

**UNITED STATES
PATENT AND TRADEMARK OFFICE**



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

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Why we are here today

- More than 150 years of Supreme Court jurisprudence on eligibility.
- Recent case law is mostly focused on the judicial exceptions:
 - Abstract Ideas;
 - Laws of Nature/Natural Principles; and
 - Natural Phenomena (including Products of Nature).

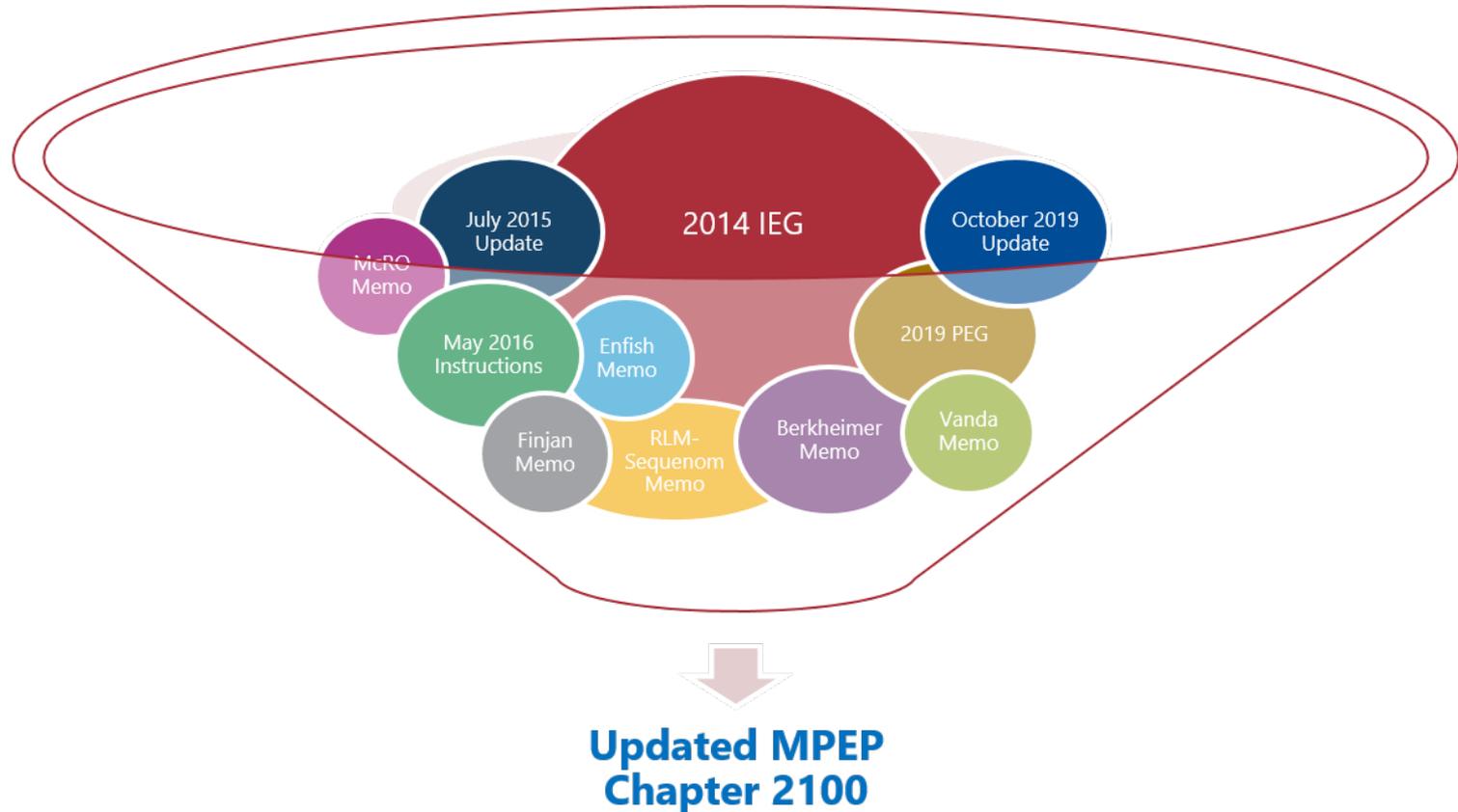


Body of case law keeps growing

- 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.

