

## Evaluating Subject Matter Eligibility Under 35 USC § 101 Biotech/Medical Device Customer Partnership January 29<sup>th</sup>, 2013



Technology Centers 1600 and 3700; Office of Patent  
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## Current Examination Guidance

- Examination instructions for subject matter eligibility
  - MPEP 2104, 2105, 2106 (Ed. 8, Rev. 9, 2012)
  - Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101, issued August 24, 2009
  - Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, issued July 27, 2010
  - 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Law of Nature, issued July 3, 2012
  - All Examination Guidance Materials are posted at:  
<http://www.uspto.gov/patents/law/exam/examguide.jsp>



# Overview

- The Requirements of 35 U.S.C. § 101
- The Four Statutory Categories
- The Judicial Exceptions

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# 35 U.S.C. § 101

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

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## 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.

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## 35 U.S.C. § 101: Requirements

### Three Requirements in § 101:

- “A” patent – means only one patent granted for each invention.
  - Basis for statutory double patenting rejections. See MPEP 804.
- “Useful” – the invention must have a specific, substantial, and credible utility.
  - “Utility” requirement – see MPEP 2107 for Utility Guidelines.
- “Process, Machine, Manufacture, Composition of Matter”
  - “Subject matter eligibility” - these categories, as interpreted by the courts, limit the subject matter that is eligible for patenting.

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

## Subject Matter Eligibility- Statutory Categories of Invention

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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.

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## 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 claim's broadest reasonable interpretation.
    - 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 that meets the definition under 35 U.S.C. § 100 (a series of steps) would be ineligible if drawn to an abstract idea with no practical application.

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## Statutory Categories

- Example of claim that does not fit within the categories:
 

A **paradigm** for marketing software, comprising:  
 a marketing company that markets software from a plurality of different independent and autonomous software companies, and carries out and pays for operations associated with marketing of software for all of said different independent and autonomous software companies, in return for a contingent share of a total income stream from marketing of the software from all of said software companies, while allowing all of said software companies to retain their autonomy. (*In re Ferguson*; claim 24)
- “Paradigm” is a business model for an intangible marketing company, not:
  - Process: series of steps; 35 U.S.C. § 100
  - Machine: a concrete thing consisting of parts or devices
  - Manufacture: an article produced from raw or prepared materials
  - Composition of matter: a composition of substances or composite article

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## Statutory Categories

# Living Subject Matter and Human Organisms

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## 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)

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## 35 USC §101: Statutory Categories

# Failure to Claim Within A Statutory Category

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## 35 USC §101: Statutory Categories Rejection

- If a claim, under the broadest reasonable interpretation, covers an invention that does not fall within the four statutory categories, a rejection under 35 U.S.C. §101 must be made.
  - Use Form ¶¶ 7.04, 7.05, 7.05.01.
    - Explain why the claimed invention does not satisfy any of the categories. See MPEP 2106(I) for definitions of the categories.
  - Use Form ¶ 7.04.01 for human organisms.
- If a claim falls within at least one of the four statutory categories, proceed to the judicial exception analysis.

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## 35 U.S.C. §101

# Judicial Exceptions – Laws of Nature, Natural Phenomena, and Abstract Ideas

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## 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.

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## 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.

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## Process Claims: Analysis for Judicial Exceptions

PROCESSES or METHODS

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## 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

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## Process Claims: Laws of Nature

### NATURAL PRINCIPLE

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

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## 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)

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## 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”?

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## 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.

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## 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.

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## 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.

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## 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.

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## 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?

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## 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.

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## 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.

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## 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?

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## 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?

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## Natural Principles and Additional Elements/Steps

- Example:

A claim that uses the natural disinfecting properties of sunlight would require additional steps beyond merely exposing an item requiring disinfection to sunlight to be eligible.

  - The additional steps could involve:
    - constructing a sanitizing device that uses ultraviolet light for disinfection with steps that **integrate** the ultraviolet light into the device and **are sufficient to confine** the use of the ultraviolet light to a particular application (not so broad as to cover all practical ways of applying ultraviolet light).

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## 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

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## Laws of Nature - Examples

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

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## Example 1

- Background:

It is a well-documented phenomenon that white light, such as sunlight, affects a person's mood. The mood changes are correlated to a change in neuronal activity due to white light striking a person's photoreceptors eliciting a chemical reaction that starts an electrical response in the receptor cells modulating neuronal circuitry.

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## Example 1, Claim 1:

1. A method for treating a psychiatric behavioral disorder of a patient, the disorder associated with a level of neuronal activity in a neural circuit within a brain of the patient, the method comprising:
  - exposing the patient to *sunlight* to alter the level of neuronal activity in the neural circuit to mitigate the behavioral disorder.

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## Example 1, Claim 1: Analysis

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

**Inquiry 2:** The claim focuses on the use of a law of nature that is a limitation of the claim (the effect of white light on a person's neuronal activity related to mood).

**Inquiry 3:** The additional step of exposing a patient to sunlight integrates the law of nature into the claimed process.

- This is no more than the law of nature + telling people to “apply it.”
- The claim recites no significant limitations on the specific manner by which the law of nature is to be applied.

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## Example 1, Claim 2:

2. A method for treating a psychiatric behavioral disorder of a patient, the disorder associated with a level of neuronal activity in a neural circuit within a brain of the patient, the method comprising:

exposing the patient to *a source of white light* to alter the level of neuronal activity in the neural circuit to mitigate the behavioral disorder.

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## Example 1, Claim 2: Analysis

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

**Inquiry 2:** The claim focuses on the use of a law of nature that is a limitation of the claim (the effect of white light on a person's neuronal activity related to mood).

**Inquiry 3:** The additional step of exposing a patient to white light integrates the law of nature into the claimed process

- The claim is broad enough to cover sunlight.
  - Sunlight is “a source of white light.”
- This is no more than the law of nature + telling people to “apply it”.
- No significant limitations on the law of nature.

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## Example 1, Claim 3:

3. A method for treating a psychiatric behavioral disorder of a patient, the disorder associated with a level of neuronal activity in a neural circuit within a brain of the patient, the method comprising:

*providing a light source that emits white light;*  
*filtering the ultra-violet (UV) rays from the white light;*  
*positioning the patient adjacent to the light source at a distance between 30-60 cm for a predetermined period ranging from 30-60 minutes to expose photosensitive regions of the brain of the patient to the filtered white light to mitigate the behavioral disorder.*

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## Example 1, Claim 3: Analysis

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

**Inquiry 2:** The claim focuses on the use of a law of nature that is a limitation of the claim (the effect of white light on a person's neuronal activity related to mood).

**Inquiry 3:** The additional step of exposing a patient to white light integrates the law of nature into the claimed process.

- Additional step of filtering the UV rays from the white light manipulates the white light.
- Additional step of positioning the patient relates to conditions of patient exposure.
- These steps are sufficient to narrow the claim to an eligible application, as together they amount to substantially more than the law of nature.

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## Example 1: 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 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.

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## Example 2:

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.

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## Example 2, 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.

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## Example 2, 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.

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## Example 2, 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.

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## Example 2: 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.

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## Example 2, Claim 3:

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

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## Example 2, 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.

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## Example 2, 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.

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## Example 2, 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.

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## Example 2: 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.

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Thank you.

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