (Flowchart Question 1)
  - If it falls within an eligible category, the claim is evaluated to determine whether it wholly embraces a **judicial exception** (Flowchart Questions 2 & 3)



# Question One:

## Is The Claim Directed To One Of The Four Statutory Categories of 35 U.S.C. § 101?





# 35 U.S.C. § 101

## § 101 - Inventions Patentable:

Whoever invents or discovers any new and useful **process, machine, manufacture, or composition of matter**, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.



# The Four Statutory Categories

1. Process: series of steps; 35 U.S.C. § 100
2. Machine: a concrete thing consisting of parts or devices
3. Manufacture: an article produced from raw or prepared materials
4. Composition of matter: a composition of substances or composite article



# Claimed Invention Must Fall Within One or More Statutory Categories

- Analyze based on the broadest reasonable interpretation of the claim as a whole.
  - A claim that covers both eligible and ineligible subject matter should be rejected under §101.
- Not necessary to identify only one particular category.
  - A claim may satisfy the requirements of more than one category.
  - Example: a claim to a bicycle may satisfy both machine and manufacture categories.
- Claimed inventions that do not fall within any statutory category are not eligible for patenting.

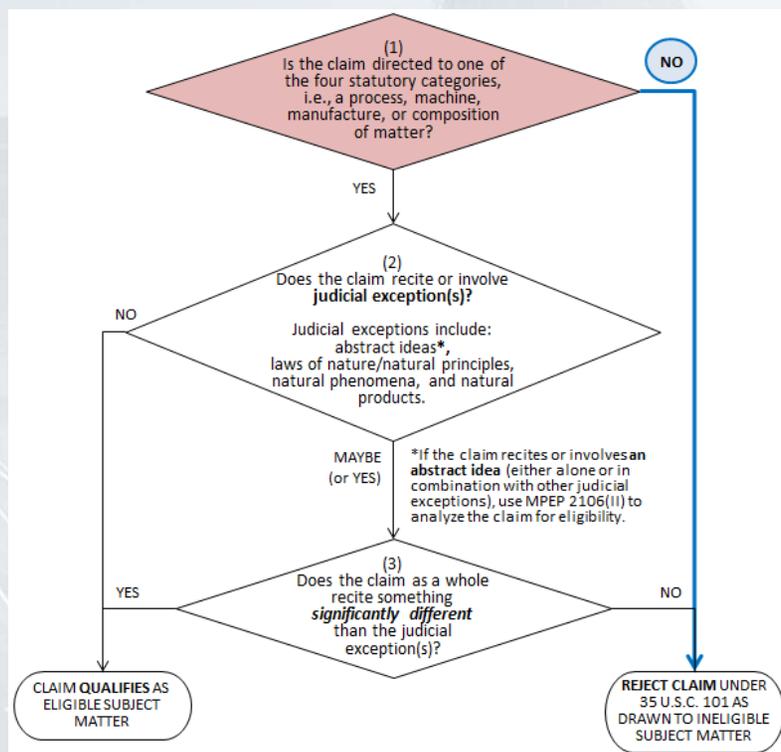


# Exclusions From The Categories

- Human organisms
  - Section 33(a) of America Invents Act codified long-standing Office policy that human organisms are not eligible subject matter
  - Existing guidance in MPEP 2105
  - Example: claim to a human embryo
- Signals *per se*
  - Existing guidance in MPEP 2106(I)
  - Example: claim to a transitory signal



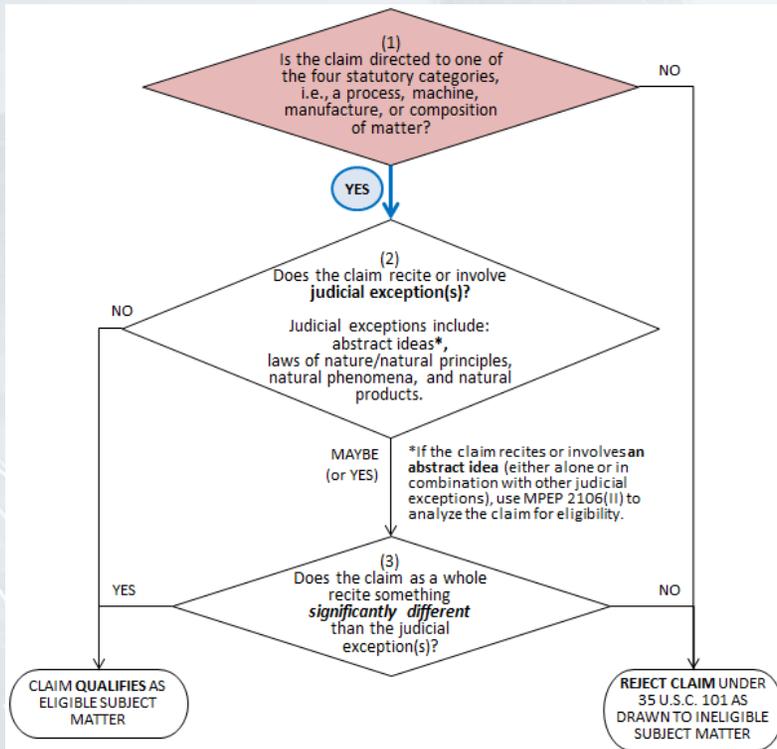
# Answer Question One: If “No” → Reject Claim



- If a claim is not directed to an invention that falls within the four statutory categories, **reject claim under 35 U.S.C. § 101**.
  - Use Form ¶¶ 7.04.01, 7.05, 7.05.01.
  - Use Form ¶ 7.04.03 for human organisms.
- Examiner should proceed to examine under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc.



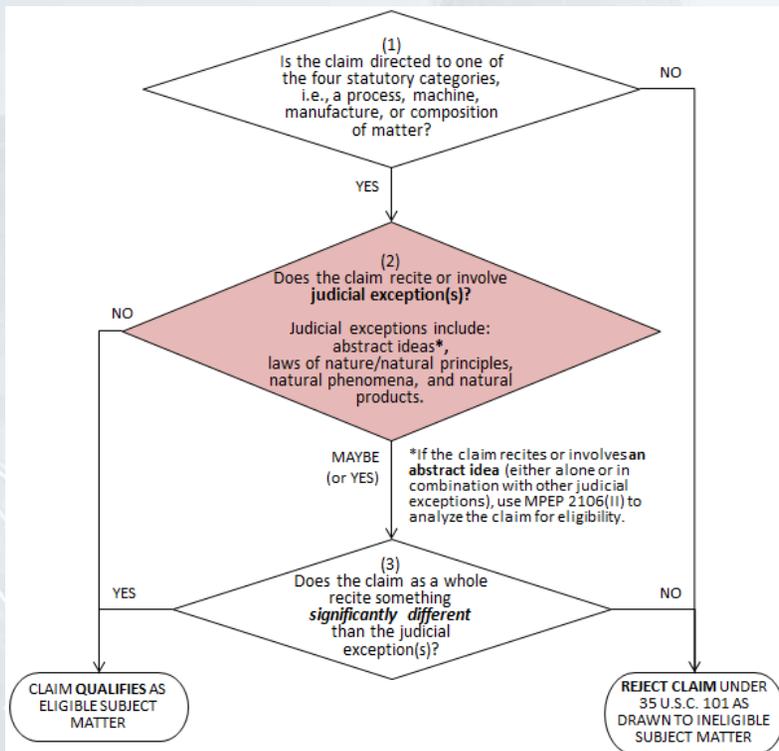
# Answer Question One: If “Yes” → Go to Question 2



If a claim falls within at least one of the four statutory categories, **proceed to Question 2.**



# Question Two: Does The Claim Recite or Involve A Judicial Exception?





# Judicial Exceptions

- The courts have interpreted the four statutory categories to *exclude* certain subject matter:
  - Abstract Ideas
  - Laws of Nature/Natural Principles
  - Natural Phenomena
  - Natural Products
- These exclusions are called the “judicial exceptions” or “judicially recognized exceptions”



