

**Biotechnology/Chemical/Pharmaceutical
Customer Partnership
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**Interim Guidance on
Patent Subject Matter Eligibility**



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Overview

- USPTO issued the Interim Guidance on December 16, 2014, after careful consideration of feedback from the public and consultation with business groups within the Office (examining corps, Solicitor, PTAB)
 - Explains the USPTO's interpretation of subject matter eligibility requirements in view of *Alice*, *Myriad*, and *Mayo*
 - Sets forth an integrated approach
 - Reflects significant changes from the March 2014 Guidance
 - Provides a straightforward eligibility analysis that promotes examination efficiency and consistency
 - Addresses common themes from the feedback to the extent allowed by controlling case law



Overview

- Interim Eligibility Guidance:
 - *Supplements* the June 25, 2014 Preliminary Instructions
 - *Supersedes* the March 4, 2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products
 - *Supersedes* MPEP 2106(II)(A), 2106(II)(B), and 2106.01
 - *Supersedes* MPEP 2105 to the extent that the section suggests that “mere human intervention” necessarily results in eligible subject matter



Changes From Prior Guidance



Integrated Approach

- Interim Eligibility Guidance sets forth an integrated approach for eligibility
 - For all categories of claims (product and process)
 - For all types of judicial exceptions (abstract ideas, laws of nature, natural phenomena, including products of nature)



“Directed To”

- Step 2A of the Interim Eligibility Guidance asks whether the claim is “directed to” a judicially recognized exception
 - “Directed to” means the exception is recited in the claim, *i.e.*, the claim **sets forth** or **describes** the exception
 - If the invention is merely *based on* or *involves* an exception, but the exception is not set forth or described in the claim, the claim is **not** directed to an exception (Step 2A: NO) and is eligible



Nature-Based Product Analysis

- The test for determining whether a claim is directed to a “product of nature” exception is separated from the analysis of whether the claim includes significantly more than the exception
 - Claims including a nature-based product are analyzed in Step 2A to identify whether the claim is directed to a product of nature exception
 - This analysis compares the nature-based product in the claim to its naturally occurring counterpart to identify markedly different characteristics
 - The analysis proceeds to Step 2B only when the claim is directed to an exception (when no markedly different characteristics are shown)



Markedly Different Characteristics

- The markedly different analysis focuses on characteristics that can include a nature-based product's structure, function, and/or other properties as compared to its naturally occurring counterpart in its natural state
 - In the March 2014 Guidance, structural changes were required to show a marked difference.



Process Claims and Marked Difference

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



Factor-Based Test

- The analysis as to whether the claim as a whole amounts to significantly more than the judicial exception (Step 2B) no longer requires weighing multiple factors
 - The considerations for “significantly more” remain similar to those in the prior *Bilski* and March 2014 guidance documents
 - Focus is on the “inventive concept”



Streamlined Eligibility Analysis

- A claim that may or may not recite a judicial exception but, when viewed as a whole, **clearly** does not seek to tie up any judicial exception such that others cannot practice it may not need to proceed through the full analysis
 - The eligibility of such claims will be self-evident
 - If the examiner has a doubt as to whether a claim seeks coverage of a judicial exception itself, a full analysis would be appropriate



Analyzing Nature-Based Products



Overview

- This segment discusses the following issues related to nature-based products:
 - How the markedly different characteristics analysis fits into the overall eligibility test;
 - When a claim reciting a nature-based product should be analyzed for markedly different characteristics; and
 - How to perform the markedly different characteristics analysis (including claim examples).



Some Nature-Based Products Are “Product of Nature” Exceptions

Nature-based products are those products derived from natural sources that require closer scrutiny to determine whether they are an exception. They fall into two categories:

1. Eligible nature-based products have markedly different characteristics from any naturally occurring counterpart. They are not judicial exceptions.

