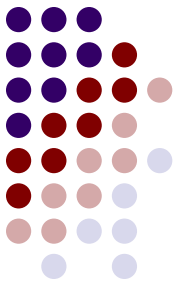


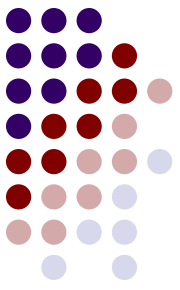
NEW USPTO GUIDELINES

- On 4 March 2014 USPTO issued “*Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*”.
- Materials address analysis for DNA sequences, as well as other products of nature and laws of nature.
- *Assoc’n for Mol. Path. v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S.Ct. 2107, 2116, 106 USPQ2d 1972 (2013)



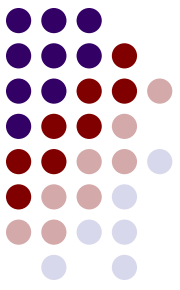
NEW USPTO GUIDELINES

- “In Summary, all claims (i.e., machine, composition, manufacture and process claims) reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products should be examined using the *Guidance*.”
- Supersedes previous memorandum of June 13, 2013



NEW USPTO GUIDELINES

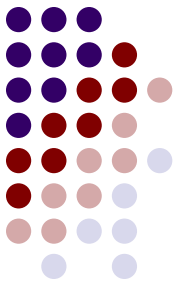
- “*Myriad* also clarified that not every change to a product will result in a marked difference, and that the mere recitation of particular words (e.g., “isolated”) in the claims does not automatically confer eligibility.”
- While *Myriad* was limited to nucleic acids, USPTO now states that all claims reciting or involving natural products should be examined for a marked difference under *Chakrabarty*’s admonition against patents on naturally occurring things.



NEW USPTO GUIDELINES

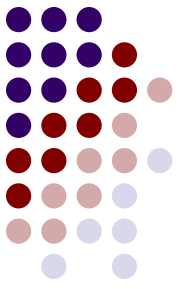
- “*Myriad* relied on *Chakrabarty* as ‘central’ to the eligibility inquiry, and re-affirmed the Office’s reliance on *Chakrabarty*’s criterion for eligibility of natural products”
- Criterion is: “whether the claimed product is a non-naturally occurring product of human ingenuity that is markedly different from naturally products” (*Myriad*, 133 S.Ct. 2107, 2116-2117)

Four Sections



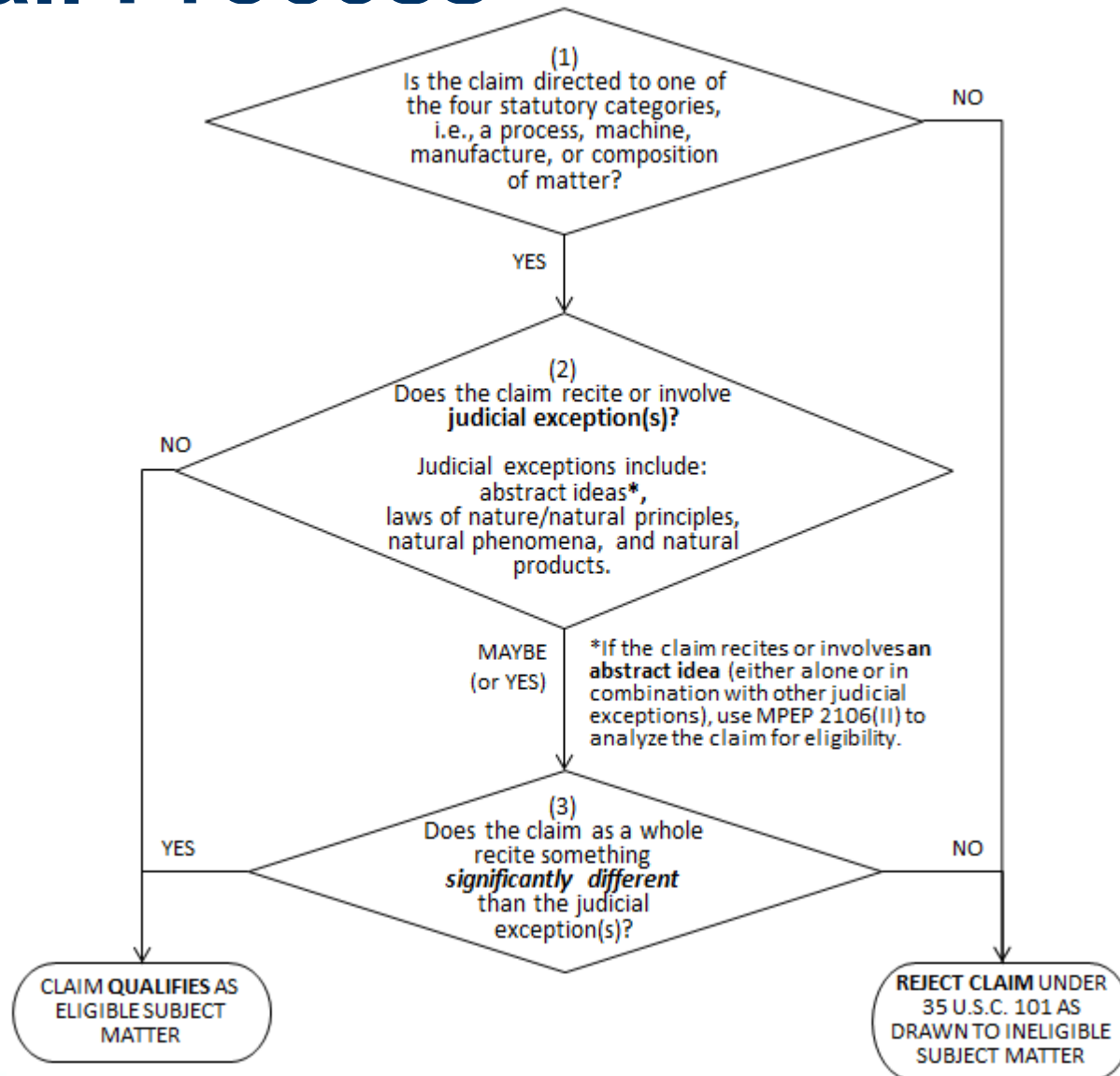
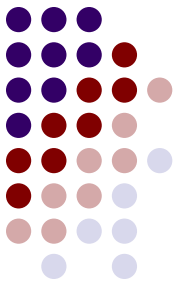
- Part I – discussing the overall process for analyzing subject matter eligibility;
- Part II – explaining how to determine whether the claim as a whole recites eligible subject matter (something significantly different than a judicial exception);
- Part III – providing multiple examples; and
- Part IV – providing a new form paragraph to be used when rejecting claims in accordance with this guidance.

