Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

# What Constitutes "Non-Naturally Occurring" Subject Matter?

## December 2014 USPTO Interim Guidance on Subject Matter Eligibility: Nature-Based Products

MIND + MUSCLE

January 14, 2015

SKGF.COM

# Three-part webinar series on subject matter eligibility in *ex parte* examination

**2014 Interim Guidance on Patent Subject Matter Eligibility**

79 Fed. Reg. 74,618 (Dec. 16, 2014)
http://www.uspto.gov/patents/law/exam/interim_guidance_subject_matter_eligibility.jsp

New **Nature Based Product Examples**
http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf

Sterne Kessler webinar schedule of :

- **What Constitutes "Non-Naturally Occurring" Subject Matter?**
  January 14, 2015, 2:00 - 3:00 pm EST
- **Effects on Software Patents**
  January 16, 2015, 2:00 - 3:00 pm EST
- **What is Left for Diagnostics?**
  January 22, 2015, 2:00 - 3:00 pm EST

# Nature-based products

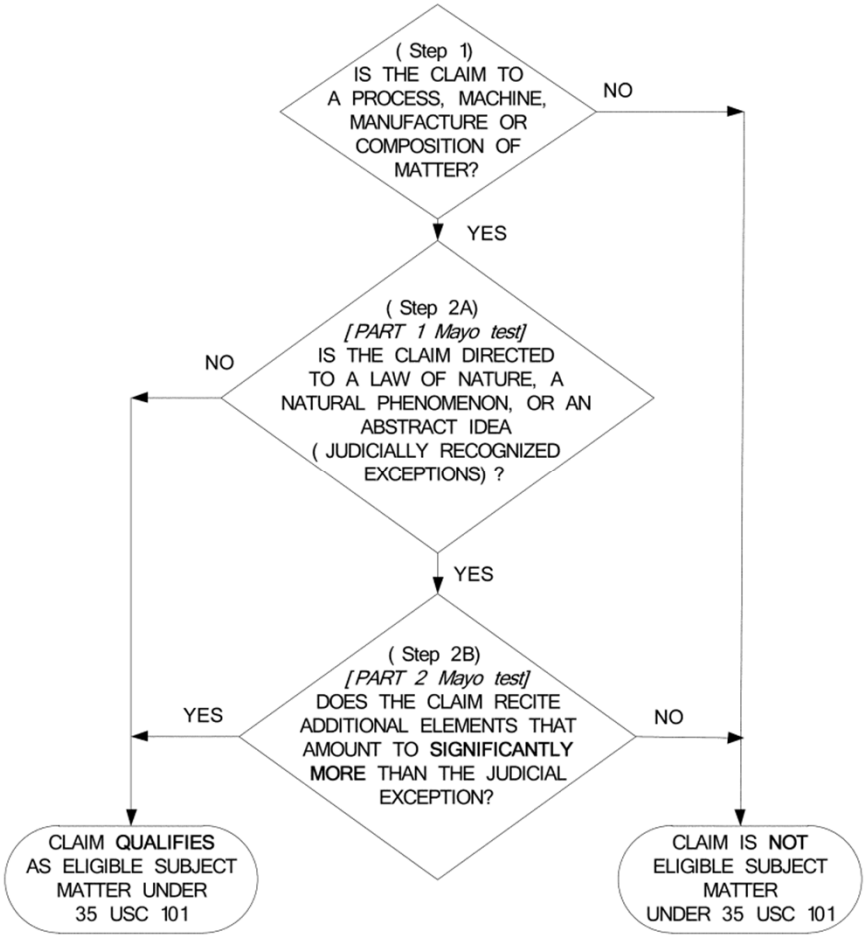
**Nature-based products**

- is a term used in the Guidance (and herein) merely to refer to the types of products that are examined to identify product of nature exceptions to patentability;
- include both patent eligible and ineligible products; and
- include both naturally occurring products and man-made products.

