

INTERIM EXAMINATION INSTRUCTIONS FOR EVALUATING SUBJECT MATTER ELIGIBILITY UNDER 35 U.S.C. § 101

I. OVERVIEW

The state of the law with respect to subject matter eligibility is in flux. The following interim instructions are for examination guidance pending a final decision from the Supreme Court in *Bilski v. Kappos*. These examination instructions do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections that are appealable. Consequently, any perceived failure by Office personnel to follow these instructions is neither appealable nor petitionable.

35 U.S.C. § 101 establishes the threshold for patentability by setting requirements for subject matter that is eligible for patenting. To pass the threshold eligibility inquiries of § 101 for patent protection, a claimed invention must be directed to statutory subject matter and must be useful. (§ 101 also provides the basis for the prohibition against double patenting.) Thus, under § 101 two separate patent eligibility considerations are raised: (1) subject matter and (2) utility.

To evaluate utility or the real world use of an invention, follow the detailed “utility” guidelines in MPEP 2107. Following the utility guidelines, the claims and supporting disclosure must be reviewed to evaluate whether the claimed invention has an asserted or well-established utility that is specific, substantial and credible. The usefulness of the invention must be commensurate with the broadest reasonable interpretation of the claimed invention in light of the specification as it would be interpreted by one of ordinary skill in the art.

This document includes instructions for evaluating subject matter eligibility and, for the interim, should be used for examining claims under 35 U.S.C. § 101 for subject matter eligibility. Since the subject matter eligibility guidelines set forth in MPEP 2106 were prepared, case law has developed that has necessitated revision to the guidelines. The following instructions supersede previous guidance on subject matter eligibility that conflicts with the Instructions, including MPEP 2106(IV), 2106.01 and 2106.02.

Subject Matter Eligibility: There are two criteria for determining subject matter eligibility and both must be satisfied. The claimed invention (1) must be directed to one of the four statutory categories, and (2) must not be wholly directed to subject matter encompassing a judicially recognized exception, as defined below. The following two step analysis is used to evaluate these criteria.

1. **Step 1: Is the claim directed to one of the four patent-eligible subject matter categories: process, machine, manufacture, or composition of matter?**

The subject matter of the claim must be directed to one of the four subject matter categories. If it is not, the claim is not eligible for patent protection and should be rejected under § 101, for at least this reason.

A summary of the four categories of invention, as they have been defined by the courts, are:

- i. Process – an act, or a series of acts or steps that are tied to a particular machine or apparatus or transform a particular article into a different state or thing.
- ii. Machine – a concrete thing, consisting of parts, or of certain devices and combination of devices. This includes every mechanical device or combination of

mechanical powers and devices to perform some function and produce a certain effect or result.

iii. Manufacture – an article produced from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.

iv. Composition of matter – all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids, for example.

Non-limiting examples of claims that are not directed to one of the statutory categories:

- i. Transitory forms of signal transmission (for example, a propagating electrical or electromagnetic signal *per se*).
- ii. A naturally occurring organism.
- iii. A human *per se*.
- iv. A legal contractual agreement between two parties.
- v. A game defined as a set of rules.
- vi. A computer program *per se*.
- vii. A company.

A claim that covers both statutory and non-statutory embodiments (under the broadest reasonable interpretation of the claim when read in light of the specification and in view of one skilled in the art) embraces subject matter that is not eligible for patent protection and therefore is directed to non-statutory subject matter. Such claims fail the first step and should be rejected under § 101, for at least this reason. For example, a claim to a computer readable medium that can be a compact disc or *a carrier wave* covers a non-statutory embodiment and therefore should be rejected under § 101 as being directed to non-statutory subject matter.

If the claimed invention is clearly not within one of the four categories, it is not patent eligible. However, when the claim fails under Step 1 and it appears from applicant's disclosure that the claim could be amended to be directed to a statutory category, Step 2 below should still be conducted.

2. Step 2: Does the claim wholly embrace a judicially recognized exception, which includes abstract ideas, mental processes or substantially all practical uses (pre-emption) of a law of nature or a natural phenomenon, or is it a particular practical application of a judicial exception?

In addition to the terms abstract ideas, mental processes, laws of nature and natural phenomena, judicially recognized exceptions have been described using various other terms, including physical phenomena, scientific principles, systems that depend on human intelligence alone, disembodied concepts, and disembodied mathematical algorithms and formulas, for example. The exceptions reflect the courts' view that the basic tools of scientific and technological work are not patentable.

