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Subject Matter Eligibility Under 35 U.S.C. §101: USPTO Guidance and Policy

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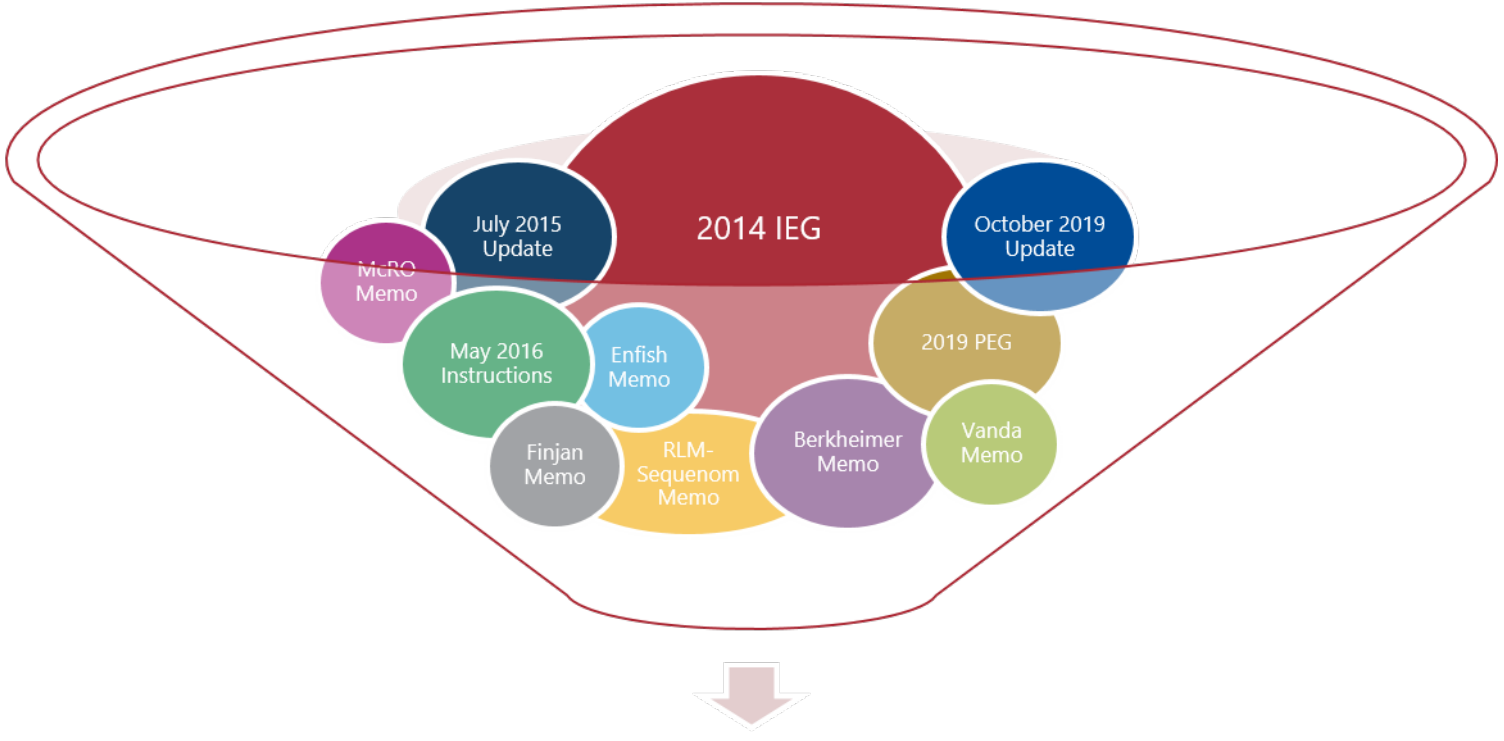
Why we are here today

- More than 150 years of Supreme Court jurisprudence on eligibility.
- Over time, emphasis has shifted from statutory categories to the judicial exceptions:
  - Abstract Ideas;
  - Laws of Nature/Natural Principles; and
  - Natural Phenomena (including Products of Nature).