Nature-based products discussed in the Examples include:

- Gunpowder
- Beverage composition
- Bacterium
- Mixture of bacteria
- Human antibody
- Isolated polypeptide/nucleic acid
- Man-made human pacemaker cell

# New Guidance maintains two-part analysis for judicial exception to patentability …

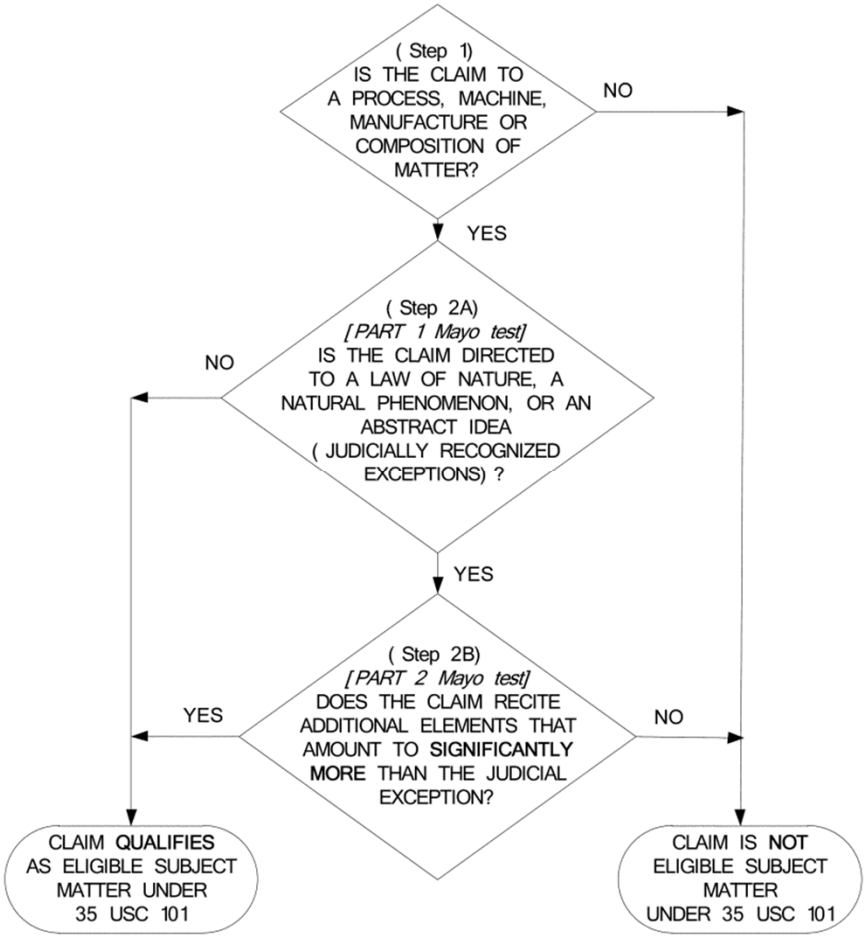



**Step 2A:** Does the nature-based product limitation exhibit markedly different characteristics from its naturally occurring counterpart?

**Yes** → claim is deemed **eligible** because it is not directed to a product of nature exception (claims reciting a law of nature or abstract idea need further analysis).

**No** → claim needs to be **further analyzed** in Step 2B because it is directed to a product of nature exception

# New Guidance maintains two-part analysis for judicial exception to patentability …



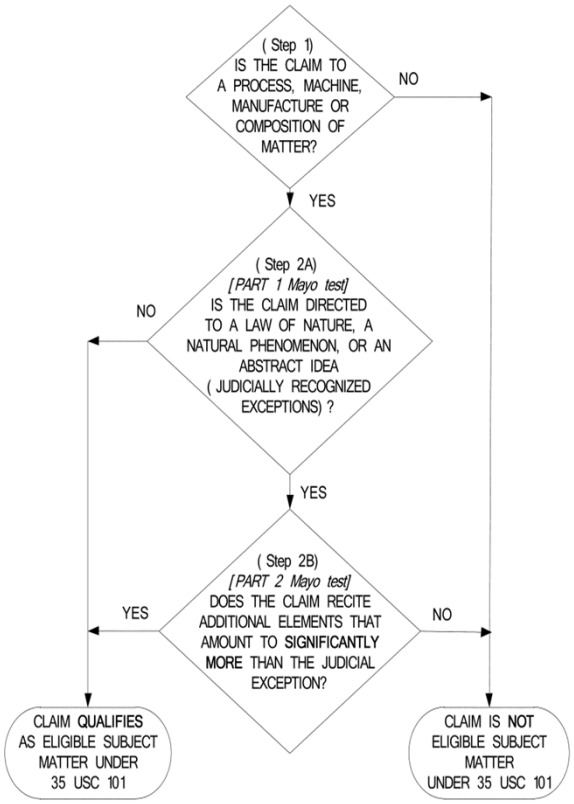

**Step 2B:** Considering the claim as a whole, is any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to significantly more than the judicial exception?

