

EVALUATING SUBJECT MATTER ELIGIBILITY UNDER 35 U.S.C. §101

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35 USC 101

Relevant Decisions

- [In re Nuijten, 84 USPQ2d 1495 \(Fed. Cir. 2007\)](#)
- [In re Comiskey, 89 USPQ2d 1641 \(Fed. Cir. 2009\)](#)
- [In re Bilski, 88 USPQ2d 1385 \(Fed. Cir. 2008\)](#)
- [Prometheus Laboratories Inc. v. Mayo Collaborative Services, 92 USPQ2d 1075 \(Fed. Cir. 2009\)](#)



SUMMARY

- The Instructions supersede previous guidance on subject matter eligibility that conflicts with the Instructions, including MPEP 2106(IV), 2106.01 and 2106.02, as of 8/24/09.
 - To determine subject matter eligibility, follow the “Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101”. See: http://www.uspto.gov/web/offices/pac/dapp/opla/2009-08-25_interim_101_instructions.pdf.
- Product claims are evaluated to determine if the claim is wholly directed to a judicial exception.
 - Functional/nonfunctional descriptive material (FDM/NFDM) is evaluated for patentable distinction over the prior art. See MPEP 2112.01(III).
- **All** process (method) claims are evaluated with the M-or-T test.



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CLAIM EVALUATION: STEP 1

- Determine whether the claim is directed to one of the four patent-eligible subject matter categories:
 - Process, Machine, Manufacture, Composition of Matter
- If not in one of the four categories, the claim is not eligible.
 - Examples of claims that are not eligible are claims directed to:
 - Transitory signals *per se*,
 - humans *per se*,
 - a company *per se*,
 - or a set of instructions *per se*
 - (such as a game or software *per se*)



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CLAIM EVALUATION: STEP 2

- A claim satisfying Step 1 is subject-matter eligible under 101 unless it wholly embraces a judicially recognized exception.
- Does the claim wholly embrace a judicially recognized exception?
 - Abstract Idea
 - Law of Nature
 - Natural Phenomena
 - The exceptions also include, for example:
 - Mental Processes
 - Mathematical Algorithms
 - Scientific Principles
- **If the claim is directed to a judicial exception itself, it is NOT eligible.**
- **A particular practical application of a judicial exception IS eligible.**



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PRODUCT CLAIM ANALYSIS

- Begin with the broadest reasonable interpretation (BRI) of the claim in view of the specification consistent with the interpretation those skilled in the art would reach. MPEP 2111
- Product Focus:
 - Does the claim meet definitions of machine, manufacture or composition of matter?
 - Is there a judicial exception recited in the claim?



COMPUTER-READABLE MEDIA

Additional information

- The functional/non-functional distinction is not an inquiry under 101. The 101 inquiry is whether a claim directed to one of the four statutory categories is wholly directed to a judicial exception.
- A tangible medium including a computer program should be evaluated to determine if there is a functional relationship between the computer program and the medium for purposes of distinguishing over prior art, not for subject matter eligibility.

SUBJECT MATTER ELIGIBILITY TEST

PRODUCT FLOWCHART

To M1

GO TO PROCESS
FLOWCHART TO TEST
FOR PRACTICAL
APPLICATION

IS THE CLAIM TO A PROCESS,
MACHINE, MANUFACTURE OR
COMPOSITION OF MATTER?

NO

YES

IS IT A
PROCESS CLAIM?

YES

NO

DOES THE CLAIM
RECITE AN ABSTRACT IDEA,
LAW OF NATURE OR NATURAL
PHENOMENON
(JUDICIALLY RECOGNIZED
EXCEPTIONS)?

NO

YES

IS THE CLAIM
AS A WHOLE DIRECTED
TO A PRACTICAL APPLICATION
OF THE ABSTRACT IDEA, LAW OF NATURE
OR NATURAL PHENOMENON?