Body of case law keeps growing

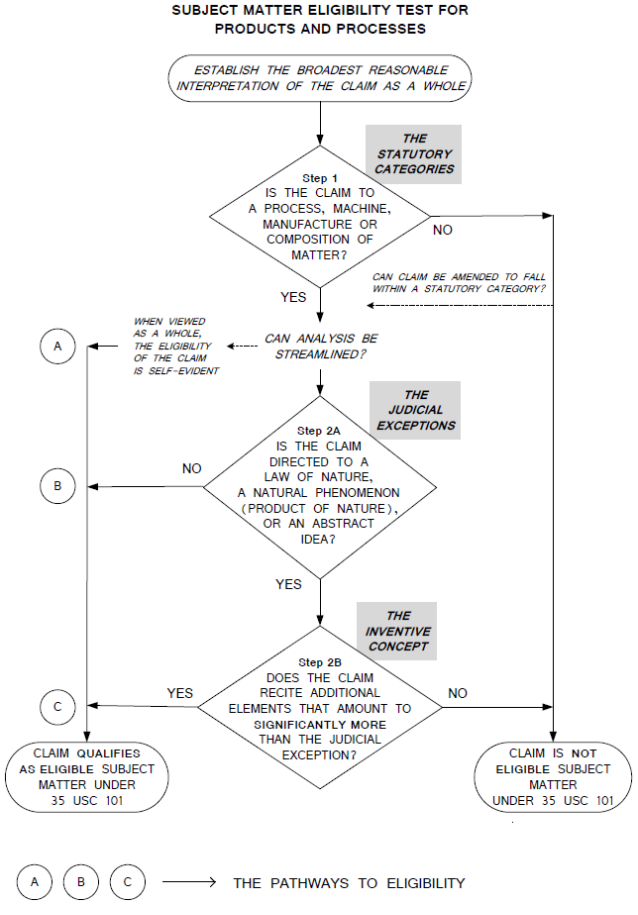
- Handful of key Supreme Court decisions.
  - Cluster in 1970s-80s: *Benson*, *Flook*, *Diehr,* and *Chakrabarty*.
  - Cluster in 2010-2014: *Bilski*, *Mayo*, *Myriad*, and *Alice Corp*.
- Dozens of relevant Federal Circuit decisions since 2012.
  - About 80% of decisions find at least one claim ineligible.
  - Life sciences (except diagnostics) are faring better than software-related technologies in terms of claims held eligible.