# Abstract Ideas

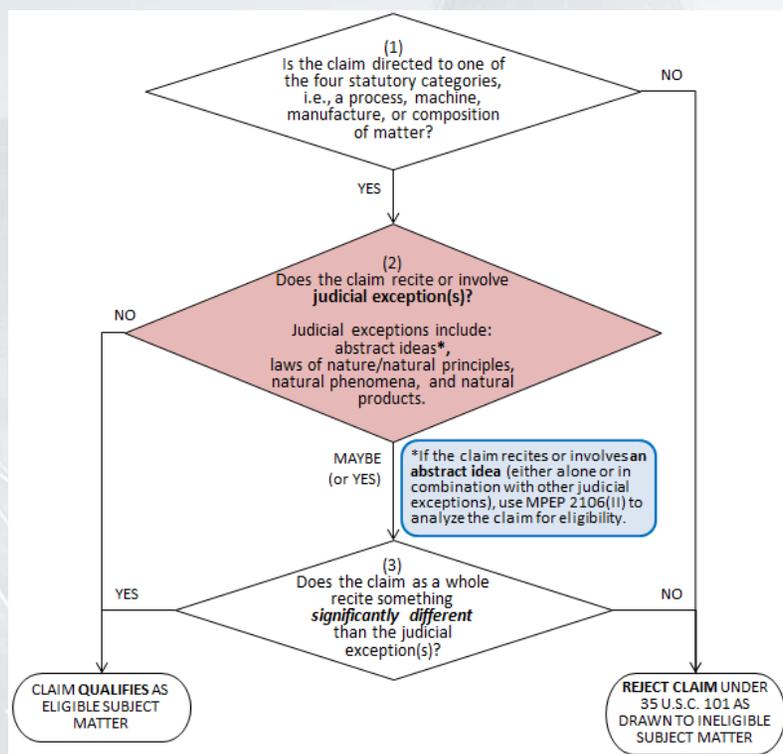
- “Abstract ideas” include mental processes, mental steps, disembodied mathematical formulas, etc.
- Example of a claim to an abstract mental process:

A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence, wherein a difference between the suspected mutant and the wild-type sequences identifies a mutant BRCA2 nucleotide sequence.

  - This claim was held ineligible by the Federal Circuit in *AMP v. Myriad*. See Example H in the Guidance.



# Claims to Abstract Ideas Must Be Analyzed Under MPEP 2106(II)



- If the claim recites an abstract idea it should be analyzed for subject matter eligibility using **only** the existing guidance in MPEP 2106(II).
  - MPEP 2106(II) controls **even if** claim recites both an abstract idea and another judicial exception (e.g., a natural product).
- Examiner should proceed to examine under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc.



# Laws of Nature/Natural Principles and Natural Phenomena

- “Laws of Nature” and “Natural Phenomena” include natural principles, naturally occurring relations or correlations, etc.
- Examples:
  - The law of gravity
  - The disinfectant qualities of ultraviolet light
  - The relationship between blood glucose levels and diabetes



# When Does A Claim Recite or Involve A Law of Nature?

## Claims That Do Recite or Involve Laws of Nature

- Diagnosing a condition based on a naturally occurring correlation of levels of a substance produced in the body when a condition is present.
- Identifying a disease using a naturally occurring relationship between the presence of a substance in the body and incidence of disease.

## Claims That Do Not Recite or Involve Laws of Nature

- Treating a patient by performing a medical procedure.
- A new way of using an existing drug.

Note that these claims are not necessarily eligible, because they may recite or involve a *different* judicial exception (e.g., a natural product).



# Claim Involving A Law of Nature (1)

1. A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down's syndrome, the method comprising the steps of:

measuring the level of at least one screening marker from a first trimester of pregnancy by: (i) assaying a sample ... for at least one first biochemical screening marker; and/or (ii) measuring at least one first ultrasound screening marker ...;

measuring the level of at least one second screening marker from a second trimester of pregnancy ... by: (i) assaying a sample ... for at least one second biochemical screening marker; and/or (ii) measuring at least one second ultrasound screening marker ...; and

determining the risk of Down's syndrome by comparing the measured levels of both the at least one first screening marker from the first trimester of pregnancy and the at least one second screening marker from the second trimester of pregnancy with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies.

**Judicial  
Exception**  
(Law of Nature)

The relationship  
between screening  
marker levels and  
the risk of fetal  
Down's syndrome.

**This claim needs  
analysis under  
Question 3.**



## Claim Involving A Law of Nature (2)

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

**Judicial  
Exception**  
(Law of Nature)

Relationship between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.

**This claim needs  
analysis under  
Question 3.**



## Claim Involving A Law of Nature (3)

3. A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:

providing a light source that emits white light;

filtering the ultra-violet (UV) rays from the white light; and

positioning the patient adjacent to the light source at a distance between 30-60 cm for a predetermined period ranging from 30-60 minutes to expose photosensitive regions of the patient's brain to the filtered white light,

wherein the exposure to the filtered white light alters the neuronal activity in the patient's brain and mitigates the mood disorder.

**Judicial  
Exception**  
(Law of Nature)

The effect of white light on human neuronal activity related to mood.

**This claim needs analysis under Question 3.**



# Natural Products

- “Natural Products” that are excluded from eligibility include:
  - naturally occurring products; and
  - non-naturally occurring products that are not markedly different from naturally occurring products.
- Examples:
  - Grapefruit plucked from a wild tree = naturally occurring
  - Grapefruit cut and sectioned = non-naturally occurring
  - Pasteurized grapefruit juice = non-naturally occurring

***Claims reciting any of these products  
must proceed to Question 3***



## Why Go To Question 3 When “Hand of Man” Is Apparent?

- Eligibility requires more than the “hand of man”.
  - To be eligible, claimed product must be both non-naturally occurring and markedly different from naturally occurring products.
- Do not make conclusory judgments based on the mere recitation of particular words in the claim.
  - E.g., words such as “cDNA”, “composition”, “isolated”, “primer”, “purified”, “recombinant”, “synthetic”, and “vector”.
  - These words may reflect “hand of man” but are not necessarily determinative of eligibility.



# Supreme Court & Natural Products

- Why are we talking about natural products that are not nucleic acids?
- Supreme Court has made it clear that “natural products” include a wide variety of things:
  - *Funk Brothers* – “patents cannot issue for the discovery of phenomena of nature” such as bacterial properties, the heat of the sun, electricity, or the properties of metals
  - *Chakrabarty* – “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity.”
  - *Myriad* – there is a “rule against patents on naturally occurring things”

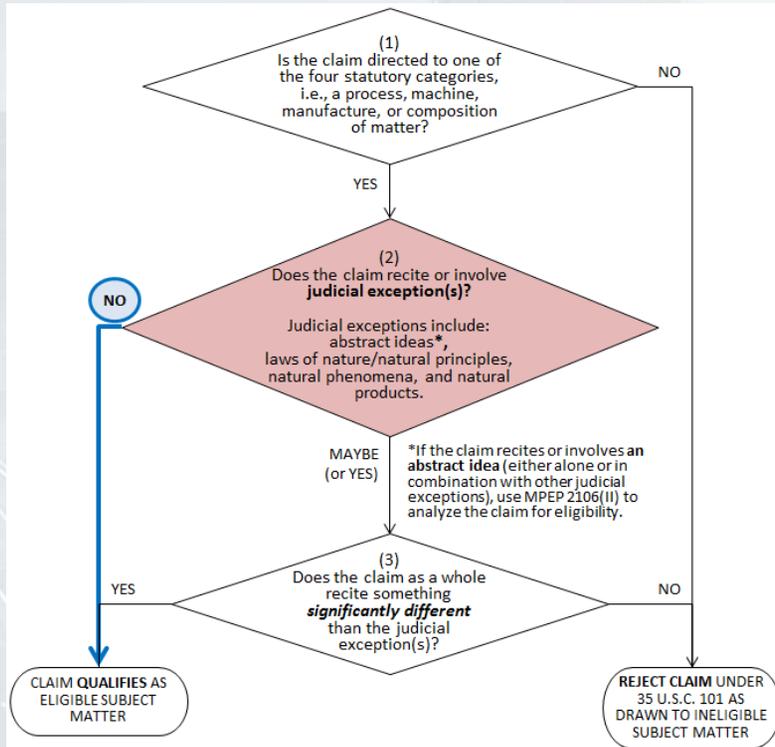


# Myriad & Natural Products

- *Myriad* relies on earlier precedent:
  - *Myriad* relies on *Chakrabarty* and serves as a reminder that *Chakrabarty*'s markedly different criterion is the eligibility test across all technologies for product claims reciting natural products.
  - *Myriad* explains that *Funk Brothers*' combination of bacteria was not eligible because the patentee "did not alter the bacteria in any way".
- *Myriad* provides guideposts for determining when an "isolated" nucleic acid is markedly different.