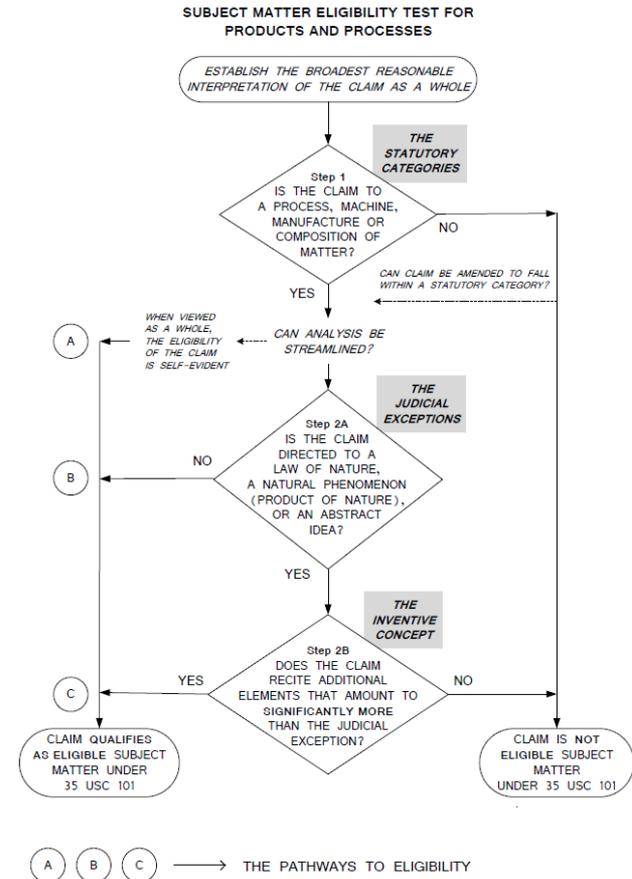


USPTO responded by developing guidance



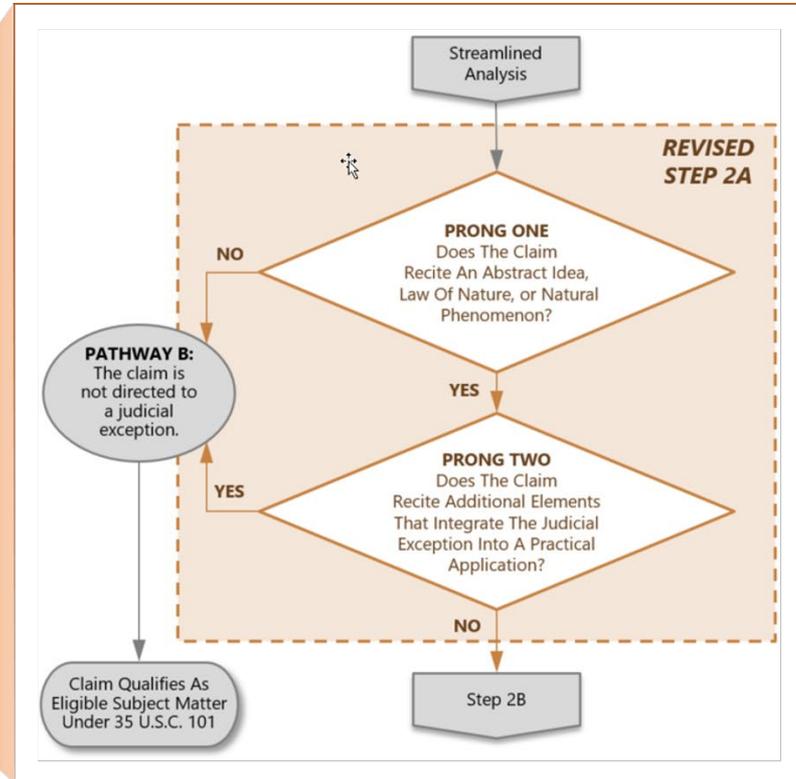
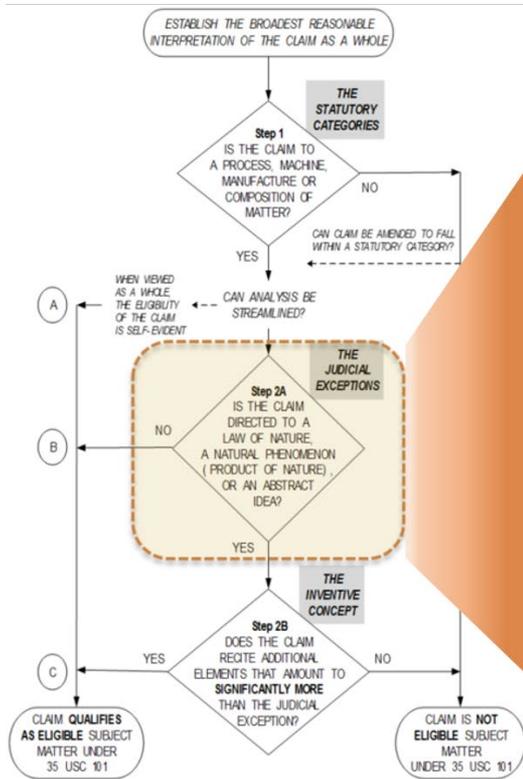
Overview of eligibility analysis

