

# Biotechnology/Chemical/Pharmaceutical Customer Partnership: Recent Examiner Training and Developments Under 35 USC § 101



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# Recent Developments

- *Mayo Collaborative Services, v. Prometheus Laboratories, Inc. (Mayo)* – Supreme Court, March 20, 2012
  - 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature - July 3, 2012
  - Examiner training on evaluating subject matter eligibility under 35 U.S.C. § 101 - August 2012
- *The Association for Molecular Pathology et al. v. Myriad et al. (AMP)* – Federal Circuit, August 16, 2012
- Next Steps:
  - Issue updated version of MPEP (edition 8, revision 9, 2012) (training uses pre-release version incorporating past guidance)
  - Conduct example based training in areas impacted by law of nature guidance, such as Technology Center 1600



# Examiner Training

- The following initial training was given to examiners in Technology Center 1600
- Follow on training with specific claim examples will be given beginning in Oct. 2012
- Citations to the MPEP refer to the pre-release version of Edition 8, Revision 9, 2012



# 35 U.S.C. § 101

## The Requirements Under 35 U.S.C. § 101



# 35 U.S.C. § 101

## § 101 - Inventions Patentable:

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.



## 35 U.S.C. §101: Subject Matter Eligibility

- The four statutory categories of invention:
  - Process, Machine, Manufacture, or Composition of Matter and Improvements Thereof
- The courts have interpreted the categories to *exclude*:
  - “Laws of nature, natural phenomena, and abstract ideas”
    - These three terms are typically used by the courts to cover the basic tools of scientific and technological work, such as scientific principles, naturally occurring phenomena, mental processes, and mathematical algorithms.
  - Called “Judicial Exceptions”
    - At times, other terms are used to describe the judicial exceptions.



## 35 USC §101: Statutory Categories

- Claimed inventions that do not fall within the statutory categories are not eligible for patenting.
  - Identification of one particular category is not necessary for eligibility.
  - A claim may satisfy the requirements of more than one category.
    - Ex., a claim to a bicycle may satisfy both machine and manufacture categories.
  - Analyze based on the broadest reasonable interpretation of the claim as a whole.
    - A claim that covers both eligible and ineligible subject matter should be rejected under §101.
- Claimed inventions that fall within the statutory categories must still avoid the judicial exceptions to be eligible.
  - For example, a process claim would be ineligible if drawn to an abstract idea with no practical application.



# Living Subject Matter and Human Organisms

- Nonnaturally occurring non-human multicellular living organisms, including animals, are eligible.
  - MPEP 2105
- Claims directed to or encompassing a human organism are ineligible (and always have been).
  - Section 33(a) of the America Invents Act 2011
  - 35 U.S.C. 101
  - See also *Animals – Patentability*, 1077 Off. Gaz. Pat. Office 24 (April 21, 1987)



# 35 U.S.C. §101: Judicial Exceptions

- The basic tools of scientific and technological work are not patentable, even when claimed as a process, machine, manufacture or composition of matter.
- The “judicial exceptions” to eligibility are typically identified as:
  - abstract ideas (e.g., mental processes)
  - laws of nature (e.g., naturally occurring correlations)
  - natural phenomena (e.g., wind)
- Also sometimes called or described as, for example:
  - physical phenomena, scientific principles, systems that depend on human intelligence alone, disembodied concepts, mental processes and disembodied mathematical algorithms and formulas.



## Judicial Exceptions: Basic Analysis

- Determine whether the claim **as a whole** is directed to a judicial exception (law of nature, natural phenomenon, or abstract idea).
  - Analyze the claim taking into account all of the elements or steps, to determine whether the exception has been practically applied.
    - A claim directed to a practical application may be eligible.
  - Determine whether the claim covers all substantial applications of the exception and thereby forecloses future innovation based on the law of nature, natural phenomenon, or abstract idea.
    - A claim directed solely to the exception itself is not eligible.