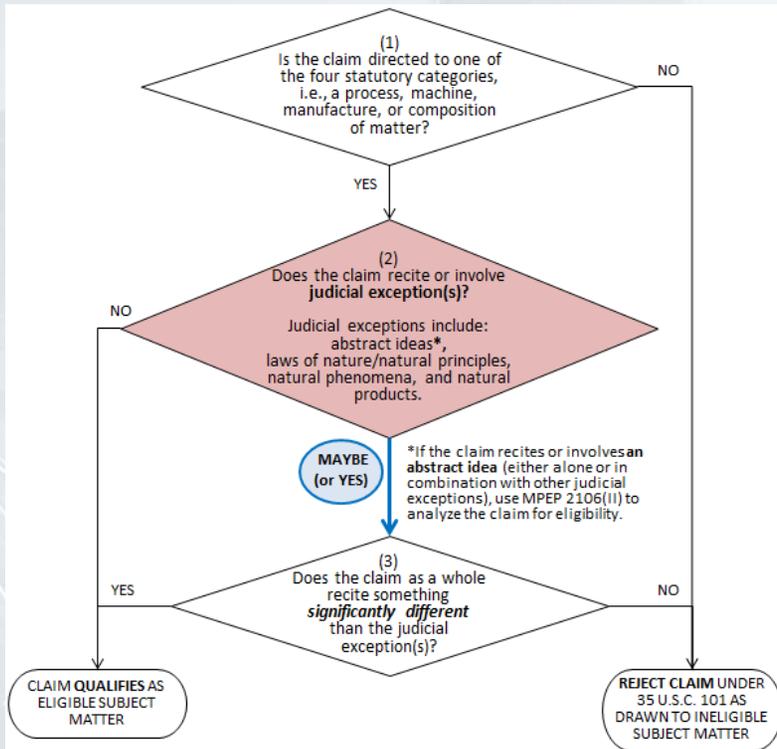
# Answer Question Two: If “No” → Claim Qualifies As Eligible



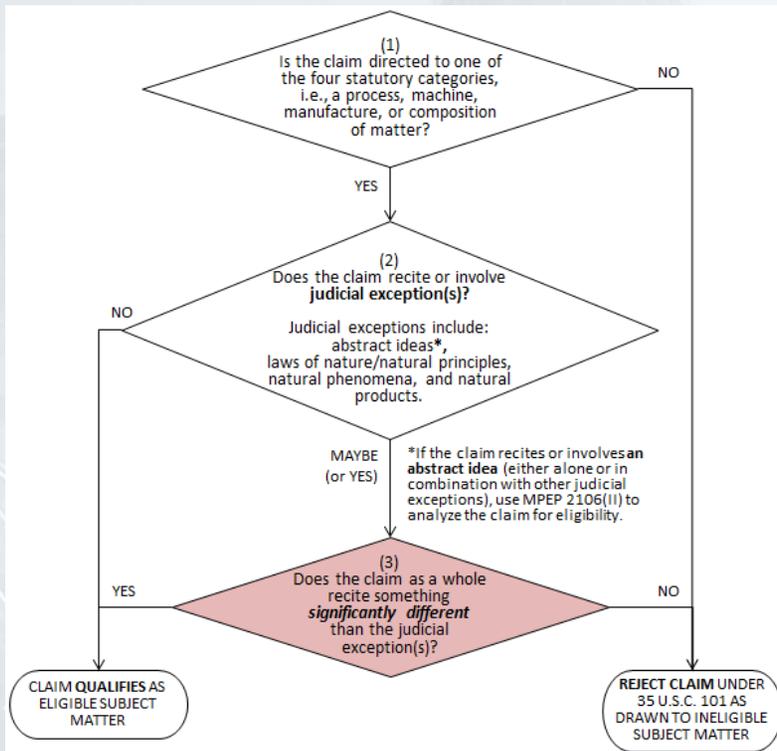
- If a claim does not recite or involve a judicial exception, it **qualifies as eligible subject matter**.
  - Eligibility analysis is complete.
- Proceed to examine under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc.



# Answer Question Two: If “Maybe”/“Yes” → Go to Question 3



If the claim recites or involves (or may recite or involve) one or more laws of nature/natural principles, natural phenomena, and/or natural products, **proceed to Question 3.**



Question Three:  
Does The Claim As A Whole Recite Something Significantly Different Than The Judicial Exception(s)?



## “Significantly Different”

- Focus is on whether the claim *as a whole* recites something **significantly different** than a judicial exception (e.g., natural product or law of nature).
- “Significantly Different” addresses two pathways to eligibility:
  1. Product claim involving or reciting a natural product includes features or steps demonstrating a **marked difference** from what exists in nature; or
  2. Claim involving or reciting a judicial exception must also recite meaningful limitations that **add something of significance** to the judicial exception



## Evaluate “Significantly Different” By Weighing Factors

- New guidance follows the common theme from previous guidance of evaluating factors that weigh for, or against, eligibility
  - There are no bright line rules
  - The factors have been culled from precedent
  - The tests are designed to be flexible to accommodate judicial developments and technological advancements
- Examiners are accustomed to weighing evidence (*e.g.*, *Wands* factors for enablement)



# Summary of Factors

## Factors that weigh toward eligibility (significantly different)

- a) Product claim recites something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products.

Claim recites elements/steps in addition to the judicial exception(s) that:

- b) Impose meaningful limits on the claim scope.
- c) Relate to the judicial exception(s) in a significant way, e.g., they are more than insignificant extra-solution activity.
- d) Do more than describe the judicial exception(s) with general instructions to apply/use it.
- e) Include a particular machine or particular transformation, which implements or integrates the judicial exception(s).
- f) Add a feature that is more than well-understood, purely conventional or routine.

## Factors that weigh against eligibility (not significantly different)

- g) Product claim recites something that appears to be a natural product that is not markedly different in structure from naturally occurring products.

Claim recites elements/steps in addition to the judicial exception(s) that:

- h) Are recited at a high level of generality.
- i) Must be used/taken by others to apply the judicial exception(s).
- j) Are well-understood, purely conventional or routine.
- k) Are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).
- l) Amount to nothing more than a mere field of use.



# Factors Fall Into Two Groups

- Group One: Two factors applicable only to product claims
  - Factors a) and g)
  - Concern the structure of natural products and things that appear to be natural products
  - Represent *Chakrabarty*'s “markedly different” pathway to eligibility
- Group Two: Ten factors applicable to all claims
  - Factors b)-f) and h)-l)
  - Concern whether the claim recites elements or steps in addition to the judicial exception(s), and whether those elements/steps add significantly more to the judicial exception(s)
  - Represent *Mayo*'s “significantly more” pathway to eligibility



# Group One: Factors Applicable To Product Claims

## Weighs Toward Eligibility (Significantly Different)

a) Product claim recites something that initially appears to be a natural product, but after analysis is determined to be **non-naturally occurring and markedly different** in structure from naturally occurring products.

## Weighs Against Eligibility (Not Significantly Different)

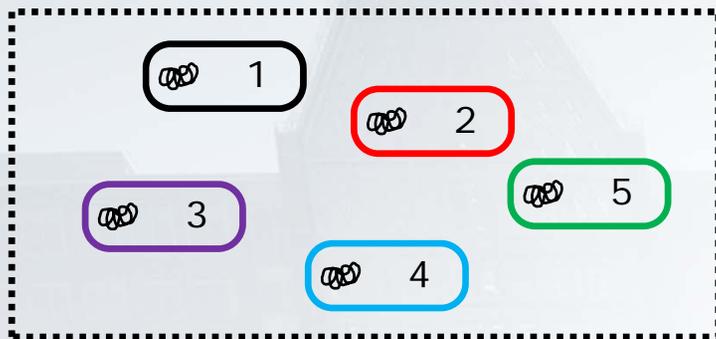
g) Product claim recites something that appears to be a natural product that is **not markedly different** in structure from naturally occurring products.