NO

*A MAN-MADE TANGIBLE EMBODIMENT
WITH A REAL WORLD USE IS
EVIDENCE OF A PRACTICAL
APPLICATION.*

YES

DOES THE CLAIM COVER
SUBSTANTIALLY ALL PRACTICAL
APPLICATIONS OF THE EXCEPTION?
(THE LIMITED OCCURRENCE OF PREEMPTION)

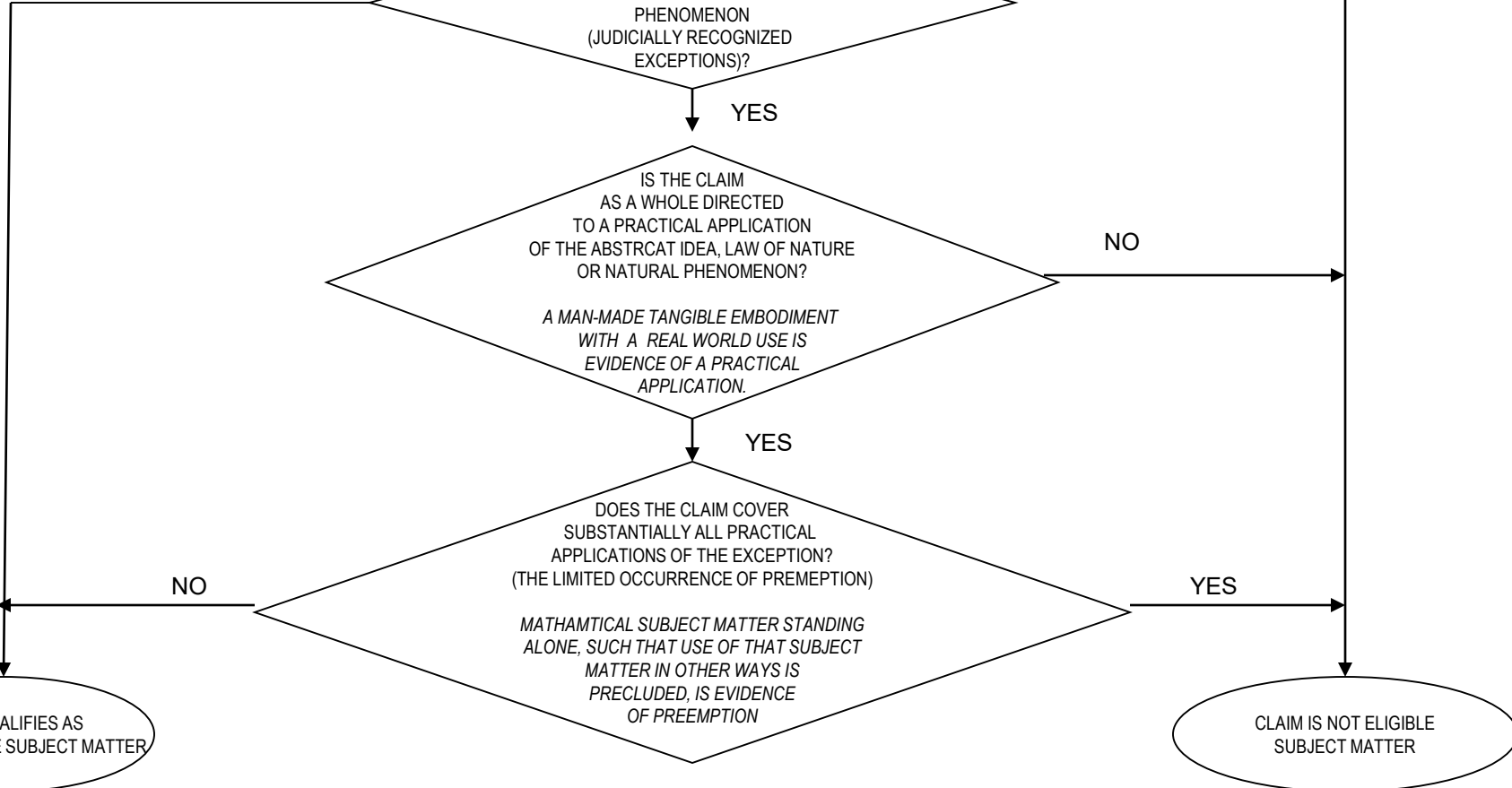
NO

YES

*MATHAMTICAL SUBJECT MATTER STANDING
ALONE, SUCH THAT USE OF THAT SUBJECT
MATTER IN OTHER WAYS IS
PRECLUDED, IS EVIDENCE
OF PREEMPTION*

CLAIM QUALIFIES AS
PATENT ELIGIBLE SUBJECT MATTER

CLAIM IS NOT ELIGIBLE
SUBJECT MATTER





Product Example 1

- Claim: A computer system for determining similarity of two peptides comprising:
 - a receiving module which receives peptide sequence information;
 - an alignment module for aligning received peptide sequences;
 - and a calculating module for calculating a degree of similarity between the aligned peptide sequences.
- BRI: The claim is directed to series of instructions, or a program per se. The specification discloses a computer, computer readable media, and programs for comparing sequences of peptides. The instructions for the program disclosed in the specification exactly reflect the claimed “modules.” Under the broadest reasonable interpretation, in view of the specification and the general knowledge in the art, the claimed “system” consists of a computer program that may exist apart from a computer or tangible media.



