

# 2014 Interim Guidance on Patent Subject Matter Eligibility





# 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

- This training will cover the core analysis in the 2014 Interim Eligibility Guidance
  - Two-part analysis for eligibility under 35 U.S.C. § 101
  - Sample analysis
  - New form paragraphs
- Separate training modules with detailed examples will address:
  - Examination of claims reciting abstract ideas
  - Examination of claims reciting nature-based products



# Overview

- This 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
  - *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



# Prepare for Analysis – What Has Applicant Invented?

- Before analyzing for eligibility or any other patentability requirement:
  - Review the detailed disclosure and specific embodiments to understand what the applicant has invented
  - Determine the broadest reasonable interpretation (BRI) of the claims
    - Identify the boundaries of protection sought by applicant
    - Understand how the claims relate to and define what applicant has indicated as the invention
- See MPEP 2103 for more information



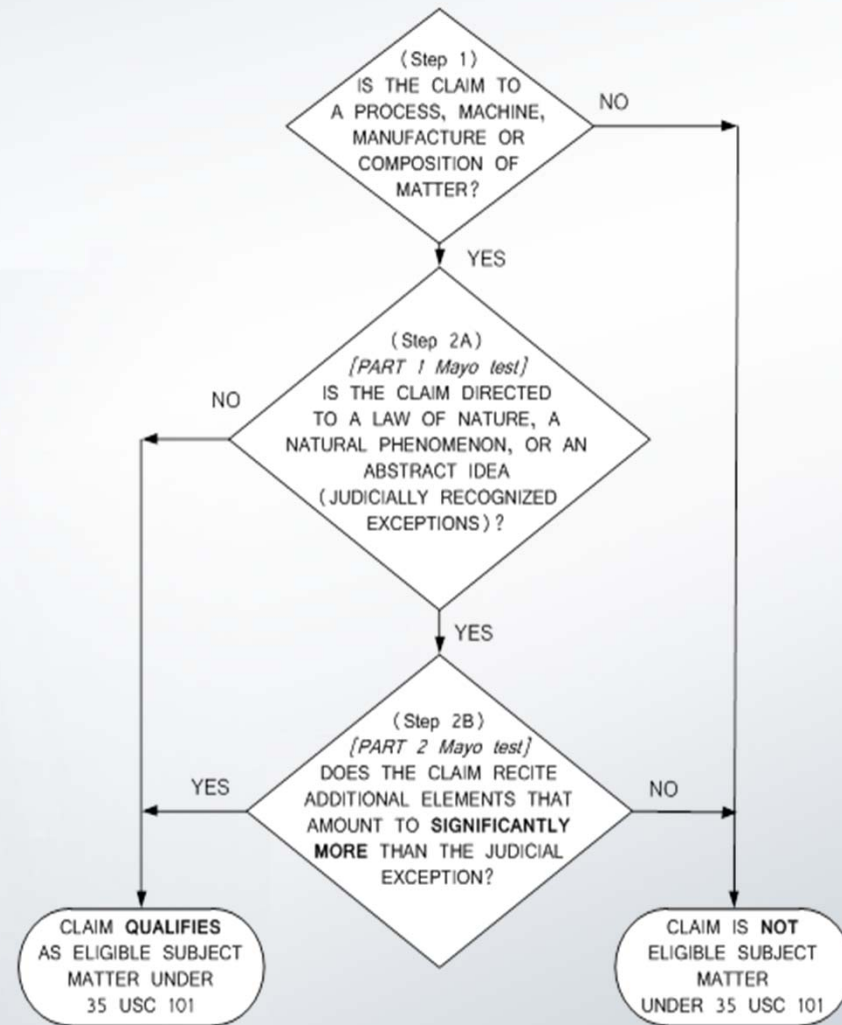


# § 101 Subject Matter Eligibility Test for Products and Processes

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
    - *Use revised form paragraphs 7.05 and 7.05.01*
  - If yes, 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*
  - See MPEP 2106(II) for a discussion of judicial exceptions – commonly called “laws of nature, natural phenomena, and abstract ideas”