# Judicial Exceptions: Analysis

- For the eligibility analysis, identify whether the claim is directed to a product (a machine, manufacture or composition of matter) or a process.
  - The form of the claim is not determinative of eligibility, but may assist in performing the analysis.
  - Use the broadest reasonable interpretation of the claim as a whole. MPEP 2111
  - Keep in mind what the applicant considers to be the invention.



# Process Claims: Analysis for Judicial Exceptions

- For process claims with a **law of nature** as a limitation, use the three inquiries that ultimately ask whether the claim amounts to more than a law of nature plus the general instructions to simply “apply it”.
  - MPEP 2106.01 (Ed. 8, Rev. 9, 2012)
  - 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Law of Nature, issued July 3, 2012
- For other process claims, eligibility should be evaluated using the factors relating to **abstract idea** determination.
  - MPEP 2106(II)(B) (Ed. 8, Rev. 9, 2012)
  - Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, issued July 27, 2010



## Process Claims: Laws of Nature

# NATURAL PRINCIPLE

A law of nature,  
a natural phenomenon, or  
a naturally occurring relation or  
correlation



## Process Claims – Laws of Nature

- A claim that attempts to patent a law of nature *per se* is ineligible.
  - Determine eligibility by using the three essential inquiries described in MPEP 2106.01.
  - This analysis should be used for process claims that include a law of nature (something that occurs without the hand of man) as a limitation of the claim.
    - Process claims that do not include a law of nature as a limitation of the claim should be analyzed using the “Bilski” factors. MPEP 2106(II)(B)

