

**UNITED STATES  
PATENT AND TRADEMARK OFFICE**



# **Subject Matter Eligibility From the USPTO's Perspective**

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# Overview

- **Trends in Examination**
  - Arguments from applicants
  - Correctness of decisions
- **Suggestions to Overcome Rejections**
- **Suggestions to Advance Prosecution**

# 35 USC §101

- **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.**

# Judicial Exceptions

- Courts have interpreted 35 USC §101 as implicitly excluding certain subject matter from eligibility.
- Judicial exceptions include
  - Abstract Ideas
  - Laws of Nature
  - Natural Phenomena
    - Products of Nature

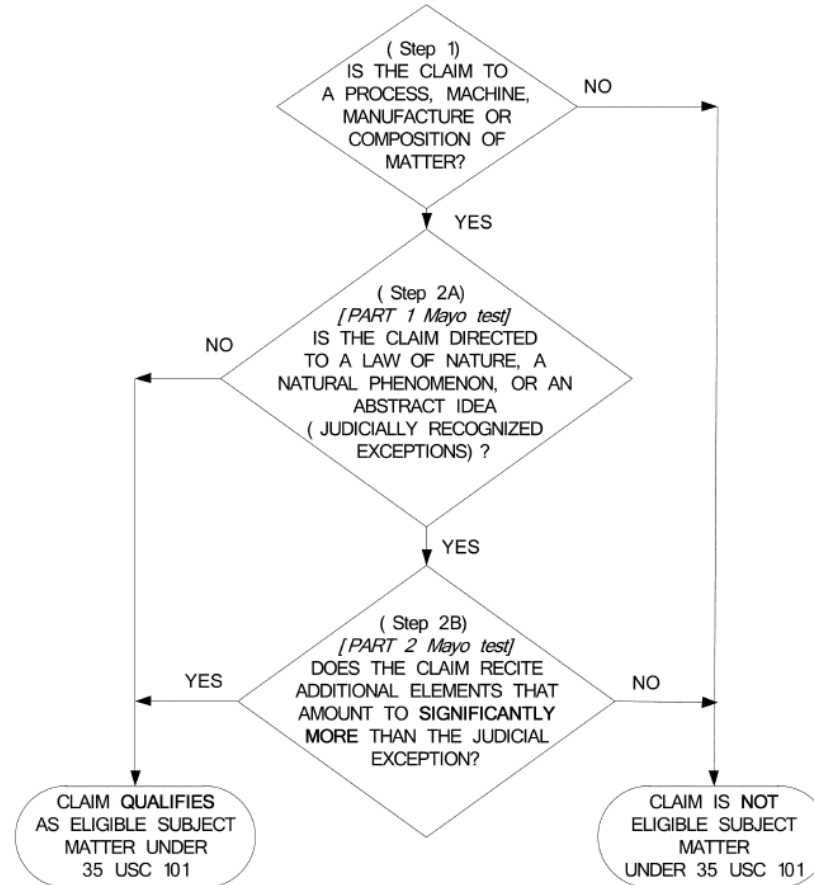
# December 2014 Interim Guidance

- Designed to apply to all claims, independent of technology or statutory class.
- General framework to apply the courts' holdings
- Two-part test from *Mayo*, re-affirmed in *Alice*
- Standard: Is the claim directed to a judicial exception without significantly more?

# December 2014 Interim Guidance

- **Step 1: Is the claim drawn to one of the four statutory categories**
- **Step 2A (Alice/Mayo Step 1): Is the claim directed to a judicial exception?**
- **Step 2B (Alice/Mayo Step 2): Do the elements in addition to the judicial exception add significantly more?**

# December 2014 Interim Guidance





# December 2014 Interim Guidance

- **Ways to find eligibility:**
  - Claim is not directed to a judicial exception (Step 2A).
  - Claim adds significantly more than a judicial exception (Step 2B).

# December 2014 Interim Guidance

- **Ways to find eligibility:**
  - Step 2A:
    - Remove judicial exception from claim
      - Delete correlation / abstract idea step
      - Markedly different product as compared to nature
    - Add steps that improve technology, to shift focus away from the exception (like *McRO*)
  - Step 2B: Add significantly more than judicial exception
    - Elements in addition to the judicial exception, either alone or in combination

# Examination Trends

## Nature-based products

- Peptides vs. full-length proteins
- New or changed property for product of nature, argument regarding concentrations. New/changed property has to be markedly different from nature

# Examination Trends

Nature-based products

- Multiple products together

# Recent PTAB Affirmances

**APPEALED**

- **US 12/426034**

65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4: 1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein

(1) omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty acids are 0.1–30% by weight of total lipids; or

(2) omega-6 fatty acids are not more than 40 grams.