**Yes** → claim is **eligible**

**No** → claim is **ineligible**

# …with significant differences

1. Method of use claims that recite, but do not focus on the nature-based product limitation are generally deemed eligible without the Step 2A or Step 2B analysis.
2. A claim that recites a nature-based product but, when viewed as a whole, clearly does not seek to tie up a product of nature such that others cannot practice it, is deemed eligible without the Step 2A or 2B analysis.
3. If the nature-based product limitation is found to exhibit markedly different characteristics from its naturally occurring counterpart, the claim is deemed eligible without the Step 2B analysis.
4. Markedly different characteristics can be shown based on differences in function, and/or properties in addition to differences in structure.



# Process claims reciting a product of nature are generally deemed eligible

A **process claims** reciting a nature based product, but not other possible exception to patentability, are generally deemed **patent eligible** and are not subjected to the markedly different analysis,

> *A method of treating breast or colon cancer, comprising: administering an effective amount of amazonic acid to a patient suffering from breast or colon cancer.*

**except** in the limited situation where a process claim is drafted in such a way that there is no difference in substance from a product claim:

> *A method of providing an apple.*

Process claims reciting a nature based product **and** a possible law of nature or abstract idea will be examined for eligibility under the Guidelines.

**Pursue method of use claims with broad nature-based product scope if the corresponding composition claim is ineligible.**

# …with significant differences (cont.)

1. Method of use claims that recite, but do not focus on the nature-based product limitation are generally deemed eligible without the Step 2A or Step 2B analysis.
2. A claim that recites a nature-based product but, when viewed as a whole, clearly does not seek to tie up a product of nature such that others cannot practice it, is deemed eligible without the Step 2A or 2B analysis.
3. If the nature-based product limitation is found to exhibit markedly different characteristics from its naturally occurring counterpart, the claim is deemed eligible without the Step 2B analysis.
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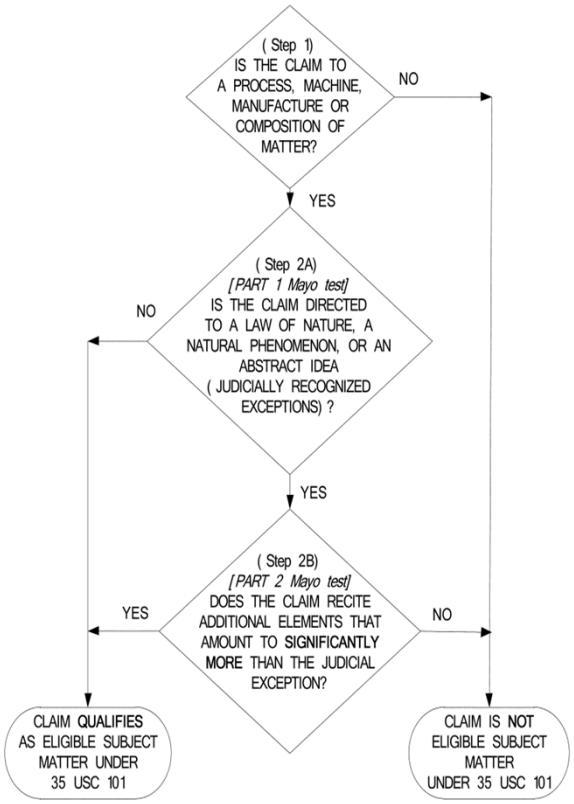

# Streamlined analysis for product claims that clearly do not seek to tie up a product-of-nature

**Claim:**

*A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) the gunpowder of claim 1, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder, and (e) a plastic ignition fuse having one end extending into the second compartment and the other end extending out of the cardboard body.*

**Analysis:**

- claim recites two nature-based products;
- claim as a whole indicates that the claim is focused on the assembly of components that together form the firework, not the nature-based products;
- **not necessary to apply the markedly different characteristics analysis** in order to conclude that the claim is not directed to an exception → **ELIGIBLE**