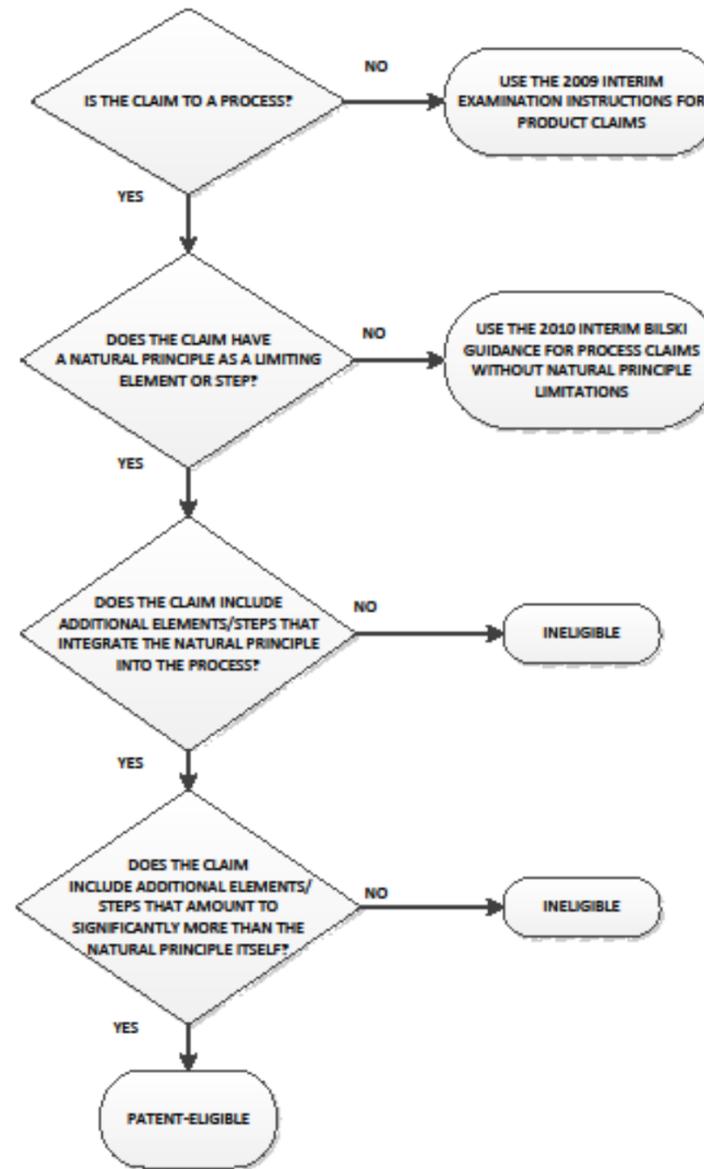


# Laws of Nature - Three Essential Inquiries

1. Is the claim directed to a **process**, defined as an act, or a series of acts or steps?
2. Does the claim focus on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation (collectively referred to as a natural principle)?
  - Is the natural principle a **limiting feature** of the claim?
3. Does the claim include **additional elements/steps**, or a combination of elements/steps, that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself?
  - Is the claim **more than** a law of nature + the general instruction to simply “apply it”?