2. Ineligible nature-based products are either:

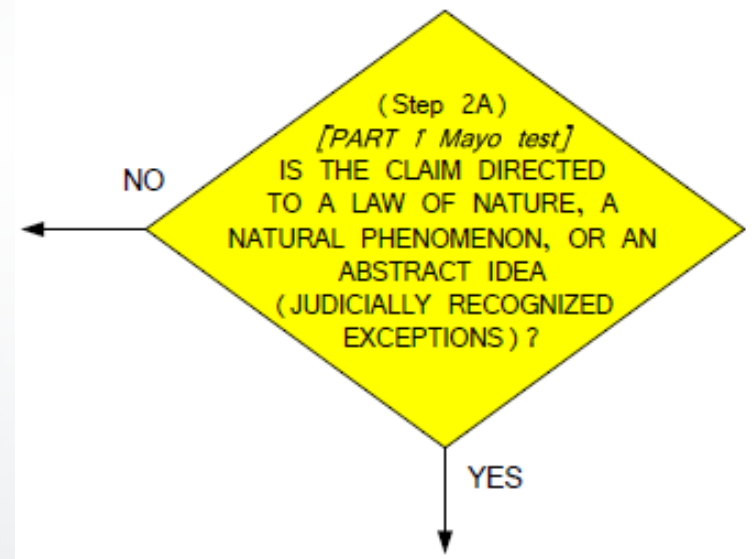
- (i) naturally occurring, or
- (ii) not naturally occurring but do not have markedly different characteristics from any naturally occurring counterpart.

They are “**product of nature**” exceptions.



The Markedly Different Characteristics Analysis is Part of Step 2A

- The markedly different characteristics analysis is used to determine if a nature-based product is a “product of nature” exception.
- The courts have held that “products of nature” fall under the laws of nature or natural phenomena exceptions.
- Thus, the markedly different characteristics analysis is part of Step 2A, *i.e.*, it helps answer the question of whether a claim is directed to an exception.





Use The Markedly Different Characteristics Analysis To Identify “Products of Nature”

- The markedly different characteristics analysis determines if a nature-based product is a “product of nature” exception.
 - If the nature-based product has markedly different characteristics, it is not an exception. The claim is **eligible** (Step 2A: NO), unless the claim recites another exception.
 - If the nature-based product does not have markedly different characteristics, it is a **“product of nature” exception**, and thus the claim is directed to an exception (Step 2A: YES). The analysis proceeds to Step 2B to determine whether the claim as a whole amounts to significantly more than the exception.



Some Claims Do Not Need The Markedly Different Characteristics Analysis

- The **streamlined eligibility analysis** applies if the claim is directed to an invention that **clearly** does not seek to tie up any judicial exception. *E.g.*, the artificial hip prosthesis coated with a naturally occurring mineral, or the plastic chair with wooden trim.
- **Process claims** are not subject to the markedly different characteristics analysis, 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 to a nature-based product. *E.g.*, the “method of providing an apple”.



Only The Nature-Based Product Limitations are Analyzed

- The markedly different characteristics analysis is not applied to claim limitations that are not nature-based.
- For example, for a claim to “probiotic composition comprising a mixture of Lactobacillus and milk in a container”:
 - The nature-based product limitation is the “mixture of Lactobacillus and milk”. This mixture is analyzed for markedly different characteristics.
 - The container is not analyzed (it will be evaluated in Step 2B if the mixture is a “product of nature”).



The Nature-Based Product Is Compared To Its Naturally Occurring Counterpart

- The markedly different characteristics analysis compares the nature-based product limitation to its naturally occurring counterpart in its natural state.
 - If there is no naturally occurring counterpart, comparison is with the closest naturally occurring counterpart.
 - If the nature-based product is a combination, the closest counterpart may be the individual nature-based components of the combination.
- For example, *Chakrabarty's* genetically modified *Pseudomonas* bacterium containing multiple plasmids was compared to naturally occurring *Pseudomonas* bacteria.



Markedly Different Characteristics = Structure, Function and/or Other Properties

- Non-limiting examples of the types of characteristics considered by the courts when determining whether there is a marked difference include:
 - Biological or pharmacological functions or activities, e.g., a bacterium's ability to infect leguminous plants, or the protein-encoding information of a nucleic acid;
 - Chemical and physical properties, e.g., the alkalinity of a chemical compound, or the ductility or malleability of metals;
 - Phenotype, including functional and structural characteristics, e.g., the shape, size, color, and behavior of an organism; and
 - Structure and form, whether chemical, genetic or physical, e.g., the physical presence of plasmids in a bacterial cell, or the crystalline form of a chemical.



Markedly Different Characteristics Must Be Changed As Compared To Nature

- To show a marked difference, the characteristic(s) must be changed as compared to nature.
 - Inherent or innate characteristics of the naturally occurring counterpart cannot show a marked difference.
 - Differences in the characteristic(s) that came about or were produced independently of any effort or influence by applicant cannot show a marked difference.