## 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?
  - If no, the claim is **eligible** and examination should continue for patentability
    - Ex., a claim to a computer including only a memory and a microprocessor is not directed to an exception
  - If yes, proceed to Step 2B to analyze whether the claim as a whole amounts to significantly more than the exception
    - Claims that are directed to an exception are not necessarily ineligible – they require further analysis to determine eligibility



## Step 2A: “Directed To” an Exception

- “Directed to” means the exception is recited in the claim, *i.e.*, the claim **sets forth** or **describes** the exception
  - *Example:* “A machine comprising elements that operate in accordance with  $F=ma$ .”
  - The claim recites the law of nature that force equals mass times acceleration ( $F=ma$ ) and is therefore directed to an exception
  - Step 2A: YES – Further eligibility analysis needed
- \* If the claim recites an exception, but when viewed as a whole, clearly does not seek to “tie up” the exception, use the “streamlined analysis” discussed at slide 30.



## Step 2A: Not “Directed To” an 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
  - *Example*: “A teeter-totter comprising an elongated member pivotably attached to a base member, having seats and handles attached at opposing sides of the elongated member”
    - This claim is based on the concept of a lever pivoting on a fulcrum, which involves the natural principles of mechanical advantage and the law of the lever
    - However, this claim does not recite these natural principles (Step 2A: NO) and thus is eligible without further analysis



## Step 2A: Directed to a “Judicial Exception”

- Law of Nature, Natural Phenomenon, Abstract Idea
  - These are the labels commonly used by the courts, but there is no bright line between the exceptions. For example, courts have labelled mathematical formulas as both abstract ideas and laws of nature, and have labelled “products of nature” as natural phenomena and laws of nature.
- Identify the exception recited in the claim:
  - The analysis is the same regardless of what the exception is called, so it is sufficient to identify the concept recited in the claim as being at least one type of exception
  - Even narrowly defined exceptions will trigger an eligibility analysis, e.g., a highly detailed mathematical formula is still a judicial exception
  - A claim that recites an exception is not automatically ineligible and will be patent eligible if it passes Step 2B



## Step 2A: Laws of Nature/ Natural Phenomena

- The types of concepts that fall under “Laws of Nature” and “Natural Phenomena” include:
  - Naturally occurring principles
    - Physical, chemical or biological principles, for instance
  - Naturally occurring substances
  - Substances that do not have markedly different characteristics compared to what occurs in nature
- Examples:
  - An isolated DNA
  - A correlation that is the consequence of how a certain compound is metabolized by the body
  - Electromagnetism to transmit signals
  - The chemical principle underlying the union between fatty elements and water





## 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)
- *See Detailed Training on Analyzing Nature-Based Products*



## 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
- When making a rejection, specifically identify the abstract idea (*e.g.*, the claim recites the steps of creating a contractual relationship), instead of categorizing it as a certain type of idea (*e.g.*, economic)



## Step 2A: Examples of Abstract Ideas

- Mitigating settlement risk
- Hedging
- Creating a contractual relationship
- Using advertising as an exchange or currency
- Processing information through a clearinghouse
- Comparing new and stored information and using rules to identify options
- Comparing a patient's gene with the wild-type gene, and identifying any differences that arise
- Using categories to organize, store, and transmit information
- Organizing information through mathematical correlations
- Managing a game of Bingo
- The Arrhenius equation for calculating the cure time of rubber
- A formula for updating alarm limits
- A mathematical formula relating to standing wave phenomena
- A mathematical procedure for converting one form of numerical representation to another