Product Example 1, continued

- Analysis: The claim is nominally directed to a product; i.e. a computer system.
 - The claim does not recite any structural limitations. In view of the BRI, the claim encompasses a program, per se. Programs per se do not fall into one of the statutory categories of invention.
- This claim is not patent eligible.



35 U.S.C. § 101

M or T Test and Process Claims

- A process claim, to be statutory under 35 U.S.C. § 101, must pass the machine or transform test (M or T test), which ensures that the process is limited to a particular practical application.
- The test ensures that the process is not simply claiming an abstract idea, mental process or substantially all practical uses of (preempting) a law of nature or natural phenomenon.



35 U.S.C. § 101

M or T Test and Process Claims

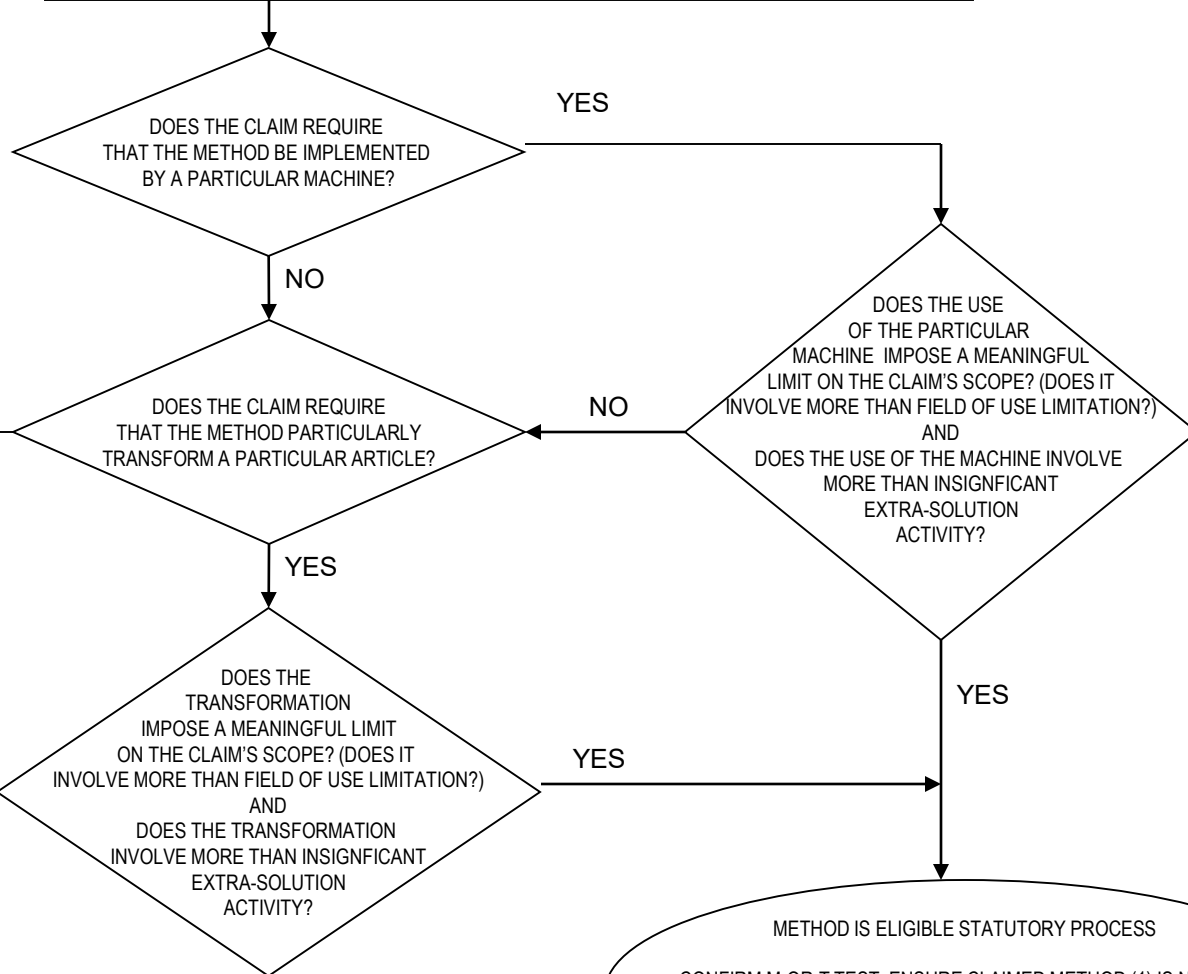
- In accordance with the M or T test, the claimed process must:
 - (1) be tied to a particular machine or apparatus (machine-implemented); **OR**
 - (2) particularly transform a particular article to a different state or thing.
- A method claim that does not require machine implementation or does not cause a transformation will fail the test and be rejected under 35 U.S.C. § 101.
- Note that the mere presence of a machine or transformation is not sufficient to pass the M or T test - the tie must be to a particular machine or the particular transformation of a particular article.