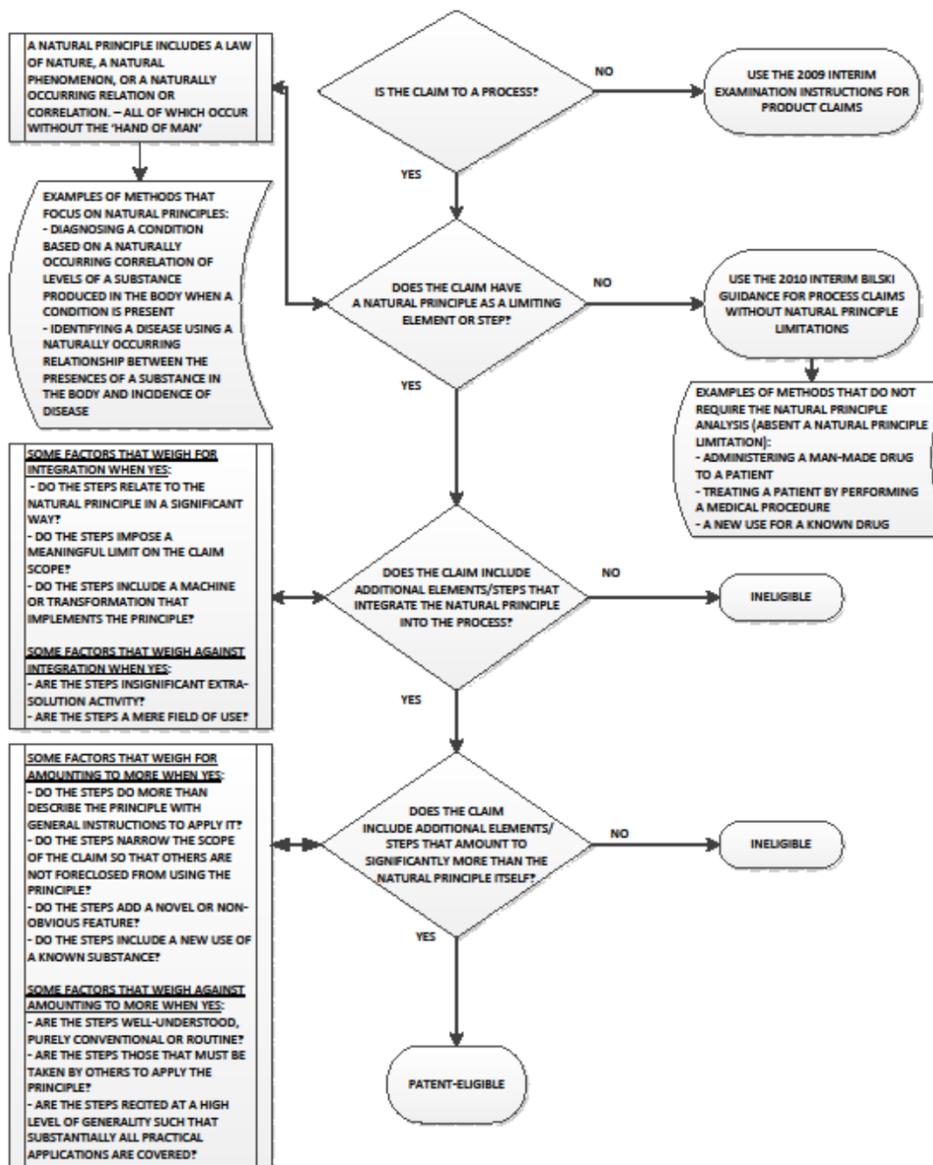


# Process Flowchart





## SUBJECT MATTER ELIGIBILITY ANALYSIS FOR CLAIMS TO LAWS OF NATURE/NATURAL PRINCIPLES



THIS IS A SUPPLEMENT TO THE 2012 INTERIM PROCEDURE FOR SUBJECT MATTER ELIGIBILITY ANALYSIS OF PROCESS CLAIMS INVOLVING LAWS OF NATURE ISSUED JULY 3, 2012



# Natural Principle as a Claim Limitation

- A natural principle is the handiwork of nature and occurs without the hand of man.
  - Includes a correlation that occurs naturally when a man-made product, such as a drug, interacts with a naturally occurring substance, such as blood, because the correlation exists in principle apart from any human action.
  - Example: the relationship between blood glucose levels and diabetes is a natural principle.



# Natural Principle as a Claim Limitation

- Examples of methods that focus on natural principles:
  - Diagnosing a condition based on a naturally occurring correlation of levels of a substance produced in the body when a condition is present.
  - Identifying a disease using a naturally occurring relationship between the presence of a substance in the body and incidence of disease.



# Natural Principle as a Claim Limitation

- Claims that do not include a natural principle as a claim limitation do not need to be analyzed under this procedure.
- Examples that do not include such limitations:
  - Administering a man-made drug to a patient.
  - Treating a patient by performing a medical procedure.
  - A new use for a known drug.



# Natural Principles and Additional Elements/Steps

- Inquiry 3 – Part I:
  - Does the claim include additional elements/steps that integrate the natural principle into the process?
    - It is not necessary that every step show integration.
    - If the additional elements/steps do not integrate the natural principle, there is no practical application.
  - If not, the claim fails the analysis and should be rejected.



# Natural Principles and Additional Elements/Steps

- Integration evaluation - some of the factors that weigh in favor of integration when YES:
  - Do the steps relate to the natural principle in a significant way?
  - Do the steps impose a meaningful limit on the claim scope?
  - Do the steps include a machine or transformation that implements the principle?



## Natural Principles and Additional Elements/Steps

- Integration evaluation - some of the factors that weigh against integration when YES:
  - Are the steps insignificant extra-solution activity?
  - Are the steps mere field of use?
    - A claim to diagnosing an infection that recites the step of (1) correlating the presence of a certain bacterium in a person's blood with a particular type of bacterial infection with only the additional step of (2) recording the diagnosis on a chart would not be eligible because the step of recording the diagnosis on the chart is extra-solution activity that is unrelated to the correlation and does not integrate the correlation into the invention.



## Natural Principles and Additional Elements/Steps

- Inquiry 3 – Part II:
  - Does the claim include additional elements/steps that amount to significantly more than the natural principle itself?
    - Is the claim as a whole more than a natural principle plus the general instructions to simply “apply it”?
  - If not, the claim fails the analysis and should be rejected.



## Natural Principles and Additional Elements/Steps

- “Amounts to significantly more” evaluation - some of the factors that weigh in favor of amounting to more when YES:
  - Do the steps do more than describe the principle with general instructions to apply it?
  - Do the steps narrow the scope of the claim so that others are not foreclosed from using it?
  - Do the steps add a novel or non-obvious feature?
  - Do the steps include a new use of a known substance?