Note that if the something recited in the claim satisfies factor a), it is not a natural product. In other words, it is not a judicial exception.

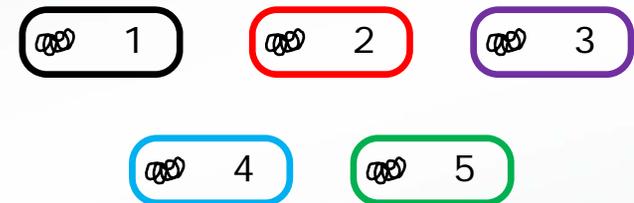


# Example: No Marked Difference Factor g) is Satisfied

Claimed Inoculant



Naturally occurring *Rhizobium* bacteria



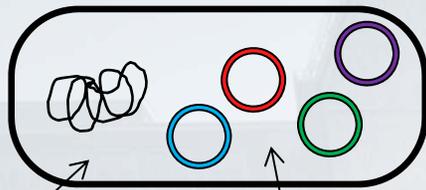
**Claimed inoculant is not markedly different**

- 1. Fails to satisfy non-naturally occurring requirement,** because bacteria all exist in nature.
- 2. No structural difference** because the mere aggregation of naturally occurring bacteria together as an “inoculant” does not change the structure of the bacteria.



# Example: Marked Difference Factor a) is Satisfied

Genetically modified claimed *Pseudomonas* bacterium

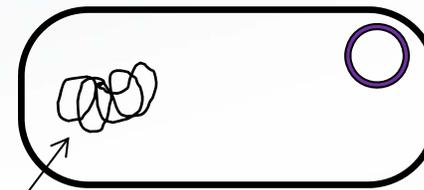


Can degrade four hydrocarbons

Bacterial chromosome

Added plasmids

Naturally occurring *Pseudomonas* bacterium



Can only degrade one hydrocarbon

Bacterial chromosome

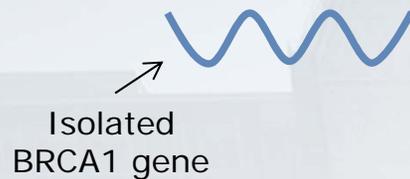
**Claimed bacterium is markedly different**

- 1. Non-naturally occurring** because bacterium with multiple plasmids does not occur in nature, but instead was created by human manipulation.
- 2. Markedly different in structure**
  - structural difference (includes multiple plasmids that are not found in naturally occurring *Pseudomonas* bacteria);
  - structural difference results in change to properties of bacterium (able to degrade multiple hydrocarbons as compared to naturally occurring *Pseudomonas* bacteria that can only degrade a single hydrocarbon).

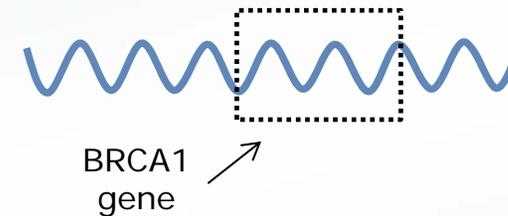


# Example: No Marked Difference Factor g) is Satisfied

Claimed  
Isolated DNA



Naturally occurring  
genomic DNA



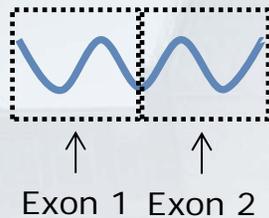
**Claimed DNA  
is not  
markedly  
different**

- 1. Non-naturally occurring** because the isolated DNA is a “stand alone” molecule, whereas in nature the gene is part of a very long strand of DNA (a chromosome).
- 2. No marked difference in structure.** Isolated DNA is structurally different from chromosomal DNA, (e.g., chemical bonds on either end of gene have been “broken”) but this difference does not rise to the level of a marked difference for this claim, because there is no change to the genetic information.

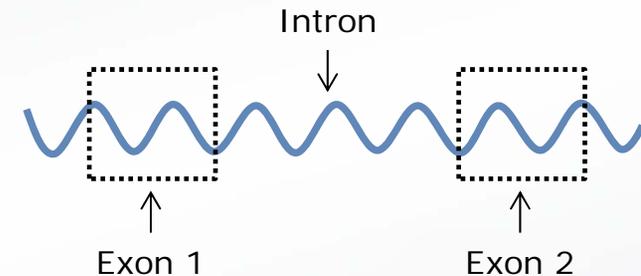


# Example: Marked Difference Factor a) is Satisfied

Claimed cDNA



Naturally occurring BRCA1 gene



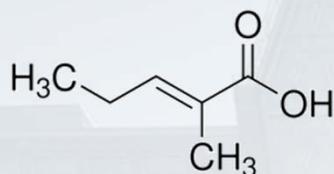
**Claimed DNA is markedly different**

- 1. Non-naturally occurring** because the exons-only cDNA molecule does not exist in nature. In nature, the gene includes both exons and introns.
- 2. Markedly different in structure.** The cDNA has an altered structure (the nucleotide sequence) that is distinct from the naturally occurring chromosomal DNA due to the removal of the intron. This altered structure rises to the level of a marked difference.



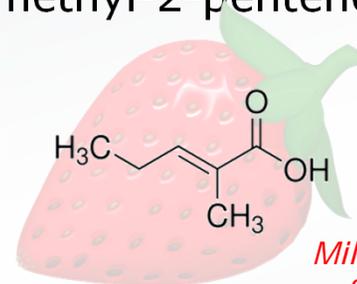
# Example: No Marked Difference Factor g) is Satisfied

Claimed purified  
2-methyl-2-pentenoic acid



*Mild fresh strawberry  
flavor and aroma*

Naturally occurring  
2-methyl-2-pentenoic acid



*Mild fresh strawberry  
flavor and aroma*

**Claimed acid  
is not  
markedly  
different**

- 1. Fails to satisfy non-naturally occurring requirement,** because the acid occurs naturally in strawberries.
- 2. No structural difference** because removal or “purification” of the acid from strawberries did not change its structure.



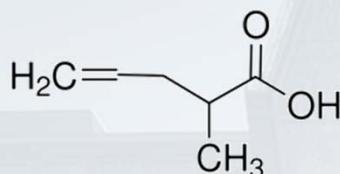
# Discussion of Purification

- In nature the acid is part of a strawberry, and as claimed it is separated from the other components of the strawberry. So why isn't the purified acid eligible?
  - Cannot base eligibility determination on the mere recitation of the word “purified” in the claim.
  - To be eligible, the product as claimed must reflect a marked difference from what exists in nature. This is a case-by-case determination.
  - In this case, although the purified acid is separated from the other components of the strawberry, the acid itself is unchanged. In other cases, the specific purification process may lead to changes that amount to a marked difference.



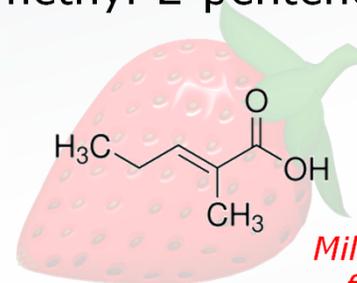
# Example: Marked Difference Factor a) is Satisfied

Claimed  
2-methyl-4-pentenoic acid



*"Cooked" strawberry jam-like  
flavor and aroma*

Naturally occurring  
2-methyl-2-pentenoic acid



*Mild fresh strawberry  
flavor and aroma*

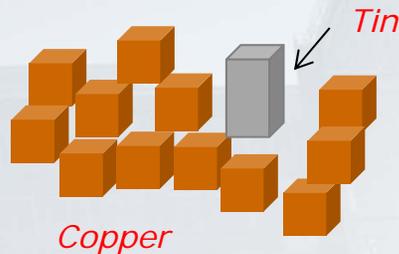
**Claimed acid  
is markedly  
different**

- 1. Non-naturally occurring** because acid does not occur in nature, but instead was created by human manipulation.
- 2. Markedly different in structure.** The claimed acid is structurally different (the double bond of the claimed acid is at the 4<sup>th</sup> carbon as compared to the naturally occurring double bond at the 2<sup>nd</sup> carbon). It is reasonable to conclude that this structural difference is a marked difference, because the structural change results in a change to the properties of the acid (flavor and aroma are "cooked" strawberry jam-like as compared to naturally occurring "fresh" strawberry flavor & aroma).