The claimed subject matter must not be wholly directed to a judicially recognized exception. If it is, the claim is not eligible for patent protection and should be rejected under § 101. However,

a claim that is limited to a particular practical application of a judicially recognized exception is eligible for patent protection. A “practical application” relates to **how** a judicially recognized exception is applied in a real world product or a process, and not merely to the result achieved by the invention. When subject matter has been reduced to a particular practical application having a real world use, the claimed practical application is evidence that the subject matter is not abstract, not purely mental and does not encompass substantially all uses (pre-emption) of a law of nature or a natural phenomenon.

II. PARTICULAR PRACTICAL APPLICATION

A. Machines, manufactures, and compositions of matter (products)

If the claimed product falls within one of the three product categories of invention and does not recite judicially excepted subject matter, e.g., an abstract idea, a mathematical algorithm, a law of nature, or a natural phenomenon, it qualifies as eligible subject matter. If a judicial exception is recited in the claim, it must be determined if the judicially excepted subject matter has been practically applied in the product.

Eligible machines, manufactures, and compositions of matter are non-naturally occurring products typically formed of tangible elements or parts that embody a particular or specific, tangible practical application of the invention. Thus, for these product categories, a particular practical application is often self-evident based on the claim limitations that define the tangible embodiment. This is because an idea that is tangibly applied to a structure is no longer abstract, and a law of nature or natural phenomenon that is practically applied to a structure is limited to that particular application of the concept. For example, a cup is the tangible application of the abstract idea of containing a liquid and is one limited embodiment of that idea (which is no longer abstract). As another example, a magnetic door latch is the tangible application of the concept of magnetism and does not wholly embrace the concept of magnetism but, rather, is one limited application of the concept.

A claim that includes terms that imply that the invention is directed to a product, for instance by reciting “a machine comprising...”, but fails to include tangible limitations in accordance with its broadest reasonable interpretation is not limited to a practical application, but rather wholly embraces or encompasses the concept upon which the invention is based. This is impermissible as such claim coverage would extend to every way of applying the abstract idea, law of nature or natural phenomenon.

A claim that includes judicially excepted subject matter and whose broadest reasonable interpretation is directed to a man-made tangible embodiment (i.e., structure) with a real world use is limited to a practical application (the subject matter has been practically applied). The reason is that the claim as a whole must be evaluated for eligibility in the same manner that a claim as a whole is evaluated for patentability under §§ 102, 103 and 112.

Once a practical application has been established, the limited occurrence of preemption must be evaluated to determine whether the claim impermissibly covers substantially all practical applications of the judicially excepted subject matter. If so, the claim is not patent-eligible. If the claim covers only a particular practical application of the judicially excepted subject matter, it is patent eligible.

Judicially excepted subject matter is often claimed as descriptive material. Descriptive material should be evaluated to determine if the material has a functional relationship to the underlying structure in order to evaluate whether it creates a patentable distinction over the prior art or whether it is merely non-functional descriptive material that creates no patentable distinction. For example, printed matter on an object or mere data (e.g., music) stored in a memory is typically non-functional descriptive material that would not create a patentable distinction over the prior art. Conversely, a printed circuit board or a computer programmed with executable instructions is typically construed as a base structure combined with functional descriptive material that could create a patentable distinction over the prior art.

The following examples show the difference between a tangible embodiment that is evidence of a particular practical application and an abstract concept that has no practical application.

(a) A claim that is directed to a machine comprising a plurality of structural elements that work together in a defined combination based on a mathematical relationship, such as a series of gears, pulleys and belts, possesses structural limitations that show that it is a tangible embodiment, providing evidence that the mathematical relationship has been applied (a practical application). Additionally, that tangible embodiment is limited by the claimed structure and would not cover all substantial practical uses of the mathematical relationship. The claim would be eligible for patent protection.

(b) On the other hand, a claim that is directed to a machine (“What is claimed is a machine that operates in accordance with $F=ma$.”) and includes no tangible structural elements under the broadest reasonable interpretation, covers the operating principle based on a mathematical relationship with no limits on the claim scope. Thus, as no tangible embodiment is claimed, there would be no evidence of a practical application. The claim would wholly embrace the mathematical concept of $F=ma$ and would not be eligible subject matter.

(c) As another example, a claim to a non-transitory, tangible computer readable storage medium *per se* that possesses structural limitations under the broadest reasonable interpretation standard to qualify as a manufacture would be patent-eligible subject matter. Adding additional claim limitations to the medium, such as executable instructions or stored data, to such a statutory eligible claim would not render the medium non-statutory, so long as the claim as a whole has a real world use and the medium does not cover substantially all practical uses of a judicial exception. The claim as a whole remains a tangible embodiment and qualifies as a manufacture. As explained above, the additional claim limitations would be evaluated in terms of whether they distinguish over the prior art.