## Natural Principles and Additional Elements/Steps

- “Amounts to significantly more” evaluation - some of the factors that weigh against amounting to more when YES:
  - Are the steps well-understood, purely conventional or routine?
  - Are the steps those that must be taken by others to apply the principle?
  - Are the steps recited at a high level of generality such that substantially all practical applications are covered?



# Process Claims – Laws of Nature Rejection

- After conducting the three inquiries, if the claim is drawn to an ineligible law of nature/natural principle, reject the claim under 35 U.S.C. § 101 as being directed to non-statutory subject matter.
  - Use Form ¶¶ 7.04, 7.05, 7.05.013.
  - See MPEP 2106.01



# Laws of Nature - Examples

The following example of § 101 determinations illustrate how the three inquiries are applied under the law of nature analysis.



## Example:

Background: There is a naturally occurring correlation between a patient having rheumatoid arthritis and their level of rheumatoid factor IgM.

- Increased levels of IgM shown by increased binding of an anti-IgM antibody indicate a higher likelihood of a patient being diagnosed with rheumatoid arthritis.
- For purposes of this example, anti-IgM antibody XYZ does not occur in nature and is novel and non-obvious.
- Assays M and N can be used for comparing the anti-IgM antibody to a control sample, but are not routinely used together.



# Example, Claim 1:

1. A method of determining the increased likelihood of having or developing rheumatoid arthritis in a patient, comprising the steps of:
  - obtaining a serum sample from a patient;
  - contacting the serum sample with an anti-IgM antibody; and
  - determining that the patient has rheumatoid arthritis or an increased likelihood of developing rheumatoid arthritis based upon the increased binding of the anti-IgM antibody to IgM rheumatoid factor in the serum sample.



# Example, Claim 1: Analysis

**Inquiry 1:** The claim is a process claim.

**Inquiry 2:** The claim includes the limitation of the correlation between rheumatoid arthritis and the rheumatoid factor IgM, which is a natural principle/law of nature.

**Inquiry 3:** All of the additional steps integrate or relate to the correlation.

- The additional steps of obtaining and contacting are well-understood steps that are routinely conducted to analyze a serum sample.
- The steps are claimed at a high level of generality.
- Considered as a whole, the steps taken together amount to no more than recognizing the law of nature itself.



## Example, Claim 2:

2. The method of claim 1 further comprising:
  - providing a positive control sample; and
  - contacting the positive control sample with an anti-IgM antibody,wherein the step of determining that the patient has rheumatoid arthritis or increased likelihood of developing rheumatoid arthritis comprises a step of comparing the anti-IgM antibody in the serum sample to the positive control sample.



# Example: Claim 2 Analysis

**Inquiry 1:** The claim is a process claim

**Inquiry 2:** The claim includes the limitation of the correlation between rheumatoid arthritis and the rheumatoid factor IgM, which is a natural principle/law of nature.

**Inquiry 3:** The additional steps relate to using a control sample in the testing and therefore directly integrate the law of nature.

- However, these steps are typically taken by those in the field to perform testing of a sample and do not add anything substantial to the process of claim 1.
- Considered as a whole, the steps taken together amount to no more than recognizing the law of nature itself.



## Example, Claim 3:

3. The method of claim 1 or 2, wherein the anti-IgM antibody is antibody XYZ.



# Example, Claim 3: Analysis

**Inquiry 1:** The claim is a process claim.

**Inquiry 2:** The claim includes the limitation of the correlation between rheumatoid arthritis and the rheumatoid factor IgM, which is a natural principle/law of nature.

**Inquiry 3:** The additional step of using a particular anti-IgM antibody (especially one that is not known in the field) integrates the law of nature as it is used to express the principle and is also sufficient to limit the application of the law of nature.

- The claim does not cover substantially all practical applications of the correlation between IgM and arthritis, because the claim is limited to those applications that use the antibody XYZ.
- Considered as a whole, the steps taken together amount to a practical application of the law of nature.