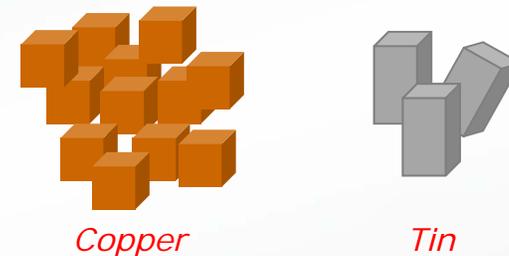


# Example: No Marked Difference Factor g) is Satisfied

Claimed  
"composition comprising  
90% copper and 10% tin"



Naturally occurring  
copper and tin



Claimed  
composition  
is not  
markedly  
different

1. **Fails to satisfy non-naturally occurring requirement**, because copper and tin exist in nature.
2. **No structural difference** because the mere mixture or aggregation of naturally occurring metals together as a "composition" does not change the metals from what exists in nature.



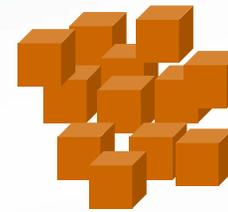
# Example: Marked Difference Factor a) is Satisfied

Claimed  
"alloy comprising  
90% copper and 10% tin"

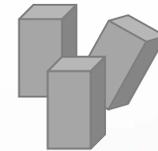


*Alloy (bronze)*

Naturally occurring  
copper and tin



*Copper*



*Tin*

**Claimed alloy  
is markedly  
different**

**1. Non-naturally occurring** because the alloy of copper and tin does not occur in nature, but instead was created by human manipulation. This particular alloy is a type of bronze.

**2. Markedly different in structure**

- structural difference (the alloy is a solid solution of tin in copper, which has a different crystalline arrangement of atoms than in the natural metals);
- structural difference results in change to properties of alloy (the alloy has a different color, tensile strength, hardness, and melting point than either natural metal).



# Focus Remains On Product, Not How It Was Made

- “Markedly Different” inquiry focuses on the structural characteristics of the product, not how it was made:
  - Don’t have to use new techniques.
  - Don’t have to use laboratory or engineering techniques.
  - Extent of effort required to make product is not relevant.
- Examples:
  - A cDNA with an altered sequence can be eligible, even though creating cDNA is routine in the biotechnology art.
  - A hybrid plant can be eligible, even if it was created via manipulation of natural pollination and fertilization processes.



# Examiner Must Provide Supporting Rationale or Evidence

- Initial burden is on the examiner to establish a *prima facie* case of ineligibility.
- When rejecting claim, examiner must provide rationale or evidence to reasonably support a determination that a product is not markedly different from what exists in nature.
  - Evidence is not limited by filing date of application.
  - Speculation about hypothetical products is not reasonable support.
- Example:
  - A theoretical possibility that nature *might* have randomly created a hybrid plant similar to the claimed hybrid plant is not enough to negate eligibility.



## Group Two: Factors Applicable to All Claims

- Remaining factors require claim to recite elements or steps that:
  - are in addition to the judicial exception(s); and
  - that add significantly more to the judicial exception(s).
- Adding “significantly more” can occur in multiple ways (that’s why there are 10 different factors).
- Same factors as in *Bilski* and *Mayo* guidance, but applied differently.



# Factors That Weigh Toward Eligibility (Significantly Different)

Claim recites elements/steps in addition to the judicial exception(s) that:

- b) Impose meaningful limits on the claim scope.
- c) Relate to the judicial exception(s) in a significant way, e.g., they are more than insignificant extra-solution activity.
- d) Do more than describe the judicial exception(s) with general instructions to apply/use it.
- e) Include a particular machine or particular transformation, which implements or integrates the judicial exception(s).
- f) Add a feature that is more than well-understood, purely conventional or routine.

Weigh toward eligibility  
(significantly different)





# Factors That Weigh Against Eligibility (Not Significantly Different)

Claim recites elements/steps in addition to the judicial exception(s) that:

- h) Are recited at a high level of generality.
- i) Must be used/taken by others to apply the judicial exception(s).
- j) Are well-understood, purely conventional or routine.
- k) Are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).
- l) Amount to nothing more than a mere field of use.



Weigh against eligibility  
(not significantly different)



# Must Balance Totality of Factors

- The examiner's analysis should carefully consider every relevant factor and related evidence before making a conclusion.
  - No one factor is controlling.
  - The determination of eligibility is not a single, simple determination, but is a conclusion reached by weighing the relevant factors, keeping in mind that the weight accorded each factor will vary based upon the facts of the application.
- Must balance the totality of the relevant factors.
  - If the totality of the relevant factors weigh toward eligibility, the claim qualifies as eligible subject matter.
  - If the totality of the relevant factors weighs against eligibility, the claim should be rejected.



## Claims That Do Not Recite An Element or Step In Addition To A Judicial Exception

- Sometimes a product claim does not contain any elements or steps in addition to a natural product or a thing that appears to be a natural product.
- Eligibility of this type of claim will turn on factors a and g.
- Examples:
  1. Purified amazonic acid.

This claim is ineligible. Factor g is satisfied because there is no structural difference between the claimed acid and naturally occurring amazonic acid. See Example B in the Guidance.
  2. A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

This claim is eligible. Factor a is satisfied because there is a structural difference between the claimed bacterium and naturally occurring bacteria, and the structural difference is marked. See Example A in the Guidance.



## Claims That Do Not Recite An Element or Step In Addition To A Judicial Exception

- What about claims that recite multiple natural products, or multiple things that appear to be natural products?
- Eligibility of this type of claim will turn on factors a and g.
- Example:

A pair of primers, the first primer having the sequence of SEQ ID NO: 1 and the second primer having the sequence of SEQ ID NO: 2.

  - This claim is ineligible. Factor g is satisfied because there is no marked structural difference between the claimed primers and naturally occurring nucleic acids. See Example E in the guidance.
  - Note that if a recited product (e.g., the first primer) is determined to be markedly different, it is not a judicial exception. Instead, it is an element in addition to the judicial exception (e.g., the second primer), and factors b-f and h-l come into play.



## Claims That Do Recite Elements/Steps In Addition To A Judicial Exception

- Many product claims contain elements/steps in addition to the natural product or thing that appears to be a natural product.
- Eligibility of this type of claim will turn on factors a through I.
- Example:

A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) gunpowder, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder...

  - This claim is eligible. Although the calcium chloride and gunpowder are not markedly different from what occurs in nature, the claim recites meaningful limitations (the cardboard body) that narrow the scope of the claim, relate to the natural products in a significant way, and do more than describe the natural products with general instructions to use or apply them. See Example C in the Guidance.



## A Note About Claim Interpretation

- The analysis in Example C is based on a broadest reasonable interpretation of the term “gunpowder” that includes multiple types of gunpowder, e.g.:
  - Type I: A mixture of three naturally occurring materials: potassium nitrate, sulfur and charcoal. Such a mixture is not markedly different because none of the components have been changed.
  - Type II: A glazed powder formed from four naturally occurring materials: sodium nitrate, sulfur and charcoal are mixed and then granulated, and then the granulated particles are coated with a thin layer of graphite.
    - This glazed powder is structurally different from what exists in nature, because the materials have been combined in a particular way to yield a manufacture that is entirely different from a mere mixture of the raw materials from which it was formed. In addition, the structural difference results in a change to the properties of the powder (it can no longer deliquesce due to the graphite coating). This powder is markedly different from what exists in nature.