## Step 2A: Abstract Ideas

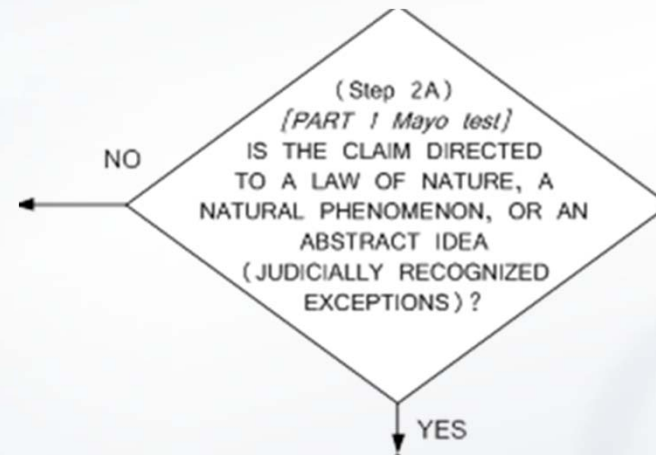
- To identify an abstract idea in a claim, keep in mind what applicant invented
  - Compare the claimed concept to the types of ideas courts have found as abstract
- Remember that software or business methods are not excluded categories of subject matter
  - ‘Software’ is not automatically an abstract idea
  - While some software may include an abstract idea (such as a step that employs a mathematical relationship), further analysis of the claim as a whole would be required to determine eligibility



## Step 2A: YES or NO?

- If the claim is not directed to an exception, the claim is eligible.

– Step 2A: NO



- If the claim is directed to an exception, proceed to Step 2B to determine whether the claim amounts to significantly more than the exception.

– Step 2A: YES





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

- 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
  - Analyze each claim as a whole
  - Consider the additional elements claimed with the exception, both individually and as an ordered combination, to ensure that the claim describes a product or process that **applies** the exception in a meaningful way
  - While this analysis no longer weighs factors, the considerations for significantly more are similar to those in the prior *Bilski* and *Mayo/Myriad* guidance



## Step 2B: Identify the Additional Limitations in the Claim

- Considering the claim **as a whole**, determine whether the claim amounts to significantly more than the recited exception itself
  - The additional elements in the claim must establish **meaningful limitations** on the exception
  - The additional elements must be **more than a drafting effort** designed to monopolize an exception
  - Individual elements when viewed on their own may not appear to add significantly more, but when **viewed in combination** may amount to significantly more than the exception
  - Consider each claim separately based on the particular elements recited therein – claims **do not automatically rise or fall** with similar claims in an application



## 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

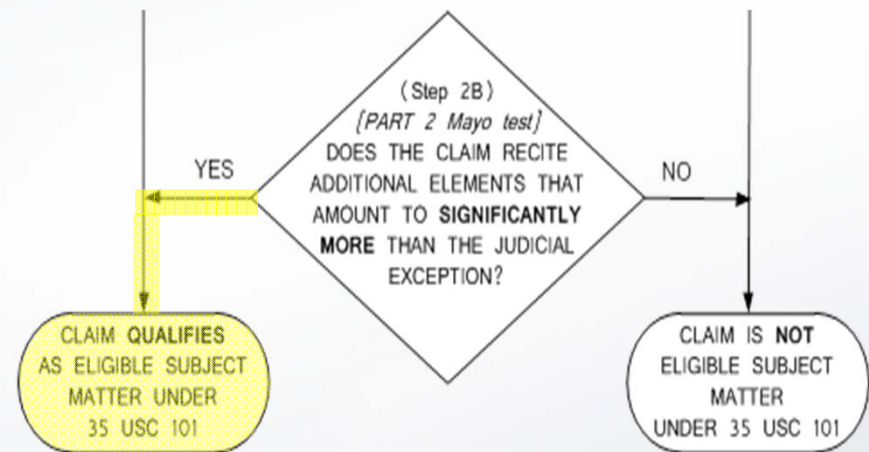
Limitations that were found not to be enough to qualify as “significantly more” when recited in a claim with a judicial exception:

- 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
  - *e.g.*, a claim to an abstract idea requiring no more than a generic computer to perform generic computer functions that are well-understood, routine and conventional activities previously known to the industry
- Adding insignificant extrasolution activity to the judicial exception
  - *e.g.*, mere data gathering in conjunction with a law of nature or abstract idea
- 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

