

2014 Interim Guidance on Patent Subject Matter Eligibility



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Overview

- **2014 Interim Guidance on Patent Subject Matter Eligibility** Issued Dec. 16, 2014, 79 FR 74618
 - For examination of all claims
 - Comprehensive view of subject matter eligibility under 35 U.S.C. § 101 that incorporates teachings from the full body of relevant case law
 - Reflects recent Supreme Court developments, particularly:
 - Alice Corp.: *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* (2014)
 - Myriad: *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.* (2013)
 - Mayo: *Mayo Collaborative Services v. Prometheus Labs. Inc.* (2012)
 - Bilski: *Bilski v. Kappos* (2010)



Overview

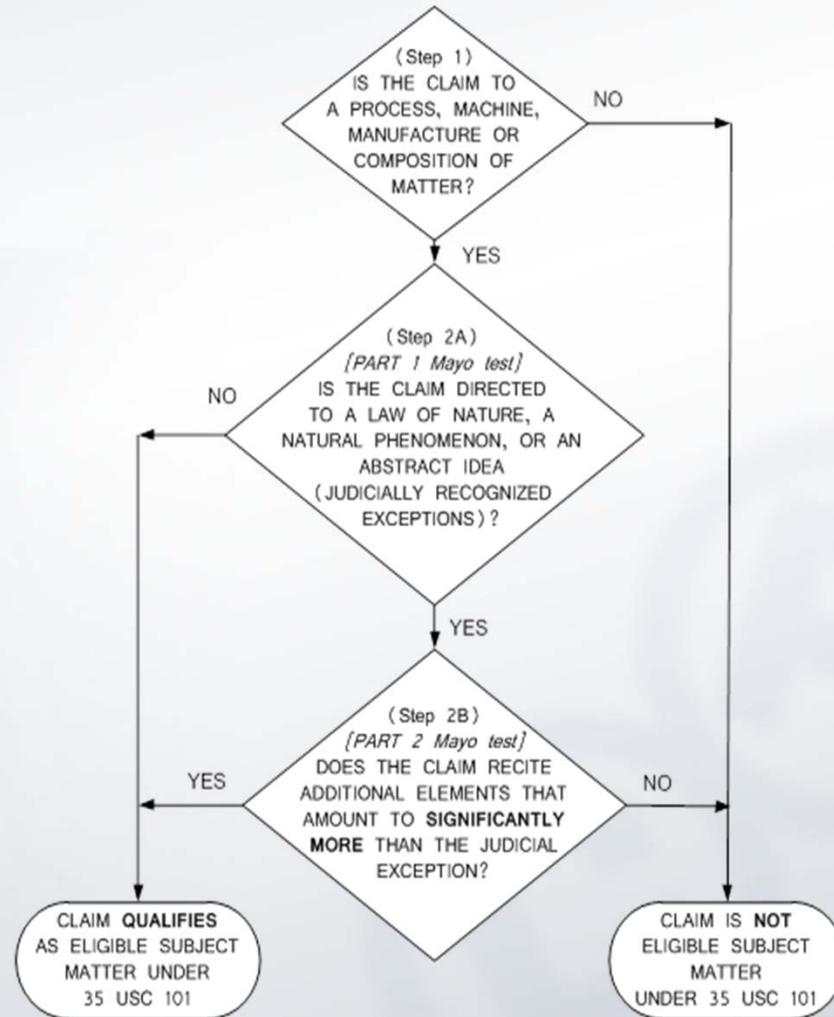
- December 2014 Interim Eligibility Guidance:
 - *Supplements* the June 25, 2014 Preliminary Instructions
 - *Supersedes* the March 4, 2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products



§101 Subject Matter Eligibility Test for Products and Processes

Examiners are to:

- Use the broadest reasonable interpretation (BRI) of the claim
- Analyze the claim as a whole
- Practice compact prosecution by fully examining under 35 U.S.C. 102, 103, 112, and 101 (utility, inventorship, and double patenting) and non-statutory double patenting





Step 1: Statutory Categories

- Step 1: Is the claim directed to a process, machine, manufacture, or composition of matter?
 - The claim must be directed to one of the four patent-eligible subject matter categories
 - *This step remains the same* - see MPEP 2106(I)
 - If no, the claim is **not eligible** and should be rejected as being drawn to non-statutory subject matter
 - If yes, examiners are to proceed to Step 2



Step 2: Judicial Exceptions

- Step 2: This is a two-part analysis to determine whether a claim that is directed to a judicial exception recites additional elements that amount to significantly more than the exception
 - This analysis should be used for all claims
 - *This step differs from previous guidance*
 - MPEP 2106(II) contains a discussion of judicial exceptions