## Claims That Do Recite Elements/Steps In Addition To A Judicial Exception

- Many process claims contain elements/steps in addition to the judicial exception(s). Eligibility of this type of claim will turn on factors b through f and h through l.
- Example:

A method for treating a mood disorder in a human patient, the mood disorder associated with neuronal activity in the patient's brain, comprising:

  - a) providing a light source that emits white light;
  - b) filtering the ultra-violet (UV) rays from the white light;
  - c) positioning the patient adjacent to the light source at a distance between 30-60 cm for a predetermined period ranging from 30-60 minutes to expose the patient to the filtered white light, wherein the exposure to the filtered white light alters the neuronal activity in the patient's brain and mitigates the mood disorder.
  - This claim is eligible. The claim recites meaningful limitations (the filtering and positioning steps) that narrow the scope of the claim, relate to the law of nature in a significant way, are more than well-understood, routine and conventional, and do more than describe the law of nature with general instructions to use or apply it. See Example G in the Guidance.



## Process Claims Reciting A Natural Product: Judicial Exception or Element in Addition?

- Many process claims recite a natural product or a thing that appears to be a natural product. As a precursor to the factorial analysis, the examiner must determine whether the recited product is markedly different or not.
- Why make this determination?
  1. If the recited product is not markedly different, it is a judicial exception. Eligibility of the claim will turn on factors b through f and h through i.
  2. If the recited product is markedly different, it is not a judicial exception. Instead, it is an element in addition to any other judicial exception(s) in the claim.
    - a) If there are no other judicial exception(s) in the claim, the claim is eligible.
    - b) If there are other judicial exception(s) in the claim, eligibility of the claim will turn on factors b through f and h through i.



# Process Claims Reciting A Natural Product: No Other Judicial Exceptions

## Recited Product Is Not Markedly Different (Claim Recites A Judicial Exception)

A method of treating colon cancer, comprising:  
administering a daily dose of purified **amazonic acid** to a patient suffering from colon cancer for a period of time from 10 days to 20 days,  
wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.

- Purified amazonic acid is not markedly different from what exists in nature. See Example B in the Guidance.
- Because it is not markedly different, amazonic acid is a judicial exception.
- When the claim is analyzed using the Group Two factors (b through f and h through l), the analysis indicates that the claim is eligible. See Example B in the guidance.



# Process Claims Reciting A Natural Product: No Other Judicial Exceptions

## Recited Product Is Markedly Different (Claim Does Not Recite A Judicial Exception)

A method of treating colon cancer, comprising:  
administering a daily dose of **5-methyl amazonic acid** to a patient suffering from colon cancer for a period of time from 10 days to 20 days,  
wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of 5-methyl amazonic acid.

- 5-methyl amazonic acid is markedly different structurally than what exists in nature. See Example B in the Guidance.
- Because it is markedly different, 5-methyl amazonic acid is not a judicial exception.
- Because there are no judicial exceptions in the claim, there is no need for the factorial analysis. The claim is eligible.



# Process Claims Reciting A Natural Product: Multiple Judicial Exceptions

A method for determining whether a human patient has degenerative disease X, comprising:

obtaining a **blood sample** from a human patient;

determining whether misfolded **protein ABC** is present in the blood sample, wherein said determining is performed by contacting the blood sample with **antibody XYZ** [and] using flow cytometry...; and

diagnosing the patient as having degenerative disease X if misfolded protein ABC was determined to be present in the blood sample.

- First, need to figure out what is a judicial exception, and what is an element/step in addition to a judicial exception.
  - **Blood** and **protein ABC** are not markedly different from what exists in nature. They are judicial exceptions (natural products).
  - The specification demonstrates that **antibody XYZ** does not exist in nature, was newly created by the inventors, and is markedly different from what exists in nature. It is *not a judicial exception*; it is an element in addition to the judicial exceptions.
  - A law of nature (natural principle) - the **correlation** between the presence of misfolded protein ABC in blood and degenerative disease X.



## Process Claims Reciting A Natural Product: Multiple Judicial Exceptions

A method for determining whether a human patient has degenerative disease X, comprising:

obtaining a **blood sample** from a human patient;

determining whether misfolded **protein ABC** is present in the blood sample, wherein said determining is performed by contacting the blood sample with **antibody XYZ** [and] using flow cytometry ...; and

diagnosing the patient as having degenerative disease X if misfolded protein ABC was determined to be present in the blood sample.

- Second, need to analyze using factors b through f and h through l, to determine if the claim as a whole recites something significantly different than the natural products and the law of nature.
  - The claim recites meaningful limitations (e.g., the obtaining and determining using antibody XYZ steps) that narrow the scope of the claim, relate to the law of nature/natural products in a significant way, are more than well-understood, routine and conventional, and do more than describe the judicial exceptions with general instructions to use or apply them.
  - Result: Claim is eligible. See Example F in the Guidance.



## A Note About “Machine or Transformation”

- Factor e) concerns the “machine or transformation” factors, and requires:
  - A particular machine or transformation of a particular article; and
  - The particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application.
- MPEP 2106(II)(B)(1) provides a detailed explanation of the machine or transformation factors. A few salient points:
  - The machine or transformation must be particular (as opposed to general).
  - The machine or transformation must be more than extrasolution activity or a field of use.
  - The result of the transformation cannot be a judicial exception itself.

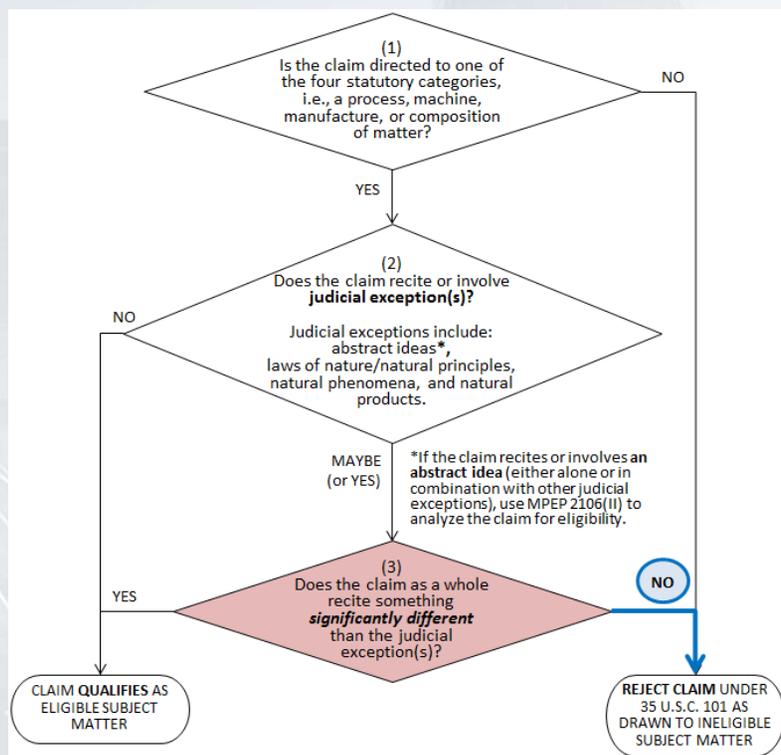


## Why Doesn't Example F Satisfy The "Machine or Transformation" Test?

- Example F in the Guidance requires "contacting the blood sample with antibody XYZ [and] using flow cytometry".
- Does Not Satisfy Machine Prong of Factor e)
  - The claim inherently recites a machine/apparatus, e.g. a machine to perform flow cytometry. However, based on the limited facts of the example, the machine is not particular/specific. For example, the claim does not specify the type of machine (e.g., bench top or high speed), or the number and type of lasers used.
- Does Not Satisfy Transformation Prong of Factor e)
  - Binding of antibody XYZ to misfolded protein ABC results in a temporary and reversible change to the protein. This is not a fundamental change in the nature of the protein itself, and so it fails to qualify as a "transformation" in the legal sense of the word.
- You may reach a different conclusion for a similar claim, based on the facts of the application, and the BRI of the claim in question.