# Recent PTAB Affirmances

**APPEALED**

- **US 13/076117**

61. A standardized extract comprising a plurality of anthocyanins and anthocyanidins, wherein at least about 35% of the composition, by weight, is a plurality of anthocyanins and anthocyanidins and wherein the anthocyanins and anthocyanidins are selected from the group consisting of delphinidin-3-0-sambubioside-5-0-glucoside, delphinidin-3,5-0-diglucoside, cyanidin-3-0-sambubioside-5-0-glucoside, cyanidin-3,5-0-diglucoside, delphinidin-3-0-sambubioside, delphinidin-3-0-glucoside, cyanidin-3-0-sambubioside, and cyanidin-3-0-glucoside; and at least about 15% of the anthocyanins or anthocyanidins or both, by weight, are sugar-free or sugar-containing delphinidins, and wherein the composition is nontoxic.

# Examination Trends

- **Applicant arguments about Diagnostic Methods**
  - Diagnosis is better based on newly-found correlation
  - Newly-found correlation is not routine and conventional
  - Markers aren't routinely measured together
  - "Apply it" limitations, i.e. further comprising treating the patient.
  - If/then claims encompass two embodiments.

# Examination Trends

- FY 2017 OPQA data: 894 office actions reviewed. TC 1600 had 98.3% compliance rate for 35 USC §101 decisions (all aspects).
- 1.2% of cases reviewed were missing a §101 eligibility rejection where one should have been made.
- 3.2% of cases reviewed had an improper eligibility rejection where one should not have been made.



# Suggestions to overcome §101 rejections

- **Nature-based products**
  - Remember BRI. Claim construction will drive the analysis.
  - Point out differences, either structural or functional, between what is claimed and what occurs in nature. Focus on what is there, not what is removed. Markedly different characteristics are needed to distinguish from nature (*Chakrabarty*, *Myriad*)

# Suggestions to overcome §101 rejections

- **Diagnostic methods**
  - Add steps of administering specific treatments to patients diagnosed as having the disease
  - Add steps to performing data gathering in an improved/unconventional manner
  - Pointing out how elements in addition to the judicial exceptions are not conventional, either individually or as an ordered combination.

# Arguments not likely to be persuasive - products

- “Pharmaceutical composition” distinguishes from nature
- Concentrated product has better properties than natural occurring dose
- Does not occur in isolated form

## **Arguments not likely to be persuasive - methods**

- **Diagnosis is better, because claimed marker(s) is better than previous markers.**
- **Score calculation is not routine and conventional.**
- **No art rejection indicates claim cannot be routine and conventional.**

# Arguments not likely to be persuasive - methods

- **Score calculation is not routine and conventional.**
  - Seeing arguments analogizing to McRO: data manipulation is enough to add significantly more.
  - Contrast McRO, where specific rules enabled automation of tasks that previously could not be automated, to generic or conventional data manipulation/display.
  - Data manipulation *can be* an abstract idea judicial exception.

# Advancing Prosecution - Generally

- Office action should walk through the Step 1 / 2A / 2B framework
  - Examiner should point to elements in claim which are judicial exception(s).
    - “Directed to” means recited, described, set forth in claim.
  - Examiner should identify elements in addition to judicial exception.

# Advancing Prosecution - Generally

- **Burden is on office to provide reasoned rationale**
  - Reasoned rationale why product claimed is not markedly different.
  - Reasoned rationale why steps are routine and conventional, individually or as a combination.
  - Examiner can support rationale by citing to case law, the specification or the art.
- **Once reasoned rationale for rejection is presented, burden shifts to applicant to rebut.**

# Advancing Prosecution - Products

- **Argument or evidence that the product as claimed has markedly different structure, function, or properties from nature.**
- **Argument or evidence that the additional elements in the claim provide significantly more than the judicial exception.**



# Advancing Prosecution - Methods

- **Focus arguments and amendments on the additional elements and why they amount to significantly more.**
  - A step or combination of steps, is more than what is routine in the field.
  - A step or combination of steps, is an improvement, or effects a transformation or reduction of a particular article to a different state or thing.
  - Amendments to add or change steps.
- **Point out combination of elements in addition to judicial exception is more than what is routine.**

# Advancing Prosecution - Interviews

- **Work with examiner to walk through the analysis and flowchart.**
  - Examiner should be able to point to the judicial exception in the claim.
- **Request a SPE or §101 specialist sit in on interview.**
  - We provide guidance and assistance with the analysis, do not instruct on the conclusion.
  - Current 101 specialists: Zac Lucas, Marjorie Moran, Dan Kolker.