# …with significant differences (cont.)

1. Method of use claims that recite, but do not focus on the nature-based product limitation are generally deemed eligible without the Step 2A or Step 2B analysis.
2. A claim that recites a nature-based product but, when viewed as a whole, clearly does not seek to tie up a product of nature such that others cannot practice it, is deemed eligible without the Step 2A or 2B analysis.
3. If the nature-based product limitation is found to exhibit markedly different characteristics from its naturally occurring counterpart, the claim is deemed eligible without the Step 2B analysis.
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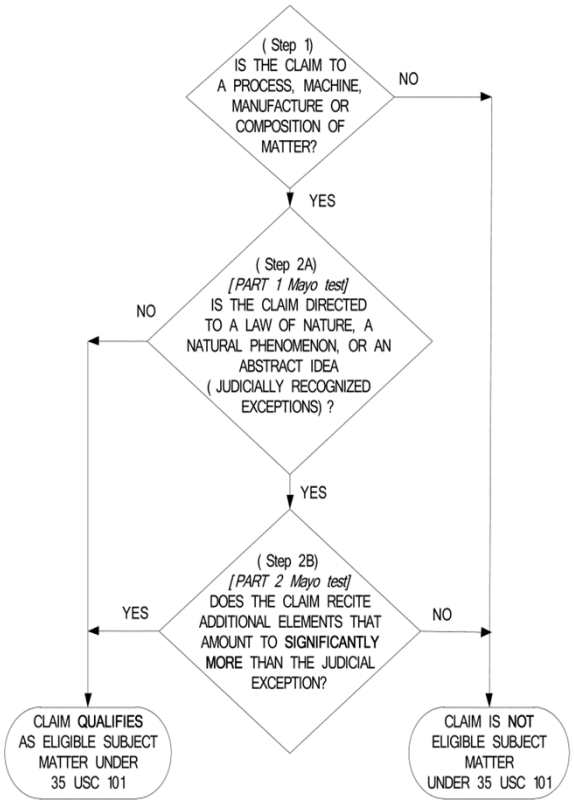

# New Nature Based Product Examples

http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf

**Facts:**

- claimed combination is explosive
- three claimed substances are not explosive

**Claim:**

1. *Gunpowder comprising: an intimate finely-ground mixture of 75% potassium nitrate, 15% charcoal and 10% sulfur.*

**Analysis:**

- claim recites combination of 3 nature-based products;
- no natural counterpart to combination, so the combination is compared to the individual components as they occur in nature;
- explosive property of the claimed combination is markedly different from the non-explosive properties of the substances by themselves in nature;
- **claimed combination has markedly different characteristics** →claim is not directed to a product of nature exception → **ELIGIBLE**

**USPTO's Nature Based Product Examples, while not legally binding, are useful for formulating arguments against rejections under 35 U.S.C. § 101.**

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# Markedly different characteristics

| Ex. | Nature based product | Naturally occurring counterpart | Markedly different characteristics |
|---|---|---|---|
| 1 | gunpowder | individual components | explosive property |
| 2 | Pomelo juice with preservative | Pomelo juice | slower spoiling |
| 3 | 5-methyl amazonic acid | amazonic acid | chemical structure and new pharmacological activity |
| 3 | deoxyamazonic acid | amazonic acid | chemical structure |
| 3 | controlled release amazonic acid core with protective natural polymer layer | amazonic acid | structure and increased bioavailability |
| 3 | stable aqueous amazonic acid composition | amazonic acid | solubility (amazonic acid is insoluble in water) |
| 4 | antibiotic L in tetrahedral crystal form | antibiotic L in hexagonal-pyramidal crystal form | different crystalline form that may result in different functional properties (*e.g.*, powder flow behavior) |

# Markedly different characteristics (cont.)

| Ex. | Nature based product | Naturally occurring counterpart | Markedly different characteristics |
|---|---|---|---|
| 4 | antibiotic L produced by yeast | antibiotic L | structure (glycosylation), immunogenicity, and *in vivo* half-life |
| 5 | genetically engineered bacteria | naturally occurring bacteria | structure (genotype) and function (phenotype) |
| 6 | mixture of two bacteria | naturally occurring individual bacteria | biological function - ability to infect new host neither bacteria alone can infect |
| 10 | mixture of two bacteria and milk | naturally occurring individual bacteria and milk | biological function - ability to ferment yoghurt with lower fat content than either bacteria can produce alone |