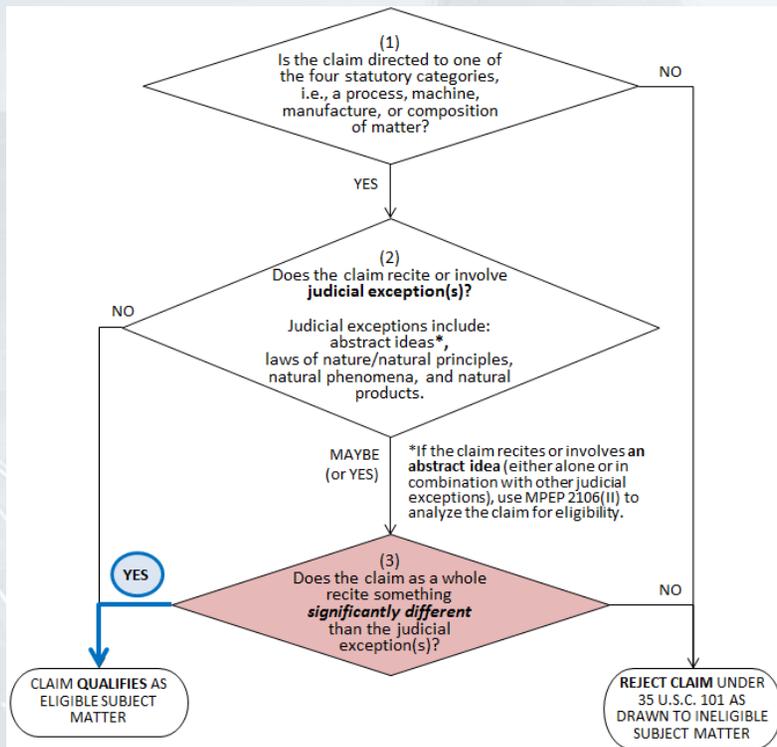
# Answer Question Three: If “No” → Reject Claim



- If a claim as a whole does not recite something significantly different than the judicial exception(s), **reject claim under 35 U.S.C. § 101.**
  - Use Form ¶¶ 7.04.01, 7.05, 7.05.013 [Revised].
- Examiner should proceed to examine under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc.



# Answer Question Three: If “Yes” → Claim Qualifies As Eligible



- If a claim as a whole recites something significantly different than the judicial exception(s), it **qualifies as eligible subject matter**.
  - Eligibility analysis is complete.
- Proceed to examine under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc.



# Examples



# Analysis of Claim 1

1. A beverage composition comprising:
  - a) pomelo juice; and
  - b) a preservative.



- **Question 1:** Answer is yes, because the claim is directed to a statutory category (composition of matter).
- **Question 2:** Answer is yes, because the claim recites a natural product (pomelo is a naturally occurring fruit).
- **Question 3:** Need to analyze the claim using factors a – I to determine if it qualifies as eligible (significantly different than the natural product itself).



# Note About Claim Interpretation

- The examiner gives the claim its broadest reasonable interpretation (BRI) in light of the specification.
- Based on the plain and ordinary meaning of “preservative” in the art in light of the specification, the BRI encompasses the use of both:
  - Naturally occurring preservatives such as vitamin E (a naturally occurring chemical) and
  - Non-naturally occurring and markedly different preservatives such as preservative X (a known preservative that is non-naturally occurring and markedly different from naturally occurring chemicals).
- The BRI of the claim thus encompasses at least two embodiments:
  1. pomelo juice and vitamin E; and
  2. pomelo juice and preservative X.
- **If any of these embodiments is ineligible, then the claim is ineligible.**



# Analysis of Claim 1

- Begin analysis with first embodiment (pomelo juice + vitamin E). Factors a & g are applicable, because the claim is a product claim.
- **Factor a is not satisfied.**
  - The pomelo juice and vitamin E are naturally occurring.
  - The BRI of the “composition” of juice and vitamin E encompasses embodiments in which neither component is changed, e.g., the two components do not chemically react with each other or otherwise combine together in a particular way that creates a structural difference from what exists in nature.
  - Thus, the claimed mixture is not markedly different from what exists in nature.
- **Factor g is satisfied.** See analysis for factor a.



# Claim 1 Is Not Eligible

- Remaining factors (b-f and h-l) are not applicable, because the claim does not include any elements in addition to the natural products (pomelo juice and vitamin E).
- First embodiment (pomelo juice + vitamin E) is not eligible.
  - Weigh the totality of the relevant factors:
    - Toward eligibility: factor a is not satisfied.
    - Against eligibility: **factor g is satisfied.**
  - Balance of factors weighs against eligibility.



# Result: Examiner Rejects

- Because the first embodiment is not eligible, the claim **does not qualify as eligible subject matter**.
  - Examiner rejects claim under 35 U.S.C. § 101, using Form ¶¶ 7.04.01, 7.05, 7.05.013 [Revised].
  - Examiner provides explanation that is sufficient to establish a *prima facie* case of ineligibility under 35 U.S.C. § 101.
- Examiner proceeds to examine under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc.



# Applicant Response

- Applicant presents arguments with respect to claim 1.
  - Claimed composition is non-natural combination of pomelo juice and vitamin E. In other words, the claim shows the “hand of man” because it is a combination of two things that do not occur together in nature. In support, applicant cites non-patent literature published after the filing date of the application, which explains that pomelo juice in nature does not contain vitamin E.
  - Claim scope also encompasses a second embodiment (pomelo juice and preservative X). This embodiment is eligible, so claim 1 should be eligible.
- Applicant adds new claims.
  2. A beverage composition comprising pasteurized pomelo juice.
  3. A beverage composition comprising:
    - pomelo juice; and
    - preservative X.



# Examiner Considers Response from Applicant

- Applicant's arguments and evidence with respect to claim 1 are not persuasive. Examiner should maintain rejection of claim 1.

Applicant Argument	Examiner Response
Claim should be eligible because pomelo juice and vitamin E do not occur together in nature.	Not persuasive. A marked difference requires a product to be both (1) non-naturally occurring <u>and</u> (2) markedly different in structure. Adding vitamin E to pomelo juice does not change the structure of either product at all, let alone to be markedly different.
Claim includes an eligible embodiment, so claim should be eligible.	Not persuasive. To be eligible, every embodiment within the BRI must be eligible.



# What If Applicant Amended The Claim To Recite Specific Amounts?

- What if applicant amended claim 1 to recite a particular amount of vitamin E in the beverage composition?
  - E.g., a beverage composition comprising 99.5% pomelo juice and 0.5% vitamin E.
  - Such an amendment would narrow the BRI, e.g., the claim would be limited to a particular amount of vitamin E.
  - However, the vitamin E (and the pomelo juice) would still be structurally identical to what exists in nature. As a result, the claim would still be ineligible.
- Why is the claim still ineligible?
  - In the *Funk Brothers* case, the Supreme Court analyzed a claim to a mixture of bacteria in any amount (claim 4), and a claim to a mixture of bacteria in a specific ratio (claim 6). Both claims were held ineligible, because the bacteria themselves were not structurally altered by being mixed together.



## Analysis of Claim 2

2. A beverage composition comprising pasteurized pomelo juice.



- **Question 1:** Answer is yes, because the claim is directed to a statutory category (composition of matter).
- **Question 2:** Answer is yes (or maybe), because the claim recites a natural product (pomelo is a naturally occurring fruit).
- **Question 3:** Need to analyze the claim using factors a – l to determine if it qualifies as eligible (significantly different than the natural product itself).



# Note About Claim Interpretation

- The examiner gives the claim its broadest reasonable interpretation (BRI) in light of the specification.
- Here, the specification defines “pasteurization” as a process of heating the juice to a temperature of at least 100 degrees Celsius for a time period of at least 20 minutes. This type of pasteurization results in structural changes to the juice.
  - The specification’s definition excludes pasteurization methods such as UHT pasteurization from the BRI.
- The BRI of claim 2 is thus limited to pomelo juice that has been pasteurized by heating the juice to a temperature of at least 100 degrees for a time period of at least 20 minutes.



## Analysis of Claim 2

- Factors a & g are applicable, because the claim is a product claim.
- **Factor a is satisfied:**
  - Naturally occurring pomelo juice contains vitamin C and flavonoids (a type of chemical that contributes to the flavor of the juice).
  - The specification describes the pasteurization process as damaging the chemical structure of the vitamin C and flavonoids in the juice. As a result, the pasteurized juice contains about 20-30% less vitamin C and about 30% fewer flavonoids than naturally occurring juice. The pasteurized juice thus has a different taste, and lower nutritional value than the naturally occurring juice.
  - Therefore, the pasteurized pomelo juice is markedly different in structure from what exists in nature.
- **Factor g is not satisfied**, because the pasteurized juice is markedly different than what exists in nature. See analysis for factor a.