## Example, Claim 4:

4. The method of claim 2, wherein the step of comparing the anti-IgM antibody to the positive control sample includes performing assay M and then performing assay N.



# Example, Claim 4: Analysis

**Inquiry 1:** The claim is a process claim.

**Inquiry 2:** The claim includes the limitation of the correlation between rheumatoid arthritis and the rheumatoid factor IgM, which is a natural principle/law of nature.

**Inquiry 3:** The additional step of comparing the anti-IgM antibody to the positive control sample includes performing assay M and then performing assay N, which integrates the correlation into the process.

- Assays M and N are not routinely used together.
- The claim does not cover substantially all practical applications of testing for the correlation.
- Considered as a whole, the steps taken together amount to a practical application of the law of nature.



# Example: Summary

- Claim 1 should be rejected as being directed to non-statutory subject matter.
- Claim 2 should be rejected as being directed to non-statutory subject matter.
- Claim 3 is a patent-eligible practical application of the recited law of nature.
- Claim 4 is a patent-eligible practical application of the recited law of nature.

Further examination is needed to determine patentability of each of the claims under §§ 101 (utility and double patenting), 102, 103, and 112, and non-statutory double patenting.



# Process Claims Abstract Ideas

## Abstract Ideas



## Process Claims - Abstract Ideas

- A claim that attempts to patent an abstract idea *per se* is ineligible.
  - Determine eligibility by weighing factors that indicate whether the claim represents a practical application of an abstract idea or the abstract idea itself.
  - The factors include inquiries from the machine-or-transformation test, which is a useful investigative tool, but not the determinative test for eligibility.



# Abstract Ideas - Factors that Weigh Toward Eligibility

- **Recitation of a machine or transformation (either express or inherent).**
  - Machine or transformation is particular.
  - Machine or transformation meaningfully limits the execution of the steps.
  - Machine implements the claimed steps.
  - The article being transformed is particular.
  - The article undergoes a change in state or thing (e.g., objectively different function or use).
  - The article being transformed is an object or substance.



# Abstract Ideas - Factors that Weigh Toward Eligibility

- **The claim is more than a mere statement of a concept.**
  - The claim describes a particular solution to a problem to be solved.
  - The claim implements a concept in some tangible way.
  - The performance of the steps is observable and verifiable.



# Abstract Ideas - Factors that Weigh Against Eligibility

- **No recitation of a machine or transformation (either express or inherent).**
- **Insufficient recitation of a machine or transformation.**
  - Involvement of machine, or transformation, with the steps is merely nominally, insignificantly, or tangentially related to the performance of the steps, e.g., data gathering, or merely recites a field in which the method is intended to be applied.
  - Machine is generically recited such that it covers any machine capable of performing the claimed step(s).
  - Machine is merely an object on which the method operates.
  - Transformation involves only a change in position or location of article.
  - “Article” is merely a general concept.



# Abstract Ideas

## Examples of General Concepts

- **Examples of general concepts include, but are not limited, to:**
  - Basic economic practices or theories (e.g., hedging, insurance, financial transactions, marketing);
  - Basic legal theories (e.g., contracts, dispute resolution, rules of law);
  - Mathematical concepts (e.g., algorithms, spatial relationships, geometry);
  - Mental activity (e.g., forming a judgment, observation, evaluation, or opinion);
  - Interpersonal interactions or relationships (e.g., conversing, dating);
  - Teaching concepts (e.g., memorization, repetition);
  - Human behavior (e.g., exercising, wearing clothing, following rules or instructions);
  - Instructing “how business should be conducted.”



# Process Claims – Abstract Idea Rejection

- After weighing the factors, if the claim is drawn to an ineligible abstract idea, reject the claim under 35 U.S.C. § 101 as being directed to non-statutory subject matter.
  - Use Form ¶¶ 7.04, 7.05, 7.05.011.
  - See MPEP 2106(II)(B)



# 35 U.S.C. § 101

Thank you.