Examples

- The following examples are excerpted from the Nature-Based Products example set issued in December 2014.
 - Amazonic Acid (Example 3: claims 1, 3 and 8)
 - Bacterial Mixtures (Example 6: claims 1 and 2)
 - Antibodies (Example 8: claims 1 and 3)



Amazonic Acid: Background

- Amazonic acid is naturally occurring in tree leaves.
 - Purified amazonic acid is structurally and functionally identical to the naturally occurring acid in the leaves.
 - Amazonic acid has anti-tumor properties.
- Applicant created deoxyamazonic acid in the laboratory, by chemically altering amazonic acid.
 - Deoxyamazonic acid is not known to exist in nature.
 - Deoxyamazonic acid is structurally different from amazonic acid ($-OH$ group replaced with $-H$), but applicant has not identified any functional difference.



Amazonic Acid: Claim 1 Analysis

1. Purified amazonic acid.

Step 1: Yes, the claim is directed to a composition of matter, which is a statutory category.

Step 2A: The claim recites a nature-based product (the purified amazonic acid). The markedly different characteristics analysis is used to determine if this nature-based product is an exception. See next slide.



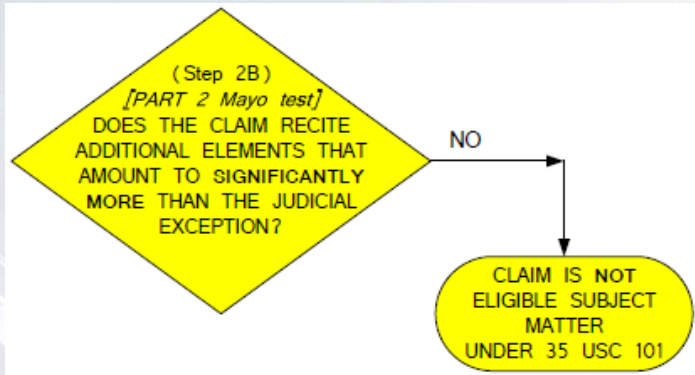
Claim 1: Markedly Different Characteristics Analysis

- Compare the nature-based product (the purified amazonic acid) to its natural counterpart(s).
- There is no indication that the purified amazonic acid has any characteristics that are different from the naturally occurring acid.
 - No difference in function (purified amazonic acid has the same anti-tumor properties as the naturally occurring acid).
 - No difference in structure (purification of amazonic acid has not resulted in any structural changes to the acid).
 - No difference in other properties.
 - Because there are no different characteristics, there are no markedly different characteristics.
- **Because the claimed acid does not have markedly different characteristics, it is a “product of nature” exception.**



Amazonic Acid: Claim 1 Analysis (Cont.)

Step 2A (cont.): Because the nature-based product (the purified amazonic acid) does not have markedly different characteristics, it is a “product of nature” exception. Thus, the claim is directed to an exception.



Step 2B: No, because the claim does not include any additional features that could add significantly more to the exception.

Claim is ineligible.



Amazonic Acid: Claim 3 Analysis

3. Deoxyamazonic acid.

Step 1: Yes, the claim is directed to a composition of matter, which is a statutory category.

Step 2A: The claim recites a nature-based product (deoxyamazonic acid). The markedly different characteristics analysis is used to determine if this nature-based product is an exception. See next slide.

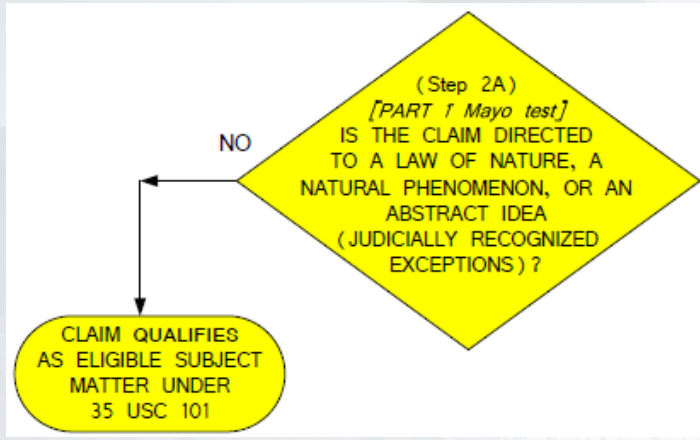


Claim 3: Markedly Different Characteristics Analysis

- Compare the nature-based product (the deoxyamazonic acid) to its natural counterpart(s).
- The specification indicates that the deoxyamazonic acid has characteristics that are different from the naturally occurring acid.
 - No difference in function (deoxyamazonic acid has the same anti-tumor properties as the naturally occurring amazonic acid).
 - There is a difference in structure (the chemical structure is different; deoxyamazonic acid has an –H group where amazonic acid has an –OH group).
 - This structural difference rises to the level of a marked difference.
- **Because the claimed compound has markedly different characteristics, it is not a “product of nature” exception.**