USPTO responded by developing guidance



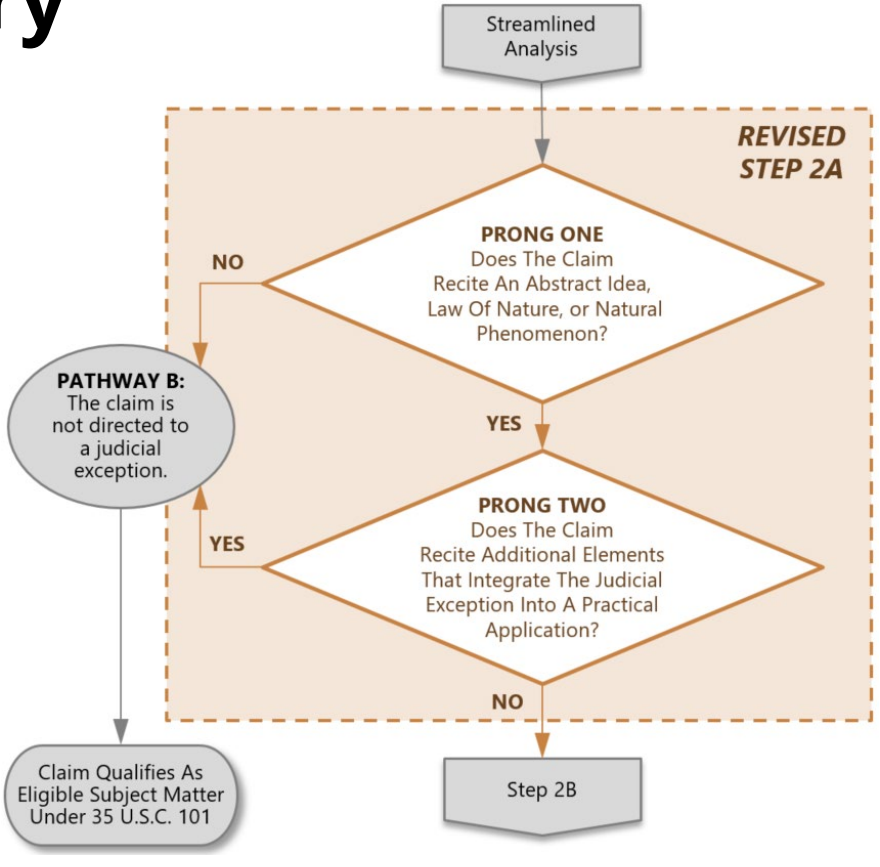
Overview of eligibility analysis

- USPTO analysis addresses the two criteria for subject matter eligibility:
  - the claimed invention must be to a statutory category (Step 1); and
  - the claimed invention must qualify as patent-eligible subject matter (Steps 2A and 2B, aka the Alice/Mayo test).
- Flowchart at right illustrates the overall analysis.



"Directed to" in Step 2A is a two-prong inquiry

- Prong One: Evaluate whether the claim recites a judicial exception.
- Prong Two: Evaluate whether the claim recites additional elements that integrate the exception into a practical application of the exception.



Step 1: Statutory categories

- MPEP 2106.03 discusses Step 1:
  - Explains how the courts have defined the four categories (process, machine, manufacture, and composition of matter).
  - Provides examples of subject matter that doesn't fall within any category (e.g., software per se, signals per se, and human organisms).
  - Provides guidance on how to evaluate whether the claimed inventions is to one of the four statutory categories.

Step 2A Prong One: products of nature

- MPEP 2106.04(c) explains that the Markedly Different Characteristics (MDC) analysis is used to determine if a claim limitation to a nature-based product is a "product of nature" exception.
- Examples demonstrate what is a marked difference, for instance:
  - Examples 16 (engineered antibodies), 28 (inactivated or attenuated virus), and 30 (gel or granulated form) demonstrate how minor and routine structural changes can create MDC; and
  - Examples 17, 28, 30, and 44 demonstrate how changes in function (e.g., rate of cell growth, immunogenic effect, changed taste, glycemic control) resulting from the combination of naturally occurring substances can create MDC.

Step 2A Prong One: abstract ideas

- MPEP 2106.04(a) explains that examiners determine if a claim recites an abstract idea by evaluating whether claim limitation(s) fall within at least one of three groupings of abstract ideas:
  - mathematical concepts;
  - mental processes; and
  - certain methods of organizing human activity.
- Examples identify claims that do not recite abstract ideas, for instance:
  - Screening Methods Example 31 claims 75 and 85 are based on Ambry Genetics (without the abstract idea); and
  - Livestock Management Example 46 claim 4 (based on but does not recite mathematical concepts).

Step 2A Prong One: laws of nature

- MPEP 2106.04(b) discusses some concepts and products that the courts have identified as examples of laws of nature and natural phenomena.
- Examples identify claims that do not recite laws of nature or natural phenomena, for instance:
  - Julitis Example 29 claim 1 based on Mayo (without the laws of nature), and
  - Kidney Disease Example 43 claim 5, which is inspired by Vanda and Mayo (without the laws of nature).