# Result: Claim 2 is Eligible

- Remaining factors (b-f and h-l) are not applicable, because the claim does not include any elements in addition to the pasteurized pomelo juice.
- Weigh the totality of the relevant factors:
  - Toward eligibility: factor a is satisfied.
  - Against eligibility: No factors are satisfied.
- Balance of factors weighs toward eligibility. **Claim 2 qualifies as eligible subject matter.**
- Examiner should proceed to examine under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc.



# Analysis of Claim 3

3. A beverage composition comprising:  
a) pomelo juice; and  
b) preservative X.



- **Question 1:** Answer is yes, because the claim is directed to a statutory category (composition of matter).
- **Question 2:** Answer is yes, because the claim recites a natural product (pomelo is a naturally occurring fruit).
- **Question 3:** Need to analyze the claim using factors a – I to determine if it qualifies as eligible (significantly different than the natural product itself).



## Analysis of Claim 3

- Factors a & g are applicable, because the claim is a product claim.
- **Factor a is satisfied in part:**
  - Not satisfied with respect to the pomelo juice.
    - Juice is naturally occurring and structurally identical to naturally occurring pomelo juice. Therefore, the pomelo juice is not markedly different.
    - The pomelo juice is a judicial exception (natural product).
  - Satisfied with respect to preservative X.
    - Preservative X is non-naturally occurring, and is structurally different from naturally occurring chemicals. It is markedly different from what occurs in nature.
    - Preservative X is not a judicial exception. Therefore, it is an “element in addition to” the judicial exception.
- **Factor g is satisfied with respect to the pomelo juice**, but is not satisfied with respect to preservative X. See analysis for factor a.



## Analysis of Claim 3

Must analyze remaining factors (b-f and h-l) to determine whether the element in addition to the judicial exception (preservative X) adds significantly more to the judicial exception (pomelo juice).

### Factors weighing in favor of eligibility:

- **Factor b is satisfied.** The presence of preservative X is in addition to the judicial exception (pomelo juice), and meaningfully limits the claim scope to a particular application of the natural product. There are many other ways in which the pomelo juice can be used/applied, e.g., a person can drink fresh-squeezed pomelo juice, a company can manufacture a pomelo beverage using a different preservative, the pomelo juice can be pasteurized, etc.



# Analysis of Claim 3

## Factors weighing in favor of eligibility (continued):

- **Factor c is satisfied.** Preservative X is more than nominally or tangentially related to the natural product, because it is part of the same composition with the pomelo juice, and it prevents the pomelo juice from spoiling (it retards the growth of bacteria that are naturally present in the juice).
- **Factor d is satisfied.** The presence of preservative X does more than describe the natural product (the pomelo juice). It is a specific instruction to use the natural product in a particular application.
- **Factor e is not satisfied.** There is no machine or transformation recited in the claim.
- **Factor f is not satisfied,** because preservative X is well-understood, purely conventional and routine in the beverage arts.



# Analysis of Claim 3

## Factors weighing against eligibility:

- **Factor h is not satisfied.** Preservative X is a particular preservative, and is not recited at a high level of generality such that the claim covers substantially all practical applications of the juice.
- **Factor i is not satisfied.** Preservative X is not required to be used in order to apply the natural product. There are many other ways in which the pomelo juice can be used/applied, e.g., a person can drink fresh-squeezed pomelo juice, a company can manufacture a pomelo beverage using a different preservative, the pomelo juice can be pasteurized, etc.
- **Factor j is satisfied,** because preservative X is well-understood, purely conventional and routine in the beverage arts.



## Analysis of Claim 3

### Factors weighing against eligibility (continued):

- **Factor k is not satisfied.** Preservative X is more than appended to the natural product, because it prevents the pomelo juice from spoiling (it retards the growth of bacteria that are naturally present in the juice).
- **Factor l is not relevant/not satisfied.** Preservative X is not a mere field of use.



# Result: Claim 3 is Eligible

- Weigh the totality of the relevant factors:
  - Toward eligibility: factors a (in part), b, c, & d are satisfied.
  - Against eligibility: factors g (in part), and j are satisfied.
- Balance of factors weighs toward eligibility. **Claim 3 qualifies as eligible subject matter.**
- Examiner should proceed to examine under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc.



# Summary of Next Office Action

- **Claim 1:** Examiner should maintain the eligibility rejection under 35 U.S.C. § 101. Any rejections under other statutory provisions should be maintained or withdrawn as appropriate.
- **Claim 2:** Qualifies as eligible subject matter. Examiner should make any appropriate rejections under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc., or indicate that claim is allowable if appropriate.
- **Claim 3:** Qualifies as eligible subject matter. Examiner should make any appropriate rejections under other statutory provisions, e.g., 35 U.S.C. §§ 101 (for utility and double patenting), 102, 103, 112, etc., or indicate that claim is allowable if appropriate.



# Additional Information



# Resources

- 35 U.S.C. § 101
- Examination instructions for subject matter eligibility:
  - Guidance For Determining Subject Matter Eligibility Of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products, issued March 4, 2014.
  - MPEP 2104, 2105, 2106 (Ed. 8, Rev. 9, 2012)
  - All Examination Guidance Materials are posted at:  
<http://www.uspto.gov/patents/law/exam/examguide.jsp>
- Additional claim examples and workshop training to follow.



# Effect of New Guidance on MPEP

- § 2105 – Superseded in part.  
This section is superseded to the extent that it suggests that mere “human intervention” necessarily results in eligible subject matter. To be eligible, “human intervention” must result in the claimed subject matter as a whole being significantly different than a judicial exception, as described in the Guidance. In other words, claimed subject matter, even if not naturally occurring, must be significantly different from natural products in order to be eligible.
- § 2106 – Updated in part.  
This section is updated to clarify that product claims reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products are evaluated for a “practical application” by determining whether the claim as a whole recites something significantly different than a judicial exception, as described in the Guidance.  
There is no change to examination of claims reciting abstract ideas.
- § 2106.01 – Superseded.  
Claims that recite or involve laws of nature/natural principles, natural phenomena, and/or natural products must be analyzed for subject matter eligibility using the Guidance.



## Form Paragraph 7.05.13 [Revised]

- Must be preceded by form paragraph 7.04.01 in first actions and final rejections.
- Where is it?
  - Will be pushed to custom form paragraphs in OACS soon.
  - Complete form paragraph and examiner notes are on the last page of the March 4th Guidance (and the following slide).



# Form Paragraph 7.05.13 [Revised]

## ¶ 7.05.13 Rejection, 35 U.S.C. 101, Non-Statutory (Law of Nature or Natural Phenomenon) [REVISED]

the claimed invention is not directed to patent eligible subject matter. Based upon an analysis with respect to the claim as a whole, claim(s) [1] do not recite something significantly different than a judicial exception. The rationale for this determination is explained below: [2]

### **Examiner Note:**

1. This form paragraph should be used when rejecting claim(s) that have a law of nature/natural principle or a natural phenomenon, e.g., a natural product, as a claim limitation.
2. In bracket 2, identify the judicial exception(s) that is/are recited or involved in the claim, and explain why the features (e.g., element(s) or step(s) in addition to the judicial exception(s)) in the claim do not result in the claim as a whole reciting something significantly different than the judicial exception itself. In particular, explain why the claim features do not add significantly more to the judicial exception and/or demonstrate that the judicial exception is in fact markedly different from what exists in nature. For instance, element(s) or step(s) in addition to the judicial exception can be shown to be extra-solution activity or mere field of use that impose no meaningful limit on the performance of a claimed method, or can be shown to be no more than well-understood, purely conventional, and routinely taken by others in order to apply the judicial exception. The explanation needs to be sufficient to establish a prima facie case of patent ineligibility under 35 U.S.C. 101.



# Case Citations

- Case citations:
  - *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. \_\_\_, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013)
  - *Mayo Collaborative Services, v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289, 101 U.S.P.Q.2d 1961 (2012)
  - *Bilski v. Kappos*, 561 U.S. \_\_\_, 130 S. Ct. 3218, 95 U.S.P.Q.2d 1001 (2010)
  - *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)
  - *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)



# Questions?

Please contact your  
TC Eligibility Team.