Amazonic Acid: Claim 3 Analysis (Cont.)



Step 2A (cont.): Because the nature-based product (deoxyamazonic acid) has markedly different characteristics, it is not a “product of nature” exception. Thus, the claim is not directed to an exception.

Claim is eligible.



Amazonic Acid: Claim 8 Analysis

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

Step 1: Yes, the claim is directed to a process, which is a statutory category.

Step 2A: No, the claim is not directed to an exception.

- The claim recites a nature-based product (purified amazonic acid).
- However, the claim is not directed to the nature-based product, because the claim clearly does not seek to tie up the product. Instead, the claim is focused on processes of practically applying the product to treat a particular disease.
- No other exceptions are recited in the claim.

Claim is eligible.



Bacterial Mixtures: Background

- It was assumed in the prior art that *Rhizobium* bacteria were mutually inhibitive based on past experience.
 - Applicant discovered that certain species are not mutually inhibitive. Such species can be isolated and used together in mixed cultures.
- Applicant also discovered that certain species, when mixed, exhibit biological properties different from what is found in nature.
 - Both *R. californiana* and *R. phaseoli* are naturally occurring bacteria. They are not known to be found together in nature.
 - In nature, *R. californiana* infects only lupine, and *R. phaseoli* infects only garden beans.
 - When *R. californiana* and *R. phaseoli* are mixed together, *R. californiana* can also infect wild indigo.



Bacterial Mixtures: Claim 1 Analysis

1. 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.

Step 1: Yes, the claim is directed to a composition of matter, which is a statutory category.

Step 2A: The claim recites a nature-based product (the mixture of *Rhizobium* bacteria). The markedly different characteristics analysis is used to determine if this nature-based product is an exception. See next slide.



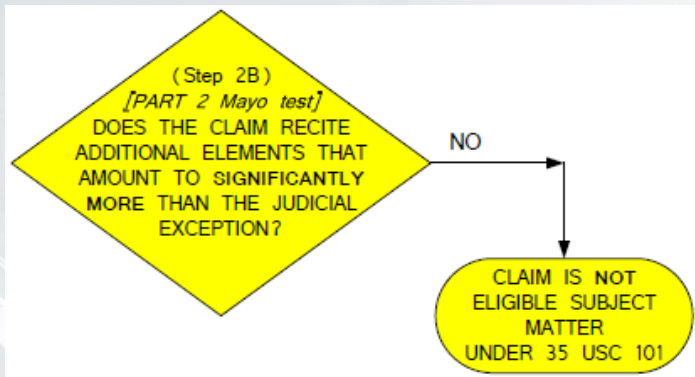
Claim 1: Markedly Different Characteristics Analysis

- Compare the nature-based product (the mixture of *Rhizobium* bacteria) to its natural counterpart(s).
- There is no indication that the mixture has any characteristics that are different from the naturally occurring bacteria.
 - No difference in function (each bacterial species infects the same plants it always infected).
 - No difference in structure (mere aggregation of naturally occurring bacteria together as an “inoculant” does not change the structure of the bacteria).
 - No difference in other properties.
 - Because there are no different characteristics, there are no markedly different characteristics.
- **Because the claimed mixture does not have markedly different characteristics, it is a “product of nature” exception.**



Bacterial Mixtures: Claim 1 Analysis (Cont.)

Step 2A (cont.): Because the nature-based product (the mixture of *Rhizobium* bacteria) does not have markedly different characteristics, it is a “product of nature” exception. Thus, the claim is directed to an exception.



Step 2B: No, because the claim does not include any additional features that could add significantly more to the exception.

Claim is ineligible.



Bacterial Mixtures: Claim 2 Analysis

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

Step 1: Yes, the claim is directed to a composition of matter, which is a statutory category.