Step 2A: “Directed to” a Judicial Exception

- Step 2A: Is the claim **directed** to a law of nature, a natural phenomenon, or an abstract idea?
 - “Directed to” means the exception is recited in the claim, *i.e.*, the claim **sets forth** or **describes** the exception
 - If no, the claim is **eligible** and examination should continue for patentability
 - If yes, examiners are to proceed to Step 2B to analyze whether the claim as a whole amounts to significantly more than the exception



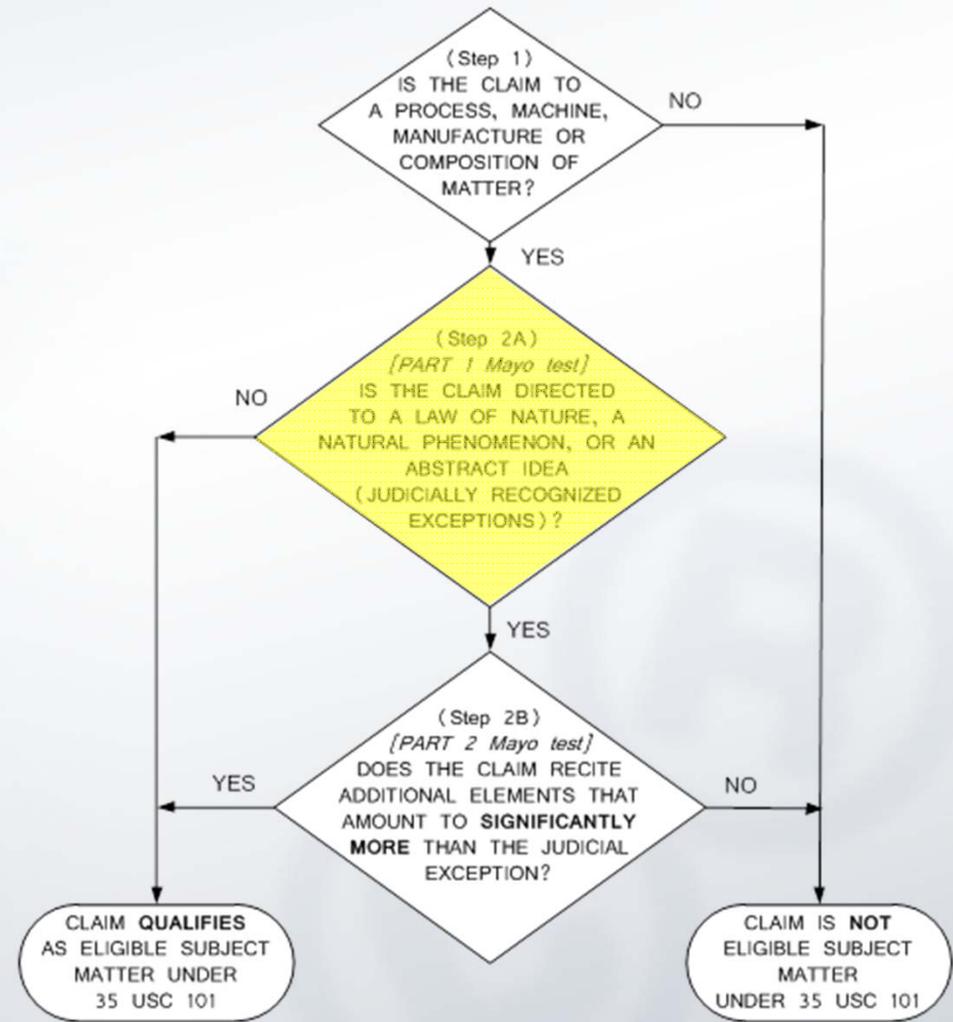
Step 2A: Claims Directed to Nature-Based Products

- Nature-based products are those products derived from natural sources that require closer scrutiny to determine whether they fall within a judicial exception
 - The term “nature-based” as used in the guidance includes both eligible and ineligible products
 - Eligible nature-based products are those that exhibit markedly different characteristics from any naturally occurring counterpart
 - Nature-based products that (i) are naturally occurring or (ii) are not naturally occurring but have characteristics that are not markedly different from a naturally occurring counterpart fall within an exception (law of nature or natural phenomena)



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





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.



Step 2A: Abstract Ideas

- The types of concepts that fall under “Abstract Ideas” have been identified by the courts only by example, and include:
 - Fundamental economic practices
 - Certain methods of organizing human activities
 - Ideas, themselves
 - Mathematical relationships/formulas



Step 2B: Does the Claim as a Whole Amount to Significantly More than the Judicial Exception?