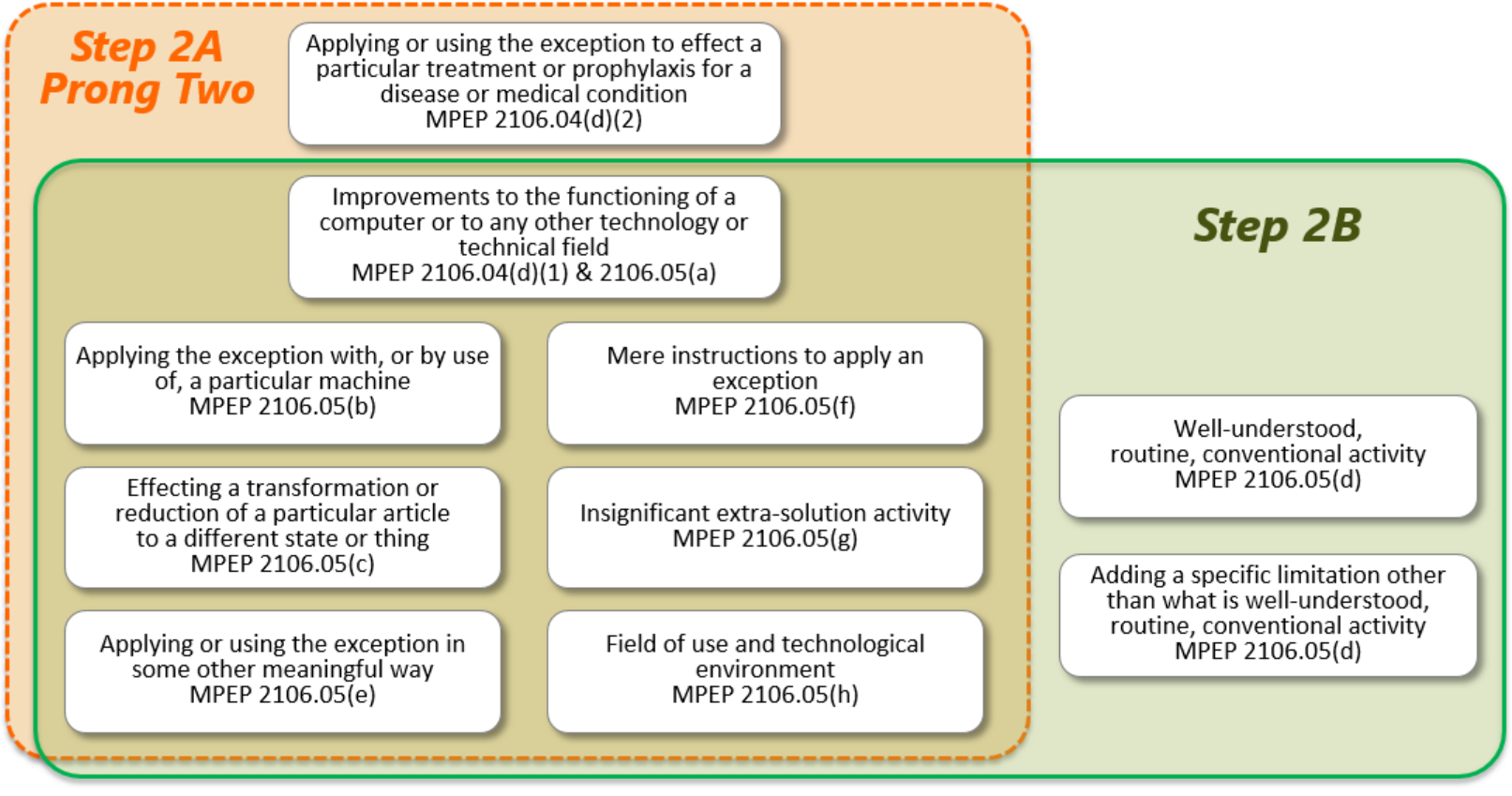
Step 2A Prong Two: integration into a practical application

- MPEP 2106.04(d) explains Step 2A Prong Two, in which examiners evaluate the additional elements in the claim to determine whether they integrate the exception into a practical application of the exception.
- Prong Two uses considerations laid out by the courts to evaluate whether the judicial exception is integrated into a practical application, including the "insignificant extra-solution activity" and "particular treatment or prophylaxis" considerations.
- Integration into a practical application requires the additional element(s) to apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the exception.

Step 2B: significantly more

- MPEP 2106.05 explains Step 2B, in which examiners evaluate whether the additional elements in the claim amount to significantly more, either individually or in combination.
- Step 2B also uses considerations laid out by the courts, including the "improvements to the functioning of a computer/other technology" and the "well-understood, routine, conventional activity" considerations. The considerations are further explained in MPEP 2106.05(a) through 2106.05(h).
- Eligibility requires that the claim recites additional elements that amount to an inventive concept (aka "significantly more") than the recited judicial exception.