- 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.



MPEP flowchart including revised Step 2A

MPEP flowchart



Revised Step 2A flowchart

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: 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:
 - Training a Neural Network Example 39 (based on but does not recite mathematical concepts); and
 - Livestock Management Example 46 claim 4.

Groupings of abstract ideas

Mathematical concepts

MPEP 2106.04(a)(2)(I)

- Mathematical relationships
- Mathematical formulas or equations
- Mathematical calculations

Mental processes

MPEP 2106.04(a)(2)(III)

- Concepts performed in the human mind (including an observation, evaluation, judgment, opinion)

Certain methods of organizing human activity

MPEP 2106.04(a)(2)(II)

- Fundamental economic principles or practices
- Commercial or legal interactions
- Managing personal behavior or relationships or interactions between people

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
 - Controller for Injection Mold Example 45 claim 4

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 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 “improvements to the functioning of a computer/other technology” 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 “insignificant extra-solution activity” 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.

Prong two vs. step 2B: Considerations

Step 2A Prong Two

Applying or using the exception to effect a particular treatment or prophylaxis for a disease or medical condition
MPEP 2106.04(d)(2)

Improvements to the functioning of a computer or to any other technology or technical field
MPEP 2106.04(d)(1) & 2106.05(a)

Applying the exception with, or by use of, a particular machine
MPEP 2106.05(b)

Mere instructions to apply an exception
MPEP 2106.05(f)

Effecting a transformation or reduction of a particular article to a different state or thing
MPEP 2106.05(c)

Insignificant extra-solution activity
MPEP 2106.05(g)

Applying or using the exception in some other meaningful way
MPEP 2106.05(e)

Field of use and technological environment
MPEP 2106.05(h)

Step 2B

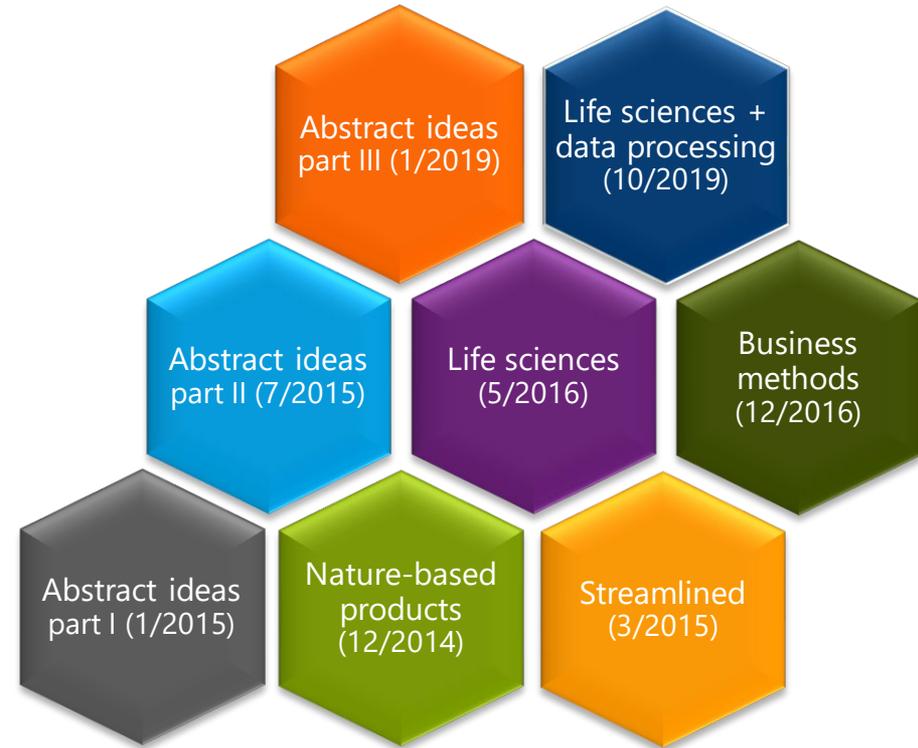
Well-understood, routine, conventional activity
MPEP 2106.05(d)