SUBJECT MATTER ELIGIBILITY TEST (M-OR-T) FOR PROCESS CLAIMS

PROCESS FLOWCHART

1. DETERMINE THAT THE CLAIM IS DIRECTED TO A PROCESS
(A METHOD OR SERIES OF ACTS OR STEPS)

2. TEST TO DETERMINE IF PROCESS IS STATUTORY BY USING THE
MACHINE OR TRANSFORMATION (M-OR-T) TEST TO DETERMINE WHETHER
THE CLAIM IS DIRECTED WHOLLY TO A JUDICIAL EXCEPTION (INELIGIBLE)
OR TO A PARTICULAR PRACTICAL APPLICATION OF A JUDICIAL
EXCEPTION (ELIGIBLE) USING THE FOLLOWING FLOW CHART:



METHOD IS NOT ELIGIBLE

METHOD IS ELIGIBLE STATUTORY PROCESS

CONFIRM M-OR-T TEST: ENSURE CLAIMED METHOD (1) IS NOT SO ABSTRACT AND SWEEPING AS TO HAVE NO REAL WORLD APPLICATION AND (2) DOES NOT PRE-EMPT SUBSTANTIALLY ALL PRACTICAL USES OF A JUDICIAL EXCEPTION



Process Example 2

- Claim: A method of identifying an inhibitor for enzyme X comprising:
 - providing enzyme X in solution,
 - contacting enzyme X with at least one substrate and at least one putative inhibitor, and
 - determining whether the substrate is cleaved.
- BRI: The method is directed to detecting activity of enzyme X. Under the broadest reasonable interpretation, in view of the specification and the general knowledge in the art, contacting solvated enzyme X with a substrate causes a change in the state of the substrate, through a chemical reaction. The presence of an inhibitor interacts with either the substrate or the enzyme X to change the chemical activity of either the substrate or the enzyme X, thus leading to a change of state of the substrate or the enzyme X.



Process Example 2, continued

- Analysis: The claim is directed to a method so the machine-or-transformation test is applied.
 - The contacting step involves a transformation whether the substrate is cleaved or not. If the substrate is cleaved, then the substrate is transformed. If the substrate is not cleaved, then either the substrate or the enzyme has undergone a biochemical change and thus a transformation.
 - With respect to the corollaries, the performance of the step of contacting is limited to such actions that result in the transformation of the at least one of the contacted materials. The transformation of the system to a different state through the contacting of the materials is therefore a meaningful limit on the claim.
 - Since the step of contacting is central to the purpose of the claim, which is determining the interaction between the contacted materials, the step of contacting is not merely extrasolution activity.
 - Therefore, the claim passes the transformation prong of the subject matter eligibility analysis. Since the claim is thus subject matter eligible, no further analysis is necessary.
- This claim is patent eligible.



Process Example 3

- Claim: A method of identifying a human sequence homologous to a prokaryotic gene comprising:
 - contacting the prokaryotic gene with an array of human oligonucleotide sequences,
 - quantitating the degree of hybridization between the prokaryotic gene and individual locations on the array.
- BRI: The array comprises sequences on a solid surface. The specification discloses use of a commercially available set of human sequences on a glass chip. Under the broadest reasonable interpretation, in view of the specification and the general knowledge in the art, hybridization is a chemical transformation of the gene and the array. Further, contacting the gene with the array will cause the gene to undergo conformational changes even in the absence of hybridization, and those conformational changes represent a change of state of the gene. The quantitating step could be performed either by inspection or by a specific machine.