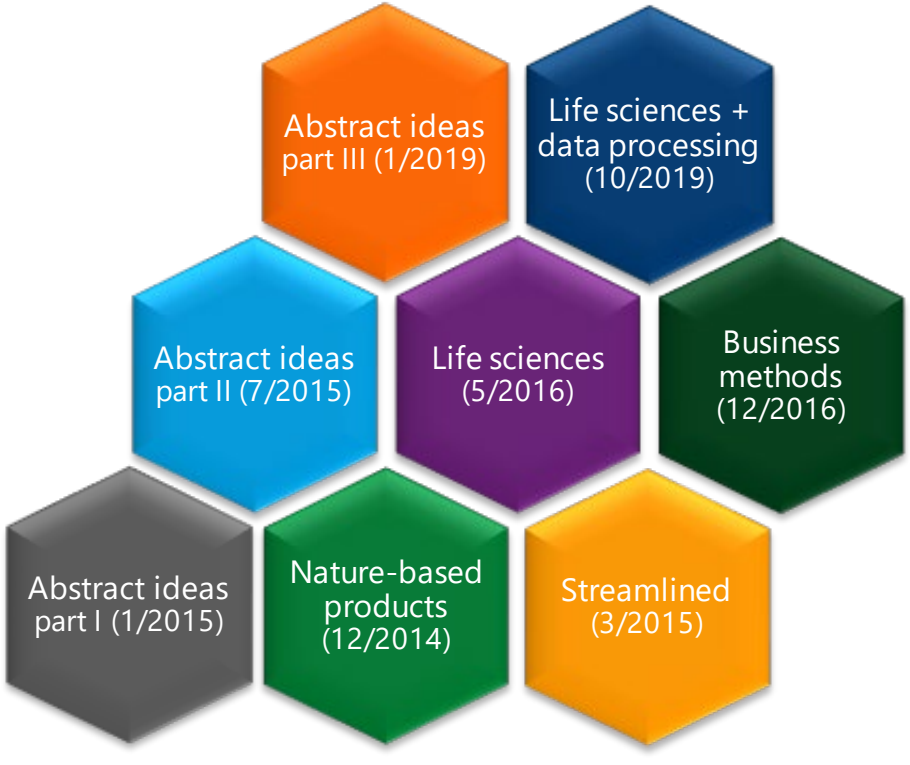
Step 2A Prong Two vs. Step 2B: Considerations



Illustrative examples

Examples

- Total of 46 examples providing an eligibility analysis of various fact patterns.
- Include eligible and ineligible claims, in accordance with case law and based on hypothetical fact patterns.
- Cover technologies including biotechnology, pharmaceuticals, antibodies, vaccines, business methods, computer-related inventions, and software.



Index of examples

- Index provides an overview of the relevance of Examples 1-46 under the current guidance.
- Index indicates which examples provide a practical application or significantly more analysis, and the considerations that are evaluated in each example.

All Examples: Issue Spotting	GUI for Relocating Obscured Text	Updating Alarm Limits	Rubber Manufacturing	Internal Combustion	BIOS System Software	Vaccines
Example Number	23	24	25	26	27	28
Claim Type aka Statutory Category						
Process	•	•	•		•	
Product (Composition of Matter, Manufacture, and/or Machine)			•	•		•
Judicial Exception						
Abstract Idea	•	•	•	•		
Law of Nature						
Product of Nature						•
Multiple exceptions in same claim			•			
No recited exception	•					•
Detailed Analysis						
Streamlined Analysis				•	•	
Step 2A Prong One: Generally *	•	•	•			•
Step 2A Prong One: Markedly Different Characteristics analysis						•
Step 2A Prong Two: Exception Integrated Into A Practical Application **	•	•	•			
Step 2B: Generally	•	•				•
Step 2B: Claim is eligible because it provides an Inventive Concept	•		•			•
Considerations Discussed in Step 2A Prong Two and/or Step 2B						
Improvements to Functioning of a Computer or Other Technology	•		•			
Particular Treatment or Prophylaxis (Prong Two only)						
Particular Machine				•		
Particular Transformation			•			
Other Meaningful Limitations			•			
Mere Instructions To Apply An Exception	•					•
Insignificant Extra-Solution Activity		•	•			•
Field of Use and Technological Environment	•	•				
Well-Understood, Routine, Conventional (WURC) Activity (Step 2B only) †		•	•			•
No additional elements, so no Prong Two or Step 2B analysis	•					

