

**UNITED STATES  
PATENT AND TRADEMARK OFFICE**



# Subject Matter Eligibility *And* Disclosure Requirements Under The Patent Law

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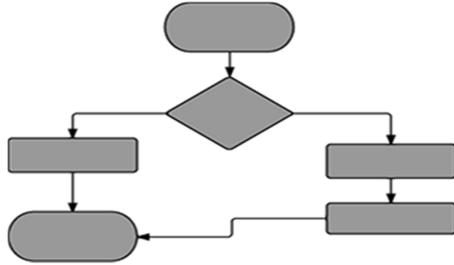
# **35 U.S.C. § 101**

## § 101 - Inventions Patentable:

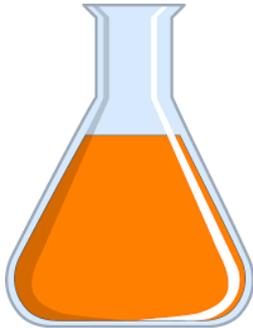
Whoever invents or discovers any new and **useful process, machine, manufacture, or composition of matter**, or any new and useful improvement thereof, may obtain **a** patent therefor, subject to the conditions and requirements of this title.

# *Four categories of patentable subject matter under § 101*

Processes



Compositions of Matter



Machines



Manufacture



# 35 U.S.C. § 101 – *judicial exceptions*

- Supreme Court has long held that § 101 *excludes* certain subject matter from patent eligibility:
  - Abstract Ideas
  - Laws of Nature/Natural Principles
  - Natural Phenomena (including Products of Nature)
- Before 2012, the Supreme Court had not addressed eligibility in the life sciences for several decades, *e.g.*:
  - *Chakrabarty* (1981) and *Funk Brothers* (1948) decisions on products of nature
  - *Tilghman* (1881) decision on laws of nature

# ***Pre-2012 eligibility guidance***

- Office eligibility guidance for life sciences stressed importance of human intervention and useful application of judicial exceptions
  - Living subject matter (*e.g.*, a genetically modified plant) was evaluated based on whether it was the result of human intervention
  - Other subject matter in the life sciences (*e.g.*, a process) was evaluated based on whether the claim “transforms” an article or physical object to a different state or thing, or otherwise produces a useful, concrete and tangible result
- Under this guidance, “isolation” of an otherwise unchanged naturally occurring product was sufficient for eligibility



# ***Mayo v. Prometheus* (2012)**

- *Mayo* decision emphasized that Supreme Court eligibility precedent such as *Flook* and *Diehr* was applicable in the life sciences
  - Claims at issue were methods of administering a drug and evaluating how patient metabolized the drug
  - Unanimous decision articulated a two-part eligibility test for claims focused on laws of nature
- Office response was to update its eligibility guidance for life sciences
  - Process claims “focused on” laws of nature and natural phenomena were examined under new guidance based on *Mayo*
  - Product claims in life sciences were examined under pre-2012 guidance
  - Claims directed to abstract ideas were examined under *Bilski* guidance

# ***AMP v. Myriad Genetics (2013)***

- *Myriad* decision emphasized that Supreme Court eligibility precedent such as *Chakrabarty* and *Funk Brothers* were still applicable today
  - Claims at issue were to isolated BRCA genes and BRCA cDNA
  - Unanimous decision made clear that claimed product must be markedly different from what occurs in nature in order to be eligible
- Office response was to update its eligibility guidance for life sciences
  - Process and product claims involving naturally occurring things (laws of nature and natural phenomena) were examined under new guidance based on *Mayo and Myriad*
  - Claims directed to abstract ideas were examined under other guidance (*Bilski* guidance and *Alice Corp.* Preliminary Examination Instructions)