# No markedly different characteristics

| Ex. | Nature based product | Naturally occurring counterpart |
|---|---|---|
| 3 | purified amazonic acid | amazonic acid |
| 7 | isolated nucleic acid comprising SEQ ID NO: 1 | natural gene comprising SEQ ID NO: 1 |
| 8 | antibody to protein S | murine antibodies to protein S |
| 9 | isolated man-made human pacemaker cell | human pacemaker cell |
| 10 | kit comprising two bacteria | individual bacteria |

# Marked difference in properties – slower spoiling

**Facts:**

- the naturally occurring pomelo tree's fruit is often eaten raw or juiced;
- naturally occurring pomelo juice spoils in a few days even when refrigerated, due to the growth of bacteria that are naturally present in the juice;
- suitable preservatives are known, and include naturally occurring preservatives and non-naturally occurring preservatives

**Claim:**

*A beverage composition comprising pomelo juice and an effective amount of an added preservative.*

**Analysis:**

- the slower spoiling property of the claimed combination is markedly different from properties of the juice by itself in nature → **ELIGIBLE**

# Marked difference in properties – biological activity

**Facts:**

- Rhizobiums are naturally occurring bacteria that infect leguminous plants such as clover, alfalfa, beans and soy;
- Each species of bacteria will only infect certain types of plants;
- Rhizobium species were assumed mutually inhibitive, because prior art combinations of different bacterial species produced an inhibitory effect on each other when mixed;
- Applicant discovered that particular strains of each Rhizobium species do not exert a mutually inhibitive effect on each other, and that these strains can be used in mixed cultures;

**Claim:**

*An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.*

**Analysis:**

- no indication that the mixture of bacteria according to **Claim 1** has any characteristics (structural, functional, or otherwise) that are different from the naturally occurring bacteria → **moves to Step 2B (INELIGIBLE** under *Funk Brothers)*

# Marked difference in properties – biological activity (cont.)

**Facts:**

- Applicant has also discovered that certain Rhizobium species, when mixed together, exhibit biological properties that are different than in nature;
- For example, in nature or by itself, *R. californiana* will only infect lupine, but when mixed with *R. phaseoli*, *R. californiana* will infect both lupine and wild indigo;
- *R. californiana* and *R. phaseoli* are not known to occur together in nature

**Claim:**

*An inoculant for leguminous plants comprising a mixture of Rhizobium californiana and Rhizobium phaseoli.*

**Analysis:**

- when part of the mixture according to **Claim 2**, *R. californiana* infects wild indigo, a new species of plant, but *R. phaseoli* continues to only infect garden beans;
- when part of the mixture of **Claim 2**, *R. californiana* has a different characteristic (biological function) that rises to the level of a marked difference → **ELIGIBLE**

**The Examples note that unless the examiner can show that this particular mixture of bacteria exists in nature, this mere possibility does not bar the eligibility of this claim.**

# Isolated Compounds

**Facts:**

- The leaves of the naturally occurring Amazonian cherry tree contain a chemical that is useful in treating breast and colon cancers. Applicant has purified the cancer-fighting chemical from the leaves and has named it amazonic acid. The purified amazonic acid is structurally and functionally identical to the amazonic acid in the leaves.
- Applicant has created two derivatives: 5-methyl amazonic acid and deoxyamazonic acid. 5-methyl amazonic acid is functionally different because it stimulates the growth of hair in addition to treating cancer. Applicant has not identified any functional difference between deoxyamazonic acid and amazonic acid.
- Amazonic acid is absorbed through the lining of the human stomach and is rapidly metabolized by the body. It is also insoluble in water.

**Claims:**

1. *Purified amazonic acid.*
2. *Purified 5-methyl amazonic acid.*
3. *Deoxyamazonic acid.*

- **Moves to Step 2B** - no marked difference (**INELIGIBLE** as it only recites the product)
- **ELIGIBLE** - markedly different structure and function
- **ELIGIBLE** - markedly different structure

# Isolated Compounds (cont.)

**Claim:**

4. *A pharmaceutical composition comprising: a core comprising amazonic acid; and alayer of natural polymeric material enveloping the core.*

**Analysis:**

- the composition of **Claim 4** is structurally different from the naturally occurring substances, and this structural difference results in different functional characteristics *in vivo (e.g., amazonic acid is not released until the composition reaches the colon, due to the relative indigestibility of the natural polymeric material, thus increasing the bioavailability of the amazonic acid)* → **ELIGIBLE**