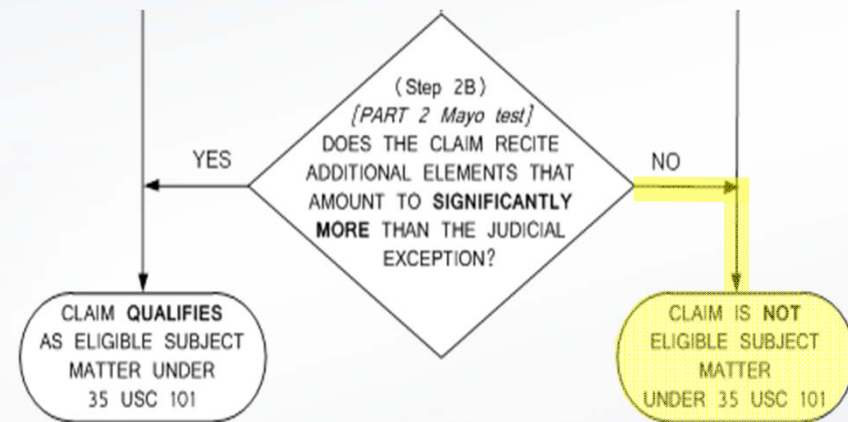






# Step 2B: If “No” → Claim Qualifies as Ineligible

- 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. 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



Use Form ¶¶ 7.05 [revised] and 7.05.015 [new]

*Note: Form ¶¶ 7.05.011, 7.05.012, 7.05.013, and 7.05.014 should no longer be used and will be deleted*



# A Claim Reciting a Plurality of Judicial Exceptions

- Conduct the eligibility analysis for one of the exceptions
- If the claim recites an element or combination of elements that amount to significantly more than that exception, consider whether those additional elements ensure that the claim does not have a preemptive effect for any other claimed exception(s)
  - If Step 2B: YES for one exception, Step 2B is likely satisfied for all exceptions in the claim
  - If Step 2B: NO for one exception, then the claim is ineligible



# Making the § 101 Rejection

- The rejection should include:
  - Identification of the judicial exception by explaining how it is recited in the claim and an explanation of why it is considered an exception
  - Identification of the additional elements in the claim, if there are any, and an explanation of why they do not add significantly more to the exception



# New § 101 Rejection Should Not Be Final

- If the examiner determines that **new** grounds of rejection should be made under § 101 that are not necessitated by applicant's amendment of the claims, the Office action should be non-final
  - Applicant should be given an opportunity to respond to new grounds of rejection for existing claims
- See MPEP 706.07(a) regarding appropriate circumstances for making a rejection final



# New Form Paragraph

- Use new form paragraph 7.05.015 in making a rejection of a claim that is directed to a judicial exception and does not recite additional elements sufficient to ensure that the claim amounts to significantly more than the exception.

Claim [*insert claim number(s)*] rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. Claim [*insert claim number(s)*] is/are directed to [*identify the judicial exception in the claim*]. The claim(s) does/do not include additional elements that are sufficient to amount to significantly more than the judicial exception because [*identify the additional elements and explain why, when considered separately and in combination, they do not add significantly more to the exception*].





# Applicant Response

A proper response to a § 101 rejection based on a failure to claim patent eligible subject matter would be:

- Persuasive arguments/evidence that the claim is not directed to a judicial exception;
- Persuasive arguments/evidence that the additional elements in the claim amount to significantly more than the judicial exception; or
- Claim amendments (e.g., removing or adding elements, or changing existing elements) that cause the claim to not be directed to the judicial exception or amount to significantly more than the judicial exception.



# Streamlined Eligibility Analysis

- For purposes of efficient examination, a streamlined analysis can be used 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 there is doubt as to whether the claim seeks coverage for a judicial exception itself, perform a full analysis
- *See Examples 1 and 2 that follow*



# Streamlined Example 1

1. A hip prosthesis comprising:  
a femoral component and  
an acetabular cup,  
wherein the acetabular cup has  
an inner concave surface for  
engaging the femoral component,  
and an outer convex surface for  
engaging a patient's acetabulum,  
and  
wherein the outer convex surface  
is coated with hydroxyapatite.