Three Questions for Analysis

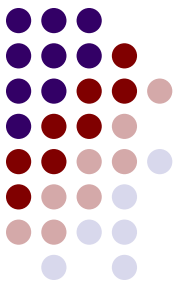


- Question 1: Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture, or composition of matter?
- Question 2: Does the claim recite or involve the judicial exceptions?
- Question 3: Does the claim as a whole recite something *significantly different* than the judicial exception(s)? (MPEP 2016(II), or see factors)

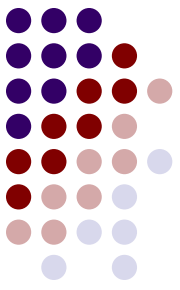
Overall Process



Key issue: does claim recite something “significantly different” than law of nature of natural product.



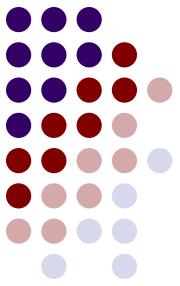
- Consider 5 factors that weigh toward eligibility.
- Consider 2 factors that weigh against eligibility



Judicial Exceptions

- Abstract ideas, laws of nature/natural principles, natural phenomena and natural products
- Includes (but not limited to): chemical compounds, foods, metals and metallic compounds that exist in nature, minerals, natural materials (rocks, sands, soils), nucleic acids, organisms (bacteria, plants and multicellular animals), proteins and peptides

MPEP 2106(II)

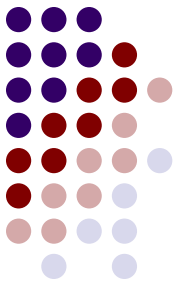


II. JUDICIAL EXCEPTIONS TO THE FOUR CATEGORIES

Step 2: Does the claim wholly embrace a judicially recognized exception, which includes laws of nature, physical phenomena, and abstract ideas, or is it a particular practical application of a judicial exception? See *Bilski v. Kappos*, 561 U.S. ____, 130 S. Ct. 3218, 3225, 95 USPQ2d 1001 (2010) (stating “The Court's precedents provide three specific exceptions to § [101](#)'s broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’”) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 206 USPQ 193, ____ (1980)).

(see handout)

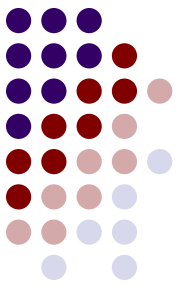
How to Analyze “Significantly Different”



A significant difference can be shown in multiple ways, such as:

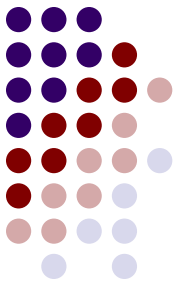
- (1) the claim includes elements or steps in addition to the judicial exception that practically apply the judicial exception in a significant way, e.g., by adding significantly more to the judicial exception; and/or
- (2) the claim includes features or steps that demonstrate that the claimed subject matter is markedly different from what exists in nature (and thus not a judicial exception).