Today's discussion

- Examples 29 (Diagnosing Julitis) and 31 (Screening Methods) were published several years ago, before Step 2A of the guidance was revised. Accordingly, the analysis presented in the written versions of these examples would be slightly different if re-written today:
  - The rationale for why the claims recite abstract ideas would refer to one of the three groupings of abstract ideas in MPEP 2106.04(a), instead of relying on a direct comparison between a claimed concept and the concepts in one or more judicial decisions; and
  - These examples would contain a Step 2A Prong Two analysis for the claims reciting judicial exceptions. However, the missing analysis can be extrapolated from the published Step 2B analysis minus the "well-understood, routine, conventional activity" consideration.
- Examples 43 (Treating Kidney Disease) and 44 (Denveric Acid) are fully compliant with the current guidance as written.

Example 44: Denveric acid

- Applicant identified denveric acid as a insulin-sensitizing agent to help reduce insulin requirements for those suffering from diabetes.
- Denveric acid is a naturally occurring protein found in the bark of the Rocky Mountain cassia tree.
- Because denveric acid is a short acting agent, Applicant discloses two ways to change the glycemic control characteristics:
    1. Modifying the amino acid structure of the acid to make it into an "intermediate acting" agent; or
    2. Mixing denveric acid with protamine, another naturally occurring protein, in a particular amount so that the mixture acts as a "long acting" agent.

Example 44: Denveric acid claim 1

1. A dosage unit comprising ***denveric acid*** in a container.

- Step 1: the claimed product is a manufacture and/or composition of matter.
- Step 2A Prong One: the claimed denveric acid is not markedly different from naturally occurring denveric acid and so is a ***product of nature*** exception.
- Step 2A Prong Two: the additional element (container) amounts to mere instructions to apply the product of nature.
- Step 2B: the additional element amounts to mere instructions to apply the product of nature.

No inventive concept

Claim 1 is ineligible

Example 44: Denveric acid claim 3

3. The dosage unit of claim 1, wherein the ***denveric acid is an intermediate-acting denveric acid***.

- Step 1: the claimed product is a manufacture and/or composition of matter.
- Step 2A Prong One: naturally occurring denveric acid is short-acting, but the claimed denveric acid is intermediate-acting. This change in glycemic control characteristics is a marked difference, so the claimed denveric acid is **NOT** a product of nature exception.

No exception recited

Claim 3 is eligible at Step 2A Prong One

Example 44: Denveric acid claim 4

4. The dosage unit of claim 1, further comprising ***protamine that is mixed with the denveric acid in the container in an amount of 0.75 mg to 1.5 mg protamine per every mg of denveric acid***.

- Step 1: the claimed mixture is a manufacture and/or composition of matter.
- Step 2A Prong One: naturally occurring denveric acid is short-acting, and naturally occurring protamine does not have glycemic control characteristics. But the claimed mixture is long-acting. This change in glycemic control characteristics is a marked difference, so the claimed mixture is **NOT** a product of nature exception.

No exception recited

Claim 4 is eligible at Step 2A Prong One

Example 29: Diagnosing julitis

- "Julitis" is a hypothetical autoimmune disease that causes chronic inflammation and an itchy and extremely painful rash on the face, hands, and feet.
- Conventionally, Julitis is diagnosed by a physical examination of the characteristic rash, but the rash is often mistaken for Rosacea.
- Applicant's specification discloses:
  - The discovery that the presence of JUL-1 protein in a person's plasma is indicative that the person has Julitis;
  - Applicant's use of conventional immunoassays, which are routine methods of detecting a protein of interest; and
  - Applicant's use of unconventional reagents (porcine antibodies) to detect JUL-1 and thus accurately diagnose patients.

Example 29: Diagnosing julitis claim 2

2. A method of diagnosing julitis in a patient, said method comprising:

a. obtaining a plasma sample from a human patient;

b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and

c. ***diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected***.