**Claim:**

5. *A stable aqueous composition comprising: amazonic acid; and a solubilizing agent.*

**Analysis:**

- changed property (*i.e.*, solubility) between amazonic acid as a part of the claimed stable aqueous composition of **Claim 5** and amazonic acid in nature is a marked difference → **ELIGIBLE**

# Genetically modified organism

**Facts:**

- Naturally occurring Pseudomonas bacteria containing one stable energy-generating plasmid and capable of degrading a single type of hydrocarbon are known. There are no known Pseudomonas bacteria in nature that contain more than one stable energy generating plasmid.

**Claim:**

*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.*

**Analysis:**

- under Chakrabarty, the difference in phenotype and genotype between the claimed and naturally occurring bacteria rises to the level of marked difference → **ELIGIBLE**

# Polynucleotides/ Polypeptides

**Facts:**

- Protein W is naturally encoded by Virginia nightshade Gene W, which has the nucleic acid sequence disclosed as SEQ ID NO:1;
- specification discloses substitution modifications of Gene W, some of which are silent; but may affect transcription rate and splicing;
- no substitution modifications of Gene W are known to occur in nature.

**Claims:**

1. *Isolated nucleic acid comprising SEQ ID NO: 1.*
2. *Isolated nucleic acid comprising a sequence that has at least 90% identity to SEQ ID NO: 1 and contains at least one substitution modification relative to SEQ ID NO: 1.*

**Analysis:**

- Under *Myriad*, this isolated but otherwise unchanged nucleic acid of **Claim 1** is **INELIGIBLE**;
- the structural differences between the nucleic acids of **Claim 2** and their natural counterparts are markedly different → **ELIGIBLE**

**Later discovered natural variant, for example the homologue of a related species may render Claim 2 ineligible. Claim may lack written description**.

# Polynucleotides (cont.)

**Facts:**

- Protein W is naturally encoded by Virginia nightshade Gene W, which has the nucleic acid sequence disclosed as SEQ ID NO:1;
- specification discloses substitution modifications of Gene W, some of which are silent; but may affect transcription rate and splicing;
- no substitution modifications of Gene W are known to occur in nature.

**Claims:**

3. *Isolated nucleic acid comprising SEQ ID NO: 1 and further comprising a fluorescent label attached to the nucleic acid.*
4. *A vector comprising the nucleic acid comprising SEQ ID NO: 1 and a heterologous nucleic acid sequence.*

**Analysis:**

- the structural and functional differences between the nucleic acids of **Claims 3 and 4** and their natural counterparts are markedly different → **ELIGIBLE**

# Antibodies

**Facts:**

- The specification describes the discovery of naturally occurring antibodies to Protein S, an antigen of the newly discovered *Staphylococcus texana* bacteria, in mice and wild coyotes.
- No human antibodies to Protein S are naturally occurring.
- It is known that murine antibodies have different constant domains than human and coyote antibodies, and that murine antibodies may cause allergic reactions when administered to humans or coyotes.

**Claims:**

1. *An antibody to Protein S.*
2. *An antibody to Protein S, wherein the antibody is a human antibody.*

**Analysis:**

- **Claim 1** encompasses naturally occurring antibodies → **moves to Step 2B (INELIGIBLE** as it only recites the product of nature exception**)**
- Because no human antibodies to Protein S are naturally occurring, the antibodies of **Claim 2** have different structure and function (*e.g.*, bind to different antigens) than what exists in nature → **ELIGIBLE**

# Antibodies (cont.)

**Facts:**

- The specification discloses a particular murine antibody comprising SEQ ID NOs: 7-12 as its six CDR sequences was created by applicants. There is no naturally occurring antibody that has the particular combination of CDR sequences recited in claim 3.

**Claims:**

3. *An antibody to Protein S, wherein the antibody is a murine antibody comprising complementarity determining region (CDR) sequences set forth as SEQ ID NOs: 7-12.*

**Analysis:**

- Because the antibodies of **Claim 3** have different CDRs than what exists in nature, they have markedly different structure and function (*e.g.*, bind to different antigens) than what exists in nature → **ELIGIBLE**

**The Examples note that unless the examiner can show that this particular murine antibody exists in nature, the mere possibility does not bar the eligibility of this claim.**

# Antibodies (cont.)

**Facts:**

- It is known that chimeric and humanized antibodies are less immunogenic to humans than murine antibodies, and that antibodies with variant Fc domains may exhibit different characteristics (e.g., increased cytotoxicity and/or serum half-life) than antibodies with wild-type Fc domains.