- The claim recites a nature-based product (hydroxyapatite is a naturally occurring mineral).
- However, the claim clearly does not seek to tie up the mineral. Instead, the claim is focused on the assembly of the femoral component and the cup that together form the hip prosthesis.
- No need to perform the markedly different characteristics analysis on the mineral.

**The claim qualifies as eligible subject matter without a full analysis.**



# Streamlined Example 2

2. A robotic arm assembly comprising:

- a robotic arm having an end effector that is capable of movement along a predetermined motion path,
- a sensor that obtains movement information about the end effector, and
- a control system that uses the movement information from the sensor to adjust the velocity of the end effector in order to achieve a smooth motion along the predetermined motion path.

- The claim operates using certain mathematical relationships, *e.g.*, velocity is a relationship between the position of an object with respect to time.
- However, the claim clearly does not seek to tie up these mathematical relationships. For example, others are clearly free to use velocity in other applications such as in a radar gun.

**The claim qualifies as eligible subject matter without a full analysis.**



# Case Law Examples

- The following two examples are based on recent Supreme Court cases in which the claims were found ineligible
  - *Mayo v. Prometheus*: claim directed to a law of nature
  - *Alice Corp. v. CLS Bank*: claim directed to an abstract idea
- The analysis is based on the eligibility framework from this guidance





# *Mayo v. Prometheus*

Claim 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.



# Mayo: Analysis

**Step 1: YES**. The claim is directed to a process, which is a statutory category.

**Step 2A: YES**. Judicial Exception?

- The claim *sets forth* the relationships between the concentration in the blood of a thiopurine metabolite (6-thioguanine) and the likelihood that the drug dosage is too low (ineffective to treat patient) or too high (will cause harmful side effects).
  - A human action (administering the drug) is needed to trigger a manifestation of the relationships.
  - The relationships themselves are natural consequences of how the body metabolizes thiopurines, and thus are laws of nature.
- Because the claim recites these laws of nature, it is directed to a judicial exception.



## Mayo: Analysis (cont.)

**Step 2B: NO.** Analyze the claim as a whole, considering the additional limitations individually and as an ordered combination.

- The “wherein” clause simply tells doctors about the laws of nature.
- The other steps of the claim consist of well-understood, routine and conventional activity already engaged in by the scientific community.
  - The “administering” step refers to the pre-existing audience of doctors who use thiopurine drugs to treat patients.
  - The “determining” step tells a doctor to determine the concentration of metabolites in the blood, using whatever process the doctor or laboratory wishes to use.
- Considering these elements as an ordered combination adds nothing significant beyond the sum of their parts taken separately.
- The claim as a whole fails to add significantly more to the exceptions (the laws of nature). The claim is **not eligible**, and should be rejected under 35 U.S.C. § 101.



# Mayo: Sample Rejection

## Use form paragraphs 7.05 and 7.05.015

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. Claim 1 is directed to a law of nature, specifically that the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

The claim does not include additional elements that are sufficient to amount to significantly more than the judicial exception because the “administering” and “determining” steps represent routine data gathering to test for the correlation. Such steps would be routinely used by those of ordinary skill in the art to identify and apply the correlation. Therefore, the additional steps do not add significantly more to the law of nature itself. Claim 1 is ineligible.





# *Alice Corp. v. CLS Bank*

## Representative System Claim:

Claim 26. A data processing system to enable the exchange of an obligation between parties, the system comprising:

a communications controller,

a first party device, coupled to said communications controller,

a data storage unit having stored therein

(a) information about a first account for a first party, independent from a second account maintained by a first exchange institution, and

(b) information about a third account for a second party, independent from a fourth account maintained by a second exchange institution; and

a computer, coupled to said data storage unit and said communications controller, that is configured to

(a) receive a transaction from said first party device via said communications controller;

(b) electronically adjust said first account and said third account in order to effect an exchange obligation arising from said transaction between said first party and said second party after ensuring that said first party and/or said second party have adequate value in said first account and/or said third account, respectively; and

(c) generate an instruction to said first exchange institution and/or said second exchange institution to adjust said second account and/or said fourth account in accordance with the adjustment of said first account and/or third account, wherein said instruction being an irrevocable, time invariant obligation placed on said first exchange institution and/or said second exchange institution.