Step 2A: The claim recites a nature-based product (the mixture of *R. californiana* and *R. phaseoli*). The markedly different characteristics analysis is used to determine if this nature-based product is an exception. See next slide.

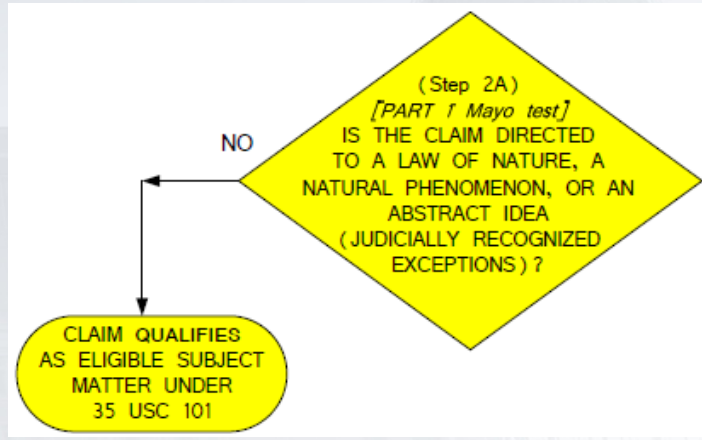


Claim 2: Markedly Different Characteristics Analysis

- Compare the nature-based product (the mixture of *R. californiana* and *R. phaseoli*) to its natural counterpart(s).
- The specification indicates that the mixture has characteristics that are different from the naturally occurring bacteria.
 - There is a difference in function (*R. californiana* in nature and by itself infects only lupine; when mixed with *R. phaseoli*, *R. californiana* now infects lupine and wild indigo).
 - No difference in structure (mere aggregation of naturally occurring bacteria together as an “inoculant” does not change the structure of the bacteria).
 - This functional difference rises to the level of a marked difference.
- **Because the claimed mixture has markedly different characteristics, it is not a “product of nature” exception.**



Bacterial Mixtures: Claim 2 Analysis (Cont.)



Step 2A (cont.): Because the nature-based product (the mixture of *R. californiana* and *R. phaseoli*) has markedly different characteristics, it is not a “product of nature” exception. Thus, the claim is not directed to an exception.

Claim is eligible.



Antibodies: Background

- Newly discovered bacteria have antigen (Protein S) on outer surface.
 - Naturally occurring antibodies to Protein S were discovered in mice and coyotes.
 - No human antibodies to Protein S are naturally occurring.
- Applicant has created a particular murine antibody comprising SEQ ID Nos: 7-12 as its six CDR sequences.
 - CDRs are the complementarity determining regions of an antibody. They vary from antibody to antibody, and determine to which antigen an antibody will bind.
 - No naturally occurring antibody has this combination of CDRs.
 - Applicant created the claimed antibody by injecting a laboratory mouse with Protein S.



Antibodies: Claim 1 Analysis

1. An antibody to Protein S.

Step 1: Yes, the claim is directed to a composition of matter, which is a statutory category.

Step 2A: The claim recites a nature-based product (an antibody). The markedly different characteristics analysis is used to determine if this nature-based product is an exception. See next slide.



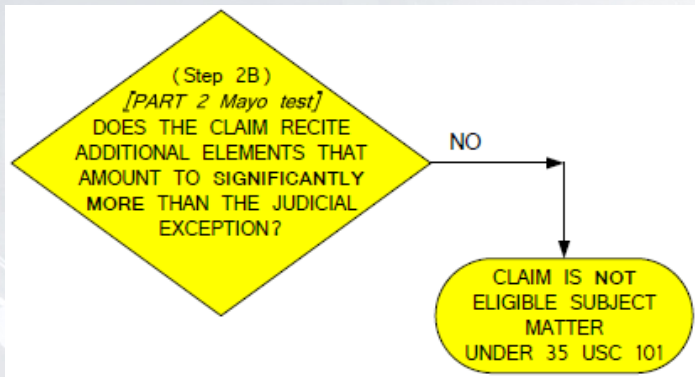
Claim 1: Markedly Different Characteristics Analysis

- Compare the nature-based product (the antibody) to its natural counterpart(s).
- The claim encompasses naturally occurring antibodies.
 - No difference in function (the antibodies all have the naturally occurring function of binding to Protein S).
 - No difference in structure (claim encompasses antibodies that are structurally identical to naturally occurring antibodies).
 - No difference in other properties.
 - Because there are no different characteristics, there are no markedly different characteristics.
- **Because the claimed antibody does not have markedly different characteristics, it is a “product of nature” exception.**



Antibodies: Claim 1 Analysis (Cont.)