Adding a specific limitation other than what is well-understood, routine, conventional activity
MPEP 2106.05(d)

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.



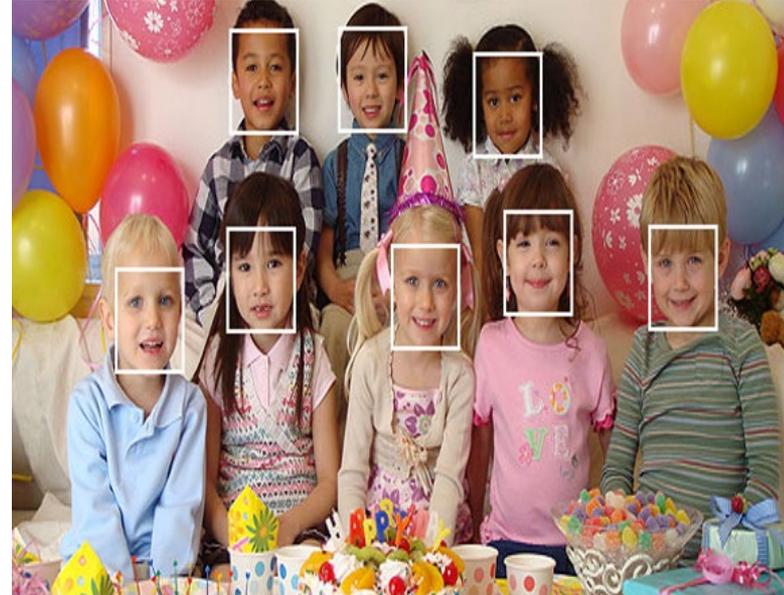
Index of examples

- 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	•					

Example 39: Facial detection - background

- Facial detection is a computer technology for identifying human faces in digital images.
- Previous methods used neural networks to detect faces but performed poorly on distorted, rotated, or shifted face patterns.
- Inventor seeks to improve the previous methods by using an expanded training set and an iterative training technique.



Example 39: Facial Detection

A computer-implemented method of training a neural network for facial detection comprising:

- collecting a set of digital facial images from a database;

- applying one or more transformations to each digital facial image including mirroring, rotating, smoothing, or contrast reduction to create a modified set of digital facial images;

- creating a first training set comprising the collected set of digital facial images, the modified set of digital facial images, and a set of digital non-facial images;

- training the neural network in a first stage using the first training set;

- creating a second training set for a second stage of training comprising the first training set and digital non-facial images that are incorrectly detected as facial images after the first stage of training; and

- training the neural network in a second stage using the second training set.

Groupings of abstract ideas

Mathematical concepts

MPEP 2106.04(a)(2)(I)

- Mathematical relationships
- Mathematical formulas or equations
- Mathematical calculations

Mental processes

MPEP 2106.04(a)(2)(III)

- Concepts performed in the human mind (including an observation, evaluation, judgment, opinion)

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creating a first training set comprising the collected set of digital facial images, the modified set of digital facial images, and a set of digital non-facial images;

training the neural network in a first stage using the first training set;

creating a second training set for a second stage of training comprising the first training set and digital non-facial images that are incorrectly detected as facial images after the first stage of training; and

training the neural network in a second stage using the second training set.

No exception recited

The claim is eligible at Step 2A Prong One

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.
- Since denveric acid is a short acting agent, Applicant discloses mixing denveric acid with protamine, another naturally occurring protein, in a particular amount to change the glycemic control characteristics to be long-lasting.