B. Processes (methods)

A process claim, to be statutory under § 101, must pass the machine-or-transformation test (M-or-T test), which ensures that the process is limited to a particular practical application. Thus, not every claimed method qualifies as a statutory process. The test ensures that the process is not simply claiming an abstract idea, a mental process or substantially all practical uses of (pre-empting) a law of nature or a natural phenomenon.

In accordance with the **M-or-T test**, the claimed process must:

- (1) be tied to a particular machine or apparatus (machine implemented); or
- (2) particularly transform a particular article to a different state or thing.

A method claim that does not require machine implementation or does not cause a transformation will fail the test and should be rejected under § 101.

However, the mere presence of a machine tie or transformation is not sufficient to pass the test. When a machine tie or transformation has been identified, it must be further determined that the tie is to a **particular** machine or the particular transformation is of a **particular** article.

Additionally, the particular machine tie or particular transformation must meet two corollaries to pass the test for subject matter eligibility. First, the use of the particular machine or transformation of the particular article must impose a **meaningful limit** on the claim's scope. So, a machine tie in only a field-of-use limitation would not be sufficient. Second, the use of the particular machine or the transformation of the particular article must involve **more than insignificant "extra-solution" activity**. If the machine or transformation is only present in a field-of-use limitation or in a step that is only insignificant "extra-solution" activity, the claim fails the M-or-T test, despite the presence of a machine or a transformation in the claim.

Using the terms within the machine-or-transformation test:

A "machine" is a concrete thing, consisting of parts, or of certain devices and combination of devices. This includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. This definition is interpreted broadly to include electrical, electronic, optical, acoustic, and other such devices that accomplish a function to achieve a certain result. The machine should implement the process, and not merely be an object upon which the process operates. The claim should be clear as to how the machine implements the process, rather than simply stating "a machine implemented process". The machine limitations should make clear that the use of the machine in the claimed process imposes a meaningful limitation on the claim's scope. An "apparatus" does not have a significantly different meaning from a machine and can include a machine or group of machines or a totality of means by which a designated function or specific task is executed.

An "article" includes a physical object or substance. The physical article or substance must be particular, meaning it can be specifically identified. An article can also be electronic data that represents a physical object or substance. For the test, the data should be more than an abstract value. Data can be specifically identified by indicating what the data represents, the particular type or nature of the data, and/or how or from where the data was obtained.

"Transformation" of an article means that the "article" has *changed* to a different state or thing. Changing to a different state or thing usually means more than simply using an article or changing the location of an article. A new or different function or use can be evidence that an article has been transformed. Manufactures and compositions of matter are the result of transforming raw materials into something new with a different function or use. Purely mental processes in which thoughts or human based actions are "changed" are not considered an eligible transformation. For data, mathematical manipulation *per*

se has not been deemed a transformation; but, transformation of electronic data has been found when the nature of the data has been changed such that it has a different function or is suitable for a different use.

A “particular” machine or apparatus or transformation of a “particular” article means that the method involves a *specific* machine or article, not any and all machines or articles. This ensures that the machine or transformation imposes real world limits on the claimed method by limiting the claim scope to a particular practical application.

For computer implemented processes, the “machine” is often disclosed as a general purpose computer. In these cases, the general purpose computer may be sufficiently “particular” when programmed to perform the process steps. Such programming creates a new machine because a general purpose computer, in effect, becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software. To qualify as a particular machine under the test, the claim must clearly convey that the computer is programmed to perform the steps of the method because such programming, in effect, creates a special purpose computer limited to the use of the particularly claimed combination of elements (i.e., the programmed instructions) performing the particularly claimed combination of functions. If the claim is so abstract and sweeping that performing the process as claimed would cover substantially all practical applications of a judicial exception, such as a mathematical algorithm, the claim would not satisfy the test as the machine would not be sufficiently particular.

A “field-of-use” limitation does not impose *actual boundaries* on the scope of the claimed invention. A field-of-use limitation merely indicates that the method is for use in a particular environment, such as “for use with a machine” or “for transforming an article”, which would not require that the machine implement the method or that the steps of the method cause the article to transform. A field-of-use limitation does not impose a meaningful limit on the claimed invention.

Insignificant “extra-solution” activity means activity that is not central to the purpose of the method invented by the applicant. For example, gathering data to use in the method when all applications of the method would require some form of data gathering would not impose a meaningful limit on the claim.

III. Interim Examining Procedure for Subject Matter Eligibility Determinations

Based on the guidance above, the following procedure should be followed during examination:

1. Determine the meaning of the claim.

Initially, the meaning of the claim as a whole must be determined using the “broadest reasonable interpretation” standard, which requires that the claims be given their broadest reasonable interpretation consistent with the specification and consistent with the interpretation that those skilled in the art would reach. See MPEP 2111 for a complete discussion of claim interpretation. See also MPEP 2111.02 for how to determine whether a preamble limits a claim.