Factors that weigh toward eligibility (significantly different)



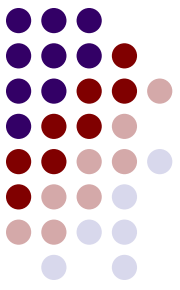
- Non-naturally occurring product; markedly different structure from naturally occurring products
- Additional elements/steps recited that impose meaningful limits on claim scope
- Additional elements/steps that are “more than nominally, insignificantly, or tangentially related to the judicial exception”
- Additional elements/steps that are more than general instructions to apply or use the judicial exception(s)
- Additional elements/steps that include a particular machine or transformation of a particular article
- Additional elements/steps that add a feature that is more than well-understood, purely conventional or routine

Factors that weigh against eligibility (not significantly different)



- Product claims reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products
- Additional elements/steps that are very general, covering all practical applications
- Additional elements/steps that must be used/taken by others to apply the judicial exception
- Additional elements/steps that are well-understood, purely conventional or routine
- Additional elements/steps that are insignificant extra-solution activity
- Additional elements/steps that amount to nothing more than a field of use limitation

Example B: Composition vs. Method Claims, Each Reciting A Natural Product



Claim 1. Purified amazonic acid.

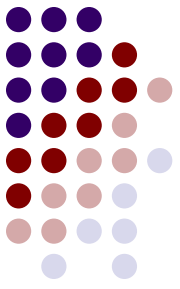
Claim 2. Purified 5-methyl amazonic acid.

Claim 3. 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.

Background

Many have tried and failed to isolate the cancer-fighting chemical from the leaves. Applicant has successfully purified the cancer-fighting chemical from the leaves and has named it amazonic acid. The purified amazonic acid is structurally identical to the amazonic acid in the leaves, but a patient only needs to eat one teaspoon ...Applicant has discovered that amazonic acid is useful to treat colon cancer as well as breast cancer, and applicant has also created a derivative called 5-methyl amazonic acid, which is structurally different from amazonic acid and is functionally different, because it stimulates the growth of hair in addition to treating cancer.

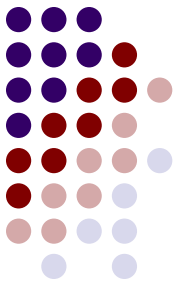




Analysis of Claim 1:

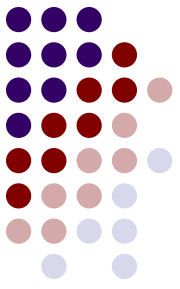
- The answer to Question 3 is “no”, because the claim as a whole does not recite something significantly different than the natural product, e.g., the claim does not include elements in addition to the judicial exception that add significantly more to the judicial exceptions, and also does not include features that demonstrate that the recited product is markedly different from what exists in nature.

Analysis of Claims 2 & 3



- The answer to Question 3 is “yes”, because the claim as a whole recites something significantly different than the natural product, e.g., the claim includes features that demonstrate that the recited product is markedly different from what exists in nature.

Example E: Composition vs. Method Claims, Each Reciting Two Natural Products



Claim 1. 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.

Claim 2. A method of amplifying a target DNA sequence comprising:

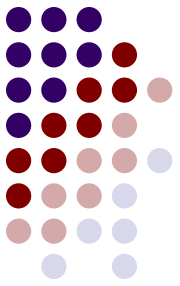
providing a reaction mixture comprising a double-stranded target DNA, the pair of primers of claim 1 wherein the first primer...;

heating the reaction mixture ...;

cooling; and

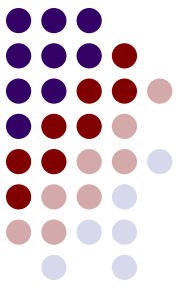
repeating steps (b) and © at least 20 times.

Analysis of Claim 1



- The answers to Questions 1-2 in the above analysis are both “yes”...
- The answer to Question 3 is “no”, ...
- Thus, the first and second primers are isolated nucleic acids. However, even though isolation structurally changes a nucleic acid from its natural state, ...Further, the first and second primers have the same function as their natural counterpart DNA, i.e., to hybridize to their complementary nucleotide sequences.

Example F: Process Claim Involving A Natural Principle And Reciting Natural Products



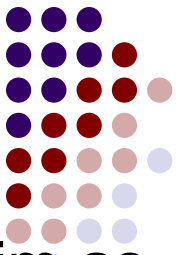
Claim: A method for determining whether a human patient has degenerative disease X, comprising:

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 detecting whether binding occurs between misfolded protein ABC and antibody XYZ using flow cytometry, wherein antibody XYZ binds to an epitope that is present on misfolded protein ABC but not on normal protein ABC; and

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

Analysis



- The answer to Question 3 is also “yes”, because the claim as a whole recites something significantly different than the natural principle, i.e., the claim includes elements in addition to the judicial exceptions (e.g., contacting the blood sample with antibody XYZ, and detecting binding using flow cytometry) that amount to a practical application of the natural principle
- Factor b) is satisfied, because the recitations of using antibody XYZ to bind to protein ABC and detecting the resultant binding using flow cytometry narrow the scope of the claim, so that others are not foreclosed from using other means to detect misfolded protein ABC in order to apply the correlation.