- When a claim is directed to a judicial exception, the analysis proceeds to Step 2B.
- To determine whether any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to **significantly more** than the judicial exception, examiners will:
 - Consider the additional elements claimed with the exception, both individually and as an ordered combination, to ensure that the claim as a whole describes a product or process that **applies** the exception in a meaningful way



Step 2B: “Significantly More” Considerations

Limitations that may be enough to qualify as “significantly more” when recited in a claim with a judicial exception:

- Improvements to another technology or technical field
- Improvements to the functioning of the computer itself
- 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
- Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment



Step 2B: “Significantly More” Considerations

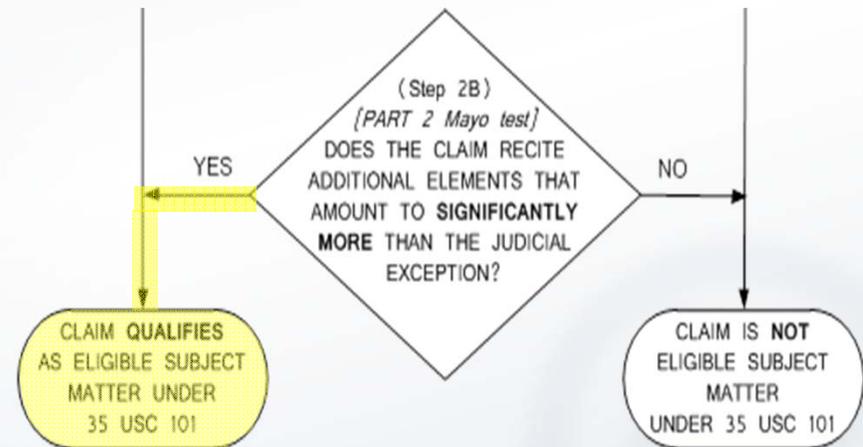
Limitations that were found not to be enough to qualify as “significantly more” when recited in a claim with a judicial exception:

- Adding the words “apply it” (or an equivalent) with the judicial exception, or mere instructions to implement an abstract idea on a computer
- Simply appending well-understood, routine and conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception
- Adding insignificant extrasolution activity to the judicial exception
- Generally linking the use of the judicial exception to a particular technological environment or field of use



Step 2B: If “Yes” → Claim Qualifies as Eligible

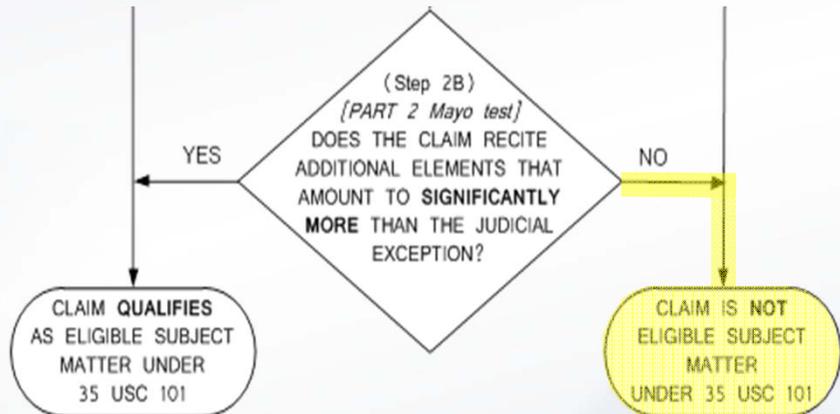
- Step 2B: If the claim as a whole recites additional elements that amount to significantly more than the judicial exception, **it qualifies as eligible subject matter**
 - Eligibility analysis complete
- Examiners should continue to examine under other statutory provisions: 35 U.S.C. 101 (utility, inventorship and double patenting), 102, 103, 112





Step 2B: If “No” → Claim Qualifies as Ineligible

- Step 2B: If the claim as a whole does not recite additional elements that amount to significantly more than the judicial exception, the claim is not eligible. Examiners are to reject the claim under 35 U.S.C. 101
- Examiners should continue examination under other statutory provisions: 35 U.S.C. 101 (utility, inventorship, and double patenting), 102, 103, 112





Streamlined Eligibility Analysis

- For purposes of efficient examination, examiners may use a streamlined analysis for claims that **clearly** do not seek to tie up any judicial exception
 - Such claims may recite an exception, but their eligibility will be self-evident, so no detailed analysis is needed
 - If the examiner has a doubt as to whether the claim seeks coverage for a judicial exception itself, the examiner is to perform a full analysis



Additional Resources

- General page for examination guidance and training materials

<http://www.uspto.gov/patents/law/exam/examguide.jsp>

- Specific page for the December 2014 Interim Eligibility Guidance

http://www.uspto.gov/patents/law/exam/interim_guidance_subject_matter_eligibility.jsp

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



Thank You!