No inventive concept

Claim 2 is ineligible

- Step 1: the claim recites a process.
- Step 2A Prong One: the "diagnosing" step sets forth a correlation that is a ***law of nature***. This step can also be performed in a doctor's mind, and thus falls within the "mental processes" grouping of ***abstract ideas*** in MPEP 2106.04(a).
- Step 2A Prong Two: the additional elements of the "obtaining" and "detecting" steps are insignificant extra-solution activity (mere data gathering necessary to use the exception), and mere instructions to apply the exception.
- Step 2B: the additional elements are extra-solution activity and mere instructions to apply the exception, and are also well-understood, routine, conventional activity.

Example 29: Diagnosing julitis claim 3

3. A method of diagnosing julitis in a patient, said method comprising:

a. obtaining a plasma sample from a human patient;

b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a porcine anti-JUL-1 antibody and detecting binding between JUL-1 and the porcine antibody; and

c. ***diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected***.

- Step 1, Step 2A Prong One, and Step 2A Prong Two are the same as for claim 2.
- Step 2B: the "obtaining" step represents insignificant extra-solution activity (mere data gathering necessary to use the exception), and mere instructions to apply the exception.

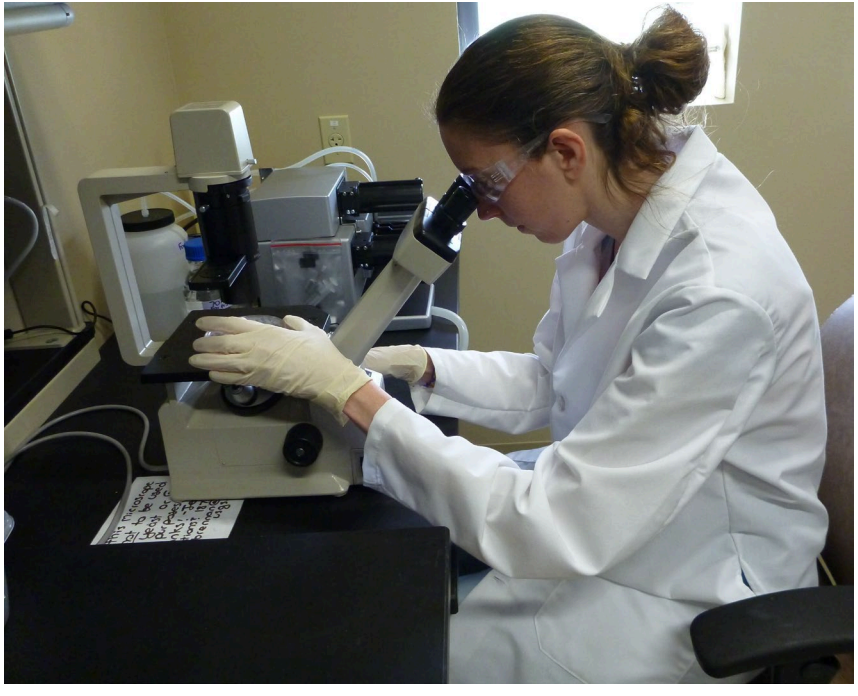
  However, the "detecting" step uses porcine antibodies to detect JUL-1. There is no evidence that porcine antibodies were routinely or conventionally used to detect human proteins such as JUL-1. Thus, this is an unconventional step that is more than mere instructions to apply the exception.

Adds inventive concept

Claim 3 is eligible

Example 31: Screening methods

- Applicant discovered the wild-type sequence of the BRCA1 gene, and also discovered naturally occurring alterations in that gene that are correlated with an increased likelihood of developing breast or ovarian cancer.
- Applicant's specification discloses:
  - Determining whether a patient has these alterations by detecting whether a wild-type BRCA1 probe hybridizes to the patient's DNA;
  - Using conventional techniques such as autoradiography to detect the hybridization; and
  - Using a known but non-routine technique called "Scanning Near-field Optical Microscopy" (SNOM) to detect the hybridization.



Example 31: Screening methods claim 1

1. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises

comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject.