**Claims:**

4. *An antibody to Protein S, wherein the antibody is a chimeric or humanized antibody.*
5. *An antibody to Protein S, wherein the antibody comprises a variant Fc domain.*

**Analysis:**

- Because the antibodies of **Claim 3** have different CDRs than what exists in nature, they have markedly different structure and function (*e.g.*, bind to different antigens) than what exists in nature → **ELIGIBLE**
- the antibodies of **Claims 4 and 5** have markedly different structure and function (*e.g.*, reduced immunogenicity or altered effector function) than what exists in nature → **ELIGIBLE**

# Eligibility of product-by-process claims turns on whether the product itself is patent eligible

**Facts:**

- naturally occurring Antibiotic L is a peptide comprising bacillosamine N-glycan;
- Antibiotic L expressed by recombinant yeast comprises high mannose N-glycan, has lower immunogenicity to humans and a different half-life *in vivo* than naturally occurring Antibiotic L

**Claims:**

1. *Antibiotic L, which is expressed by recombinant yeast.*

**Analysis:**

- claimed Antibiotic has structurally different N-glycans, and the structural difference results in a change to its immunogenicity and half-life
- claimed Antibiotic L has markedly different characteristics → **ELIGIBLE**

**The USPTO construes the terms "recombinant antibody" and "monoclonal antibody" as products-by-process for the purpose of examination.**

# Composition claims encompassing both eligible and ineligible nature based product embodiments are directed to product of nature

**Facts:**

- naturally occurring human pacemaker cells express marker P, but never marker Z on the cell surface;
- human stem cells were differentiated into pacemaker cells *in vivo*;
- some isolated man-made pacemaker cells are genetically and phenotypically identical to naturally occurring pacemaker cells; others are genetically identical, but have a different phenotype (*e.g.*, express marker Z and exhibit increased efficiency in utilizing oxygen)

**Claims:**

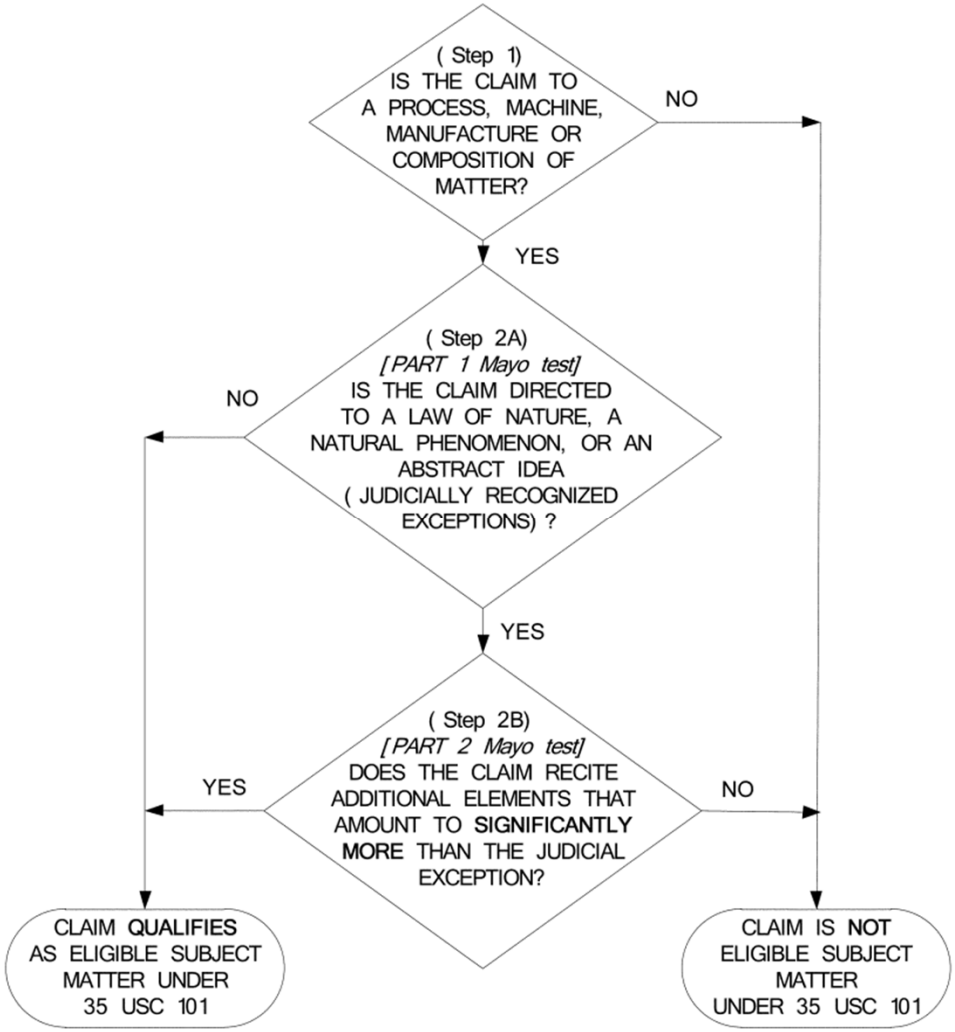
1. *An isolated man-made human pacemaker cell.*
2. *An isolated man-made human pacemaker cell expressing marker Z.*