Example 44: Denveric acid

- Step 2A, Prong 1 – the claim recites “denveric acid” and it is not markedly different from naturally occurring denveric acid (i.e. no changes in structure, function, etc.)
- Step 2A, Prong 2 – the additional limitation (container) does not meaningfully limit the claim and amounts to mere instructions to apply the natural product
- Step 2B – the container amounts to merely adding the words “apply it”

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

No inventive concept

Claim 1 is ineligible

Example 44: Denveric acid

- Step 2A, Prong 1 – comparing the intermediate-acting denveric acid to naturally occurring denveric acid demonstrates a marked difference in the glycemic control characteristics (i.e., a change in its functional characteristics).

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

No exception recited

Claims 3 is eligible at
Step 2A Prong One

Example 45: Controller for injection mold



- The invention involves an injection mold for producing skateboard wheels.
- A feedback controller is used to receive temperature measurements inside the mold to calculate the percentage of curing completion and opens the mold at the precise time the target percentage of cure is reached.

Example 45: Controller for injection mold

1. A controller for an injection molding apparatus having a mold defining a cavity for receiving uncured polyurethane that is heated to form a molded article during a cycle of operation of the apparatus, the controller configured to:

(a) repeatedly obtain measurements of the temperature of a mold;

(b) calculate an extent of curing completion of polyurethane in the mold using the obtained temperatures and the Arrhenius equation; and

(c) determine the extent that the polyurethane is cured as a percentage.

- Step 2A, Prong 1 – recites the “Arrhenius equation” which is a law of nature (and abstract idea) and the abstract idea of calculating a percentage.
- Step 2A, Prong 2 – step (a) represents mere data gathering and is insignificant extrasolution activity
- Step 2B – step (a) is disclosed as well known in the specification and, therefore, does not provide significantly more

No inventive concept
Claim 1 is ineligible

Example 45: Controller for injection mold

4. A controller for an injection molding apparatus having a mold defining a cavity for receiving uncured polyurethane that is heated to form a molded article during a cycle of operation of the apparatus, the controller configured to:

(a) send a control signal to the injection molding apparatus to regulate injection of uncured polyurethane into the mold, and to heat the mold to a target temperature to cure the polyurethane;

(b) repeatedly obtain temperature measurements of the mold;

(c) compare the obtained temperatures to a target temperature; and

(d) maintain temperature of the mold within two degrees of the target temperature by sending a control signal to the apparatus to selectively heat or cool the mold when the obtained temperature of the mold is more than two degrees different than the target temperature.

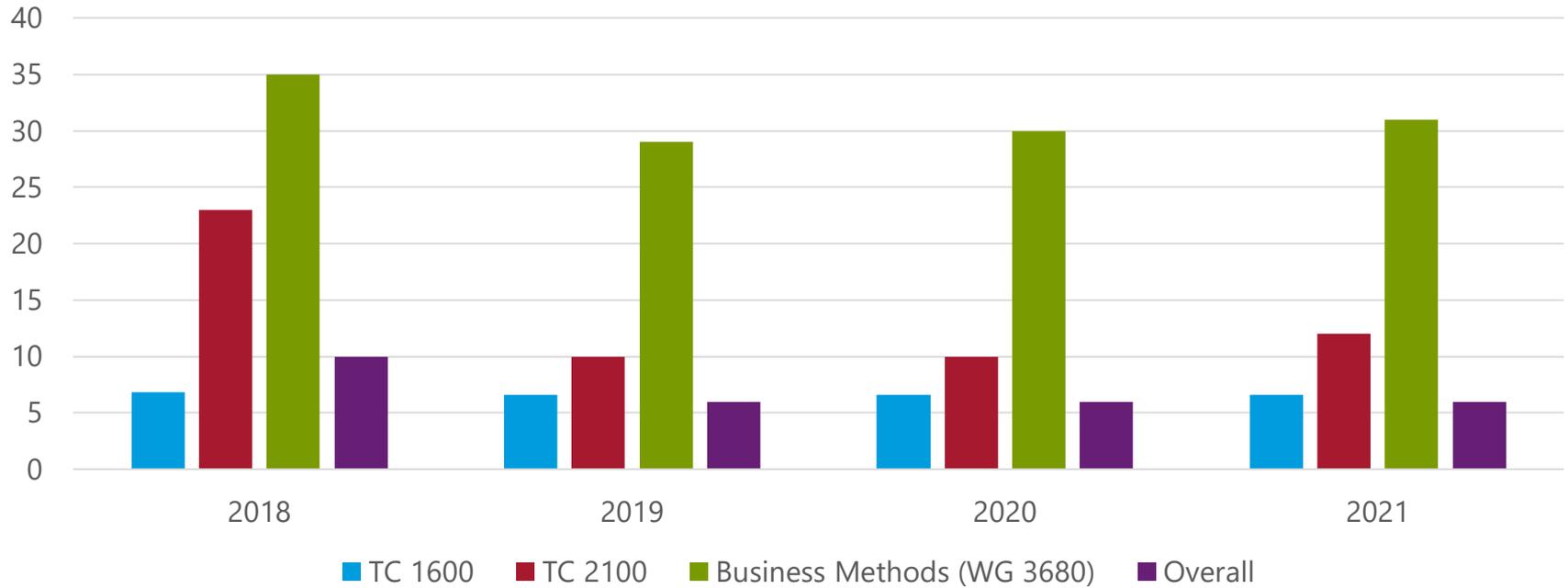
- Step 2A, Prong 1 – step (c) is a mental process that can be practically performed in the human mind.
- Step 2A, Prong 2 – step (d) integrates the mental process in step (c) into the practical application of controlling the injection molding apparatus.