Step 2A (cont.): Because the nature-based product (the antibody) does not have markedly different characteristics, it is a “product of nature” exception. Thus, the claim is directed to an exception.



Step 2B: No, because the claim does not include any additional features that could add significantly more to the exception.

Claim is ineligible.



Antibodies: Claim 3 Analysis

3. The antibody of claim 1, wherein the antibody is a murine antibody comprising complementarity determining region (CDR) sequences set forth as SEQ ID Nos: 7-12.

Step 1: Yes, the claim is directed to a composition of matter, which is a statutory category.

Step 2A: The claim recites a nature-based product (the murine antibody). The markedly different characteristics analysis is used to determine if this nature-based product is an exception. See next slide.

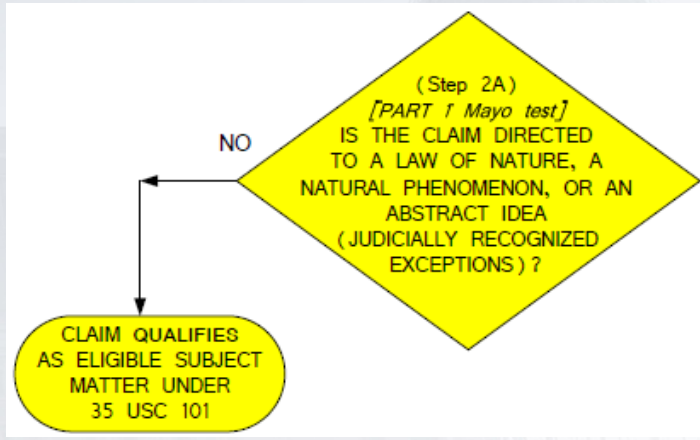


Claim 3: Markedly Different Characteristics Analysis

- Compare the nature-based product (the murine antibody) to its natural counterpart(s).
- The specification indicates that the murine antibody has characteristics that are different from naturally occurring antibodies.
 - There is a difference in structure (e.g., the different CDRs yield different amino acid sequences and three-dimensional structures).
 - There may be a difference in function (e.g., binds to a different epitope on Protein S).
 - These differences rise to the level of a marked difference.
- **Because the claimed murine antibody has markedly different characteristics, it is not a “product of nature” exception.**



Antibodies: Claim 3 Analysis (Cont.)



Step 2A (cont.): Because the nature-based product (the murine antibody) has markedly different characteristics, it is not a “product of nature” exception. Thus, the claim is not directed to an exception.

Claim is eligible.



Next Steps



Continued Public Engagement

- Developing guidance is an ongoing process
- Updates will be provided based on feedback from the public and the examining corps
 - Currently processing public feedback from the forum held January 21, 2015, and the comment period that closed on March 16, 2015
- Additional examples will be developed



Monitor Judicial Developments

- Federal Circuit decisions relating to subject matter eligibility may continue to fill in gaps
 - For example, screening/diagnostic claims are not addressed in detail in 2014 Interim Eligibility Guidance as the law in this area is in flux
 - Federal Circuit has since decided *University of Utah Research Foundation v. Ambray Genetics* (December 17, 2014) finding certain methods of screening ineligible
 - Other cases involving screening/diagnostic claims are pending at the Federal Circuit



Now Pending At Federal Circuit: *Ariosa Diagnostics v. Sequenom*

- U.S. Patent 6,258,540 claims methods for detecting paternally inherited cell-free fetal DNA (cffDNA) in maternal serum or plasma
- District court held claims ineligible:
 - Identified the exception as the paternally inherited cffDNA
 - “the only inventive part of the patent is that the conventional techniques of DNA detection known at the time of the invention are applied to paternally inherited cffDNA as opposed to other types of DNA. Thus, the only inventive concept contained in the patent is the discovery of cffDNA, which is not patentable.”



Additional Resources

- General examination guidance and training materials

<http://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidance-and-training-materials>

- December 2014 Interim Eligibility Guidance

<http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0>

- Includes the Guidance document, additional claim examples, training materials, and relevant case law
- Includes links to public comments
- Any updates will be posted to this page



Thank You!