# Alice Corp.: Analysis

**Step 1: YES.** The claim is directed to a machine (a system), which is a statutory category.

**Step 2A: YES.** Judicial Exception?

- The claim *describes* procedures an intermediary should take in managing “settlement risk” between two parties, i.e., specific details of intermediating settlement. “Settlement risk” is the risk that only one party to an agreed-upon financial exchange will satisfy its obligation.
  - While intermediated settlement is not a preexisting fundamental truth, it is a longstanding commercial practice (a method of organizing human activity).
- Because the claim recites this abstract idea, it is directed to a judicial exception.



## *Alice Corp.: Analysis (cont.)*

**Step 2B: NO.** Analyze the claim as a whole, considering the additional limitations individually and as an ordered combination.

- A programmed computer acts as an intermediary, maintains accounts, obtains data, adjusts account balances, and issues automated instructions.
  - These functions (recordkeeping, obtaining data, adjusting balances, and issuing automated instructions) are basic functions of a computer, and are “well-understood, routine, conventional activit[ies]” previously known to the industry.
  - The recited hardware (communications controller, first party device, data storage device and computer) is generic hardware that nearly every computer will include.
- Considering these elements as an ordered combination adds nothing significant beyond the sum of their parts taken separately.
- The claim as a whole fails to add significantly more to the exceptions (abstract idea). The claim is **not eligible**, and should be rejected under 35 U.S.C. § 101.



# Alice Corp.: Sample Rejection

## **Use form paragraphs 7.05 and 7.05.015**

Claim 26 is rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. Claim 26 is directed to the abstract idea of intermediated settlement. While the claim does not explicitly recite “intermediated settlement”, the concept of “intermediated settlement” is described by the receiving, adjusting, and generating steps in claim 26.

*[Continued on next slide]*



# Alice Corp.: Sample Rejection (cont.)

*[Continued from previous slide]*

The claim does not include additional elements that are sufficient to amount to significantly more than the judicial exception because the computer as recited is a generic computer component that performs functions (*i.e.*, maintaining “shadow accounts”, obtaining data, adjusting account balances, and issuing automated instructions). These are generic computer functions (*i.e.*, record keeping, obtaining data, adjusting balances, and issuing automated instructions) that are well-understood, routine, and conventional activities previously known to the industry. The claim also recites a communications controller, a first party device, and a data storage device, which do not add meaningful limitations to the idea of intermediated settlement beyond generally linking the system to a particular technological environment, that is, implementation via computers. The claim does not amount to significantly more than the underlying abstract idea of intermediated settlement. Accordingly, claim 26 is ineligible.



# Next Steps

- Developing guidance is an ongoing process
  - Updates will be provided based on feedback from the public and the examining corps
    - A public comment period is now open
  - Claim examples are now available to illustrate the analysis set forth in the guidance
    - Nature-based Product Examples are available at:  
[http://www.uspto.gov/patents/law/exam/mdc\\_examples\\_nature-based\\_products.pdf](http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf)
    - Abstract Idea Examples are available at:  
[http://www.uspto.gov/patents/law/exam/abstract\\_idea\\_examples.pdf](http://www.uspto.gov/patents/law/exam/abstract_idea_examples.pdf)
    - Additional examples are being developed
  - Pending cases at the Federal Circuit relating to subject matter eligibility may provide additional information





# Questions and Comments?

Please see your SPE for questions who can direct you to TC subject matter eligibility points of contact (POCs) if needed.

Training Time Code: ATRAIN-0000-090101