**Analysis:**

- **Claim 1** encompasses cells that are identical (no difference in characteristics) to naturally occurring cells → **moves to Step 2B (INELIGIBLE** under *Roslin)***;**
- **Claim 2** is limited to human pacemaker cells that are phenotypically different from naturally occurring cells and the differences are the result of applicant's efforts → **ELIGIBLE**

**Claim scope must not encompass any embodiment without a marked difference to a natural product.**

# Two-part analysis for judicial exception to patentability




- **Step 2B:** Considering the claim as a whole, is any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to significantly more than the judicial exception?
- **Yes** → claim is **eligible**
- **No** → claim is **ineligible**

# Case law on the application of the "significantly more" analysis is sparse

Limitations discussed in the Guidance that may be enough to qualify as significantly more include:

- improvements to another technology or technical field;
- 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, or adding unconventional steps that confine the claim to a particular useful application;
- meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment.

**Case law on "significantly more" analysis of composition claims is limited → examination of composition claims may be subjective. Reliance on "markedly different characteristics" to establish eligibility is likely more predictable.**

# Example "significantly more" analysis

**Facts:**

- some isolated man-made pacemaker cells are genetically and phenotypically identical to naturally occurring pacemaker cells;

**Claim:**

*A composition comprising a population of isolated man-made human pacemaker cells in a* **container.**

**Analysis:**

- claims 1 and 2 are directed to a "product of nature" exception;
- use of a container in **claim 1** to hold cells is well-understood, routine and conventional activity;
- container is required for growing and using the cells;
- container is recited at a high level of generality
- claim adds nothing significantly more to product of nature → **INELIGIBLE**

# Example "significantly more" analysis (cont.)

**Facts:**

- no indication that placing cells into scaffold results in the cells or the scaffold having any characteristics different from the naturally occurring cells or scaffold;
- specification specifically excludes cardiac tissue from the definition of "biocompatible three-dimensional scaffolds"

**Claim:**

*A composition comprising a population of isolated man-made human pacemaker cells in a **biocompatible three-dimensional scaffold**.*

**Analysis:**

- biocompatible scaffold in **claim 2** not required for growing or using cells;
- scaffold not recited at a high level of generality;
- claim confined to a particular useful application of the scaffold (repair of cardiac tissue);
- combination improves the technology of regenerative medicine;
- claim amounts to significantly more than product of nature → **ELIGIBLE**

# Practice tips

- Use Guidance and Examples to craft strategy for establishing eligibility of nature based compositions.
- For new application, describe properties and include data that show markedly different characteristics.
- For existing applications, draft claims to compositions that are markedly different from naturally occurring products.
- Rely on the “significantly more” prong only if there are no markedly different characteristics.
- Establish multiple markedly different characteristics to support eligibility to ward against a later-discovered naturally existing composition rendering the claim ineligible.
- Draft claims to cover only embodiments that encompass the markedly different characteristics.
- Pursue method of use claims for compositions that encompass a naturally occurring product.
- Be prepared for surprises; this is a rapidly evolving area of patent law.

# For More Information

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