Process Example 3, continued

- Analysis: The claim is directed to a method so the machine-or-transformation test is applied.
 - The claim does not require a specific machine to perform any of the steps in the method so the claim does not pass the machine prong of the inquiry.
 - A step of contacting a nucleic acid with another directly results in a physical transformation of matter either through hybridization or through biochemical changes in the gene.
 - With respect to the corollaries, the performance of the step of contacting is limited to such actions that result in the transformation of the at least one of the contacted materials. The transformation of the system to a different state through the contacting of the materials is therefore a meaningful limit on the claim.
 - Since the step of contacting is central to the purpose of the claim, which is determining the interaction between the contacted materials, the step of contacting is not merely extrasolution activity.
 - This claim is patent eligible.



Process Example 4

- A process for plant selection, comprising:
 - providing a database of plant species;
 - eliminating a portion of the plant species using at least two criteria to eliminate unsuitable plant species; and
 - selecting at least one image of the plant species meeting desirable criteria, at least one of said images comprising desirable characteristics of leaf, flower and/or fruit.
- BRI: The eliminating and selecting steps may be performed by eye by merely viewing images. Although the specification discloses a computerized database and an algorithm for searching the database for plant images which meet specified criteria, the broadest reasonable interpretation of the claim language “providing a database” does not require use of a machine as it could reasonably include providing a book or set of images.



- Analysis: The claim is directed to a process so the machine-or-transformation test is applied. Based on the BRI, no step explicitly or inherently requires a machine so the claim does not pass the machine prong of the inquiry.
 - No step requires a transformation of a particular article to a different state or thing so the claim also does not pass the transformation prong of the inquiry.
- This claim is NOT patent eligible.



Process Example 5

- Claim: A method for displaying a three dimensional representation of a structure of a protein comprising:
 - obtaining three dimensional coordinates for the protein;
 - determining a three dimensional representation of a structure based on the three dimensional coordinates; and
 - displaying the three dimensional representation of the protein structure.
- BRI: Based on the broadest reasonable interpretation, the obtaining step does not require a particular machine or a particular transformation, since the specification teaches obtaining 3D coordinates of peptides and proteins from known and publicly available sources (textbooks and online databases). Therefore the “obtaining” step does not require a transformative step such as protein crystallization or the use of a machine such as an X-ray diffractometer.
 - The displaying step does not require a particular machine, since although the specification discloses use of a commercially available program to display the structure using the 3D coordinates, the claim does not explicitly define or limit the display to a computerized display. Moreover, one of ordinary skill in the art would reasonably understand the displaying step to include displaying the protein structure using a drawing or a model.



Process Example 5, continued

- Analysis: The claim is directed to a method so the machine-or-transformation test is applied.
 - The broadest reasonable interpretation of the claim is that no step requires a particular machine so the claim does not pass the machine prong of the inquiry.
 - With respect to transformation, the step of obtaining coordinates does not require actually performing crystallization, and in view of the specification, may be interpreted as a step of obtaining data from a table, therefore the claim does not recite a physical transformation of matter.
 - Therefore, there is neither a machine tie nor a transformation required by the claim.
- The claim is NOT patent eligible.



Process Example 6

- Claim: A method for displaying a three dimensional representation of a structure of a protein comprising:
 - crystallizing the protein;
 - obtaining three dimensional coordinates from a crystal analysis of the protein;
 - determining a three dimensional representation of a structure based on the three dimensional coordinates; and
 - displaying the three dimensional representation of the protein structure.
- BRI: Crystallizing a protein is a transformation of the protein from a solvated phase to a solid phase, and thus represents a change in state. While 3D coordinates can be obtained from a table for a KNOWN crystal, obtaining 3D coordinates from a “crystal analysis” cannot be performed by inspection, and requires the use of a particular machine to perform this step. The examiner has made this determination by reading the specification, which teaches crystallizing the protein and obtaining 3D coordinates by X-ray diffraction, in view of one having ordinary skill in the art.



Process Example 6, continued

- Analysis: The claim is directed to a method so the machine-or-transformation test is applied.
 - The step of crystallization necessarily involves a physical transformation of matter.
 - With respect to the corollaries, the performance of the step of “crystallizing the protein” is limited to such actions that result in the transformation of the protein. The transformation of the sample is a therefore a meaningful limit on the claim.
 - The crystallization step is central to the purpose of the claim, displaying the structure of the crystal, and is therefore not merely extrasolution activity.
 - Therefore, the claim passes the transformation prong of the subject matter eligibility analysis. Since the claim is thus subject matter eligible, no further analysis is necessary.
- This claim is patent eligible.



Questions?

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