2014 Interim Guidance on Patent Subject Matter Eligibility

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Overview

  
  – 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)
    
    
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
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” \(\rightarrow\) 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!