2. Determine if the claim as a whole falls within one of the four categories of invention (Step 1 in section I above).

When the claim has been properly interpreted, conduct Step 1 to determine if the claim falls within one of the four statutory categories of invention. If the claim covers subject matter outside of the four categories, reject the claim because it is directed to non-statutory subject matter. Additionally, in the interest of compact prosecution, if it appears from the specification that the claim could be amended to fall within a statutory category, it is suggested to proceed to Step 2 to evaluate practical application.

3. Determine if the claim as a whole is directed to a particular practical application of a judicial exception (abstract idea, law of nature or natural phenomenon) or a judicial exception in its entirety (Step 2 in section I above).

a. Products (see the attached flowchart and the discussion above regarding practical application):

When no judicially excepted subject matter is present in a claim and the claim satisfies Step 1, the subject matter of the claim is statutory (patent-eligible).

When a judicially recognized exception is present in the claim, determine if the claim recites structural limitations for it to qualify as a practical application of the judicial exception. A man-made tangible embodiment with a real world use is evidence of a practical application. If the claim does not recite a tangible embodiment (has no practical application), reject the claim as being directed to non-statutory subject matter. If the claim recites a tangible embodiment, the next step is to confirm that the claim does not cover substantially all practical uses of the judicial exception (the limited occurrence of preemption). When the claim is limited to a particular practical application (i.e., no preemption is found), the claim is directed to statutory subject matter and is eligible. If preemption is found because substantially all practical uses of the judicial exception are covered, the claim should be rejected under § 101 because it is directed to non-statutory subject matter.

b. Processes (see the attached flowchart and the discussion above regarding practical application):

For ease of implementation of this interim guidance, conduct the machine-or-transformation test for all method claims. For purposes of efficiency, it is recommended that the claim be first evaluated for the presence of the prong (M or T) most likely to be satisfied in the particular technological field because once one prong is satisfied, it is not necessary to evaluate the claim under the other prong. For example, in the mechanical and electrical arts, it may be more likely that a process is machine implemented, while in the chemical arts it may be more likely that a process results in a transformation of a substance.

Using the broadest reasonable interpretation of the claim, identify a machine or transformation, either explicitly or inherently, in the claim.

If no machine or transformation is present, reject the claim because it is directed to non-statutory subject matter as it does not qualify as a statutory process and state on the record that no machine or transformation is present in the claim. Additional explanation should be provided if it could be argued that a machine or transformation is inherent to the claim but is not required under the broadest reasonable interpretation.

If a machine or transformation is present, determine if the machine or article is “particular”. If the machine or article transformed covers all machines or transformation of all articles and/or cannot be specifically identified, it is not “particular”. Reject the

claim because it is directed to non-statutory subject matter as it does not qualify as a statutory process. State on the record why the machine or article is not “particular”.

If a particular machine or transformation of a particular article is found, confirm that the particular machine or transformation meets the two corollaries. (1) Confirm that the use of the particular machine or the transformation of the particular article imposes a meaningful limitation on the claim’s scope by, for example, being present in more than a mere field-of-use limitation. (2) Confirm that the use of the particular machine or the transformation of the particular article involves more than insignificant extra-solution activity. If a particular machine or transformation is not found and it appears from applicant’s disclosure that the claim could be amended to include a particular machine or transformation, in the interest of compact prosecution, the corollaries should also be addressed.

If the corollaries are confirmed, the claim is a statutory process. If the corollaries are not met, reject the claim because it is directed to non-statutory subject matter as it does not qualify as a statutory process. State on the record why the machine or transformation is not adequate to pass the test (e.g., the method does not pass the machine-or-transformation test as the [identify the particular machine or transformation] [does not impose a meaningful limit on the claim’s scope or merely involves extra-solution activity in this method] because [provide specific reasons]).

When the machine or article is inherently, and not explicitly, required by the claimed method, and the examiner believes that the record of the prosecution as a whole does not make clear that the method involves a particular machine or a particular article, the examiner should identify the inherent machine on the record. The record should also be clear as to which step (or steps) invokes the machine or article. Such reasoning may be stated on the record, preferably as early as possible during prosecution. Such reasoning, if provided, will assist in understanding the broadest reasonable interpretation given to the claim during examination.

Confirm that the machine-or-transformation test was conducted correctly by considering whether the method is so abstract and sweeping as to have no real world application or pre-empts substantially all practical uses of a mathematical algorithm, a law of nature or a natural phenomenon. In either case, the claim would be ineligible and should not have passed the M-or-T test.

4. When the subject matter eligibility analysis is concluded, continue full examination on the merits of the claims, including evaluating utility under § 101, statutory and non-statutory double patenting, compliance with § 112, novelty under § 102, and non-obviousness under § 103.