**Not directed to the recited
abstract idea**

Claim 4 is eligible at Step 2A Prong Two

Statistics

101 Rejections as a Percentage of all Rejections



Deferred Subject Matter Eligibility (DSMER) pilot program

DSMER pilot program

- Initiated in response to a letter from Senators Thom Tillis and Tom Cotton
- The DSMER pilot program is designed to evaluate how deferred applicant responses to subject matter eligibility rejections affect examination efficiency and patent quality as compared to traditional compact prosecution practice
 - Partial waiver of 37 CFR 1.111(b); response does not need to address SME rejection to be compliant
- Announced in a Federal Register Notice on January 6, 2022. (87 FR 776)
- Complete details can be found on the DSMER webpage:
<https://www.uspto.gov/patents/initiatives/patent-application-initiatives/deferred-subject-matter-eligibility-response>

Patent application criteria

- Original non-provisional utility application
- Does not claim benefit of an earlier-filed U.S. non-provisional
 - i.e., is not a CON, DIV, or CIP of a U.S. application
 - 371 or CON/DIV/CIP of PCT is ok
 - Claiming benefit to U.S. provisional or a prior application filed in a foreign country is ok
- **No FAOM mailed yet**
 - RCEs are not eligible
- **No special cases**
 - Track 1, Cancer Immunology, PPH, Petition to Make Special (MPEP 708.02) are not eligible
- **FAOM includes at least one SME rejection and at least one other rejection**
 - SME rejection may be based on any of the steps of SME analysis (MPEP 2106)

DSMER pilot program process - overview

- Two-phase process.

Invitation phase: Examiner selects an eligible application, invites applicant to participate in the pilot

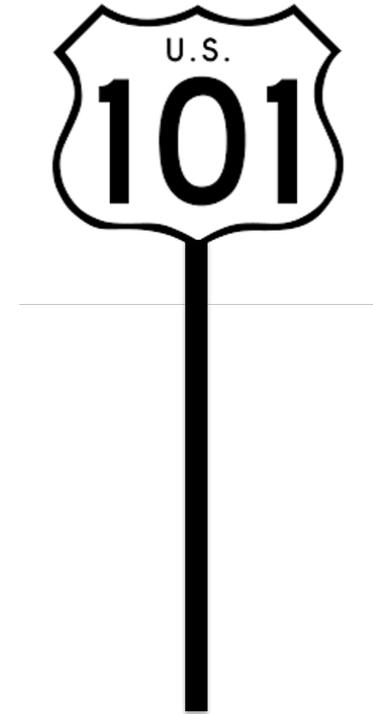
- Applicant cannot initiate a request to participate in the pilot; the initial invitation must come from the examiner

Examination phase: Applicant elects to participate

- Application is only in the pilot if both parties agree
- Once applicant elects to participate, prosecution conducted according to pilot parameters

What's next?

- USPTO will continue public engagement.
 - Currently evaluating comments received in response to RFC regarding economic impacts of eligibility jurisprudence
 - Ongoing initiatives on Artificial Intelligence and Expanding Innovation
- Supreme Court and Federal Circuit decisions relating to subject matter eligibility may fill in gaps.
- Legislative developments may address eligibility.



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