No inventive concept
Claim 1 is ineligible

- Step 1: the claim recites a process.
- Step 2A Prong One: the "comparing" step is a mental step that can be performed in a person's mind, and thus falls within the "mental processes" grouping of ***abstract ideas*** in MPEP 2106.04(a).
- Step 2A Prong Two: there are no additional elements.
- Step 2B: there are no additional elements.

Note: This is claim 1 from U.S. Patent No. 5,753,441, which was held ineligible by the Federal Circuit in *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), aff'd in part and rev'd in part on other grounds, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

Example 31: Screening methods claim 70

70. The method of claim 1, wherein said comparing BRCA1 sequences further comprises:

hybridizing a wild-type probe to a BRCA1 gene isolated from said sample; and

detecting the presence of a hybridization product by measuring conformational changes in the probe that are indicative of hybridization to the BRCA1 gene with scanning near-field optical microscopy.

Adds inventive concept

Claim 70 is eligible

- Step 1 and Step 2A Prong One are the same as for claim 1.
- Step 2A Prong Two: the additional elements of the "hybridizing" and "detecting" steps are insignificant extra-solution activity (mere data gathering necessary to use the exception), and mere instructions to apply the exception.
- Step 2B: the "hybridizing" step represents insignificant extra-solution activity (mere data gathering necessary to use the exception), and mere instructions to apply the exception.

  However, the "detecting" step uses scanning near-field optical microscopy (SNOM) to detect hybridization products. There is no evidence that SNOM was routinely or conventionally used to detect DNA hybridization. Thus, this is an unconventional step that is more than mere instructions to apply the exception.

Example 43: Treating kidney disease

- Nephritic Autoimmune Syndrome Type 3 (NAS-3) is a hypothetical autoimmune disease that quickly causes chronic kidney disease and kidney failure if not adequately treated.
- Conventionally, NAS-3 is treated with glucocorticoids. Some patients do not respond to this treatment, but by the time their non-responsiveness is clinically apparent, the disease has often progressed to the point of causing irreversible kidney damage.
- Applicant's specification discloses:
  - The discovery that a particular ratio between two proteins (C11 and C13) in a patient's blood is indicative that they have a "non-responder phenotype"; and
  - Applicant's use of conventional treatments for NAS-3, including glucocorticoids and non-steroidal agents such as rapamycin.

Example 43: Treating kidney disease claim 1

1. A treatment method comprising:

(a) ***calculating a ratio of C11 to C13 levels measured in a blood sample from a patient diagnosed with Nephritic Autoimmune Syndrome Type 3 (NAS-3) to identify the patient as having a non-responder phenotype***;

(b) administering a treatment to the patient having a non-responder phenotype.

- Step 1: the claim recites a process.
- Step 2A Prong One: the "calculating a ratio" step requires an arithmetic operation (division) that can be performed in the mind. It thus falls within the "mathematical calculations" and "mental processes" groupings of ***abstract ideas*** in MPEP 2106.04(a). The step also describes a relationship between the ratio and the phenotype that is a ***law of nature***.
- Step 2A Prong Two: the additional element of the "administering" step is recited at such a high level of generality that it is at best mere instructions to apply the exception.
- Step 2B: the additional element is at best mere instructions to apply the exception.

No inventive concept

Claim 1 is ineligible

Example 43: Treating kidney disease claim 3

3. The method of claim 1, wherein the treatment is rapamycin.

- Step 1 and Step 2A Prong One are the same as for claim 1.
- Step 2A Prong Two: the step of administering rapamycin is an additional element that represents a "particular treatment", because it uses the recited abstract idea in a manner that imposes a meaningful limit on it. In particular, the abstract idea is used to identify the patient as being non-responsive to glucocorticoids, and the patient is then administered a treatment that is particular to that identified phenotype (rapamycin is not a glucocorticoid).

Integrates exception into a practical application

Claim 3 is eligible

USPTO resources

- Eligibility webpage: www.uspto.gov/PatentEligibility
  - Includes guidance documents, examples, training materials, and information about case law
  - Includes links to public comments

- MPEP webpage: www.uspto.gov/MPEP
  - Includes current and archived versions of MPEP
  - "Change Summary" document explains changes since last version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