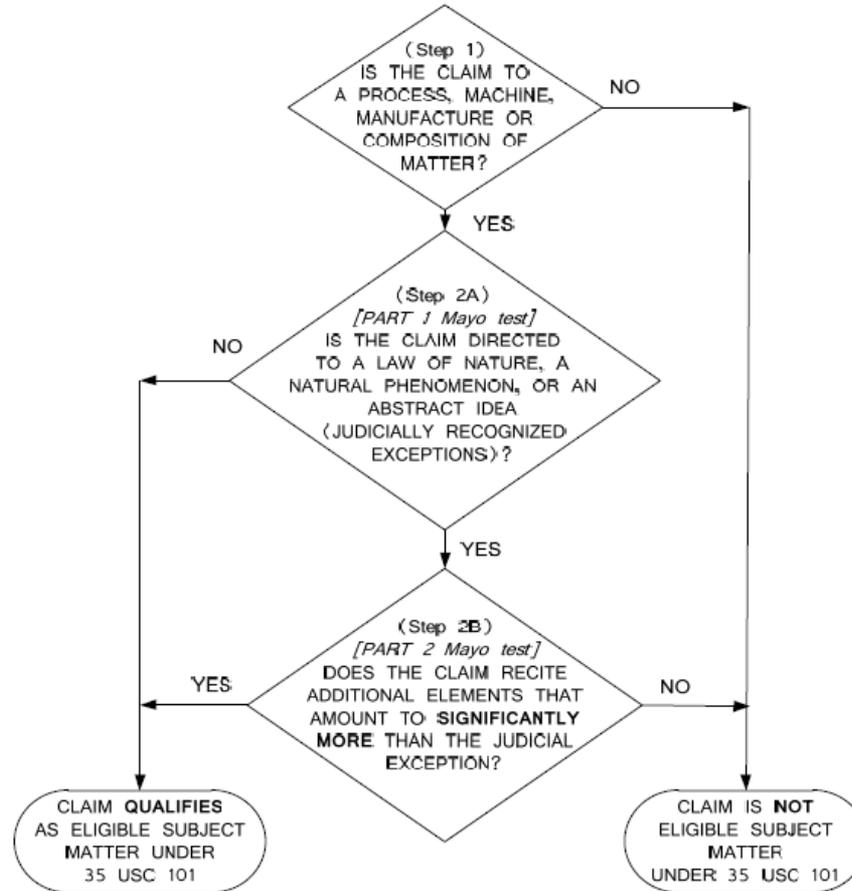
# ***Alice Corp. v. CLS Bank (2014)***

- *Alice Corp.* decision emphasized the importance of Supreme Court eligibility precedent, particularly *Mayo*
  - Claims at issue were to products, processes, and computer-readable media that implemented intermediated settlement on a computer
  - Unanimous decision made clear that two-part eligibility test from *Mayo* applies to all claims (product and process) directed to any judicial exception (laws of nature, natural phenomena, and abstract ideas)
- Decision created unified framework for eligibility analysis:
  - Part 1: Determine whether the claim is directed to a judicial exception
  - Part 2: If so, analyze the claim as a whole to determine if the claim amounts to significantly more than the judicial exception itself

# Other developments in 2014 – Federal Circuit

- ***In re Roslin Institute (Edinburgh)* - just prior to *Alice Corp.***
  - Claims at issue were to cloned mammals, *e.g.*, Dolly the sheep
  - Court affirmed Office’s application of “markedly different characteristics” analysis to evaluate eligibility of products of nature
  - Decision made clear that *Myriad* applied to more than just DNA
- ***Ambry Genetics* - just after 2014 Interim Eligibility Guidance**
  - Claims at issue were to DNA primer pairs and methods of screening for gene alterations
  - Court found the primers, which utilize the innate ability of DNA to bind to itself, to be ineligible relying on *Myriad*
  - Court found the methods ineligible explaining that steps of comparing BRCA sequences as well-understood, routine, and conventional activity engaged in by scientists at the time of *Myriad*’s application

# Mayo/Alice Two-Step Test



# ***USPTO Strategic Plan***

- Since 2014 the Office has issued multiple Interim Guidance to:
  - Set forth integrated approach to eligibility applicable to claims in all technological areas
  - Explain the USPTO's interpretation of subject matter eligibility requirements in view of *Alice Corp.*, *Myriad*, *Mayo*, etc.
  - Respond to feedback on prior guidance and case law developments from stakeholders
  - Reflect significant changes from prior guidance, particularly for claims to “products of nature”
  - Include discussion of case law precedent, and examples illustrating application of eligibility analysis to various types of claims
  - As the USPTO Director has explained, “[r]eliable patent rights are key to economic growth. Providing high quality, efficient examination of patent applications will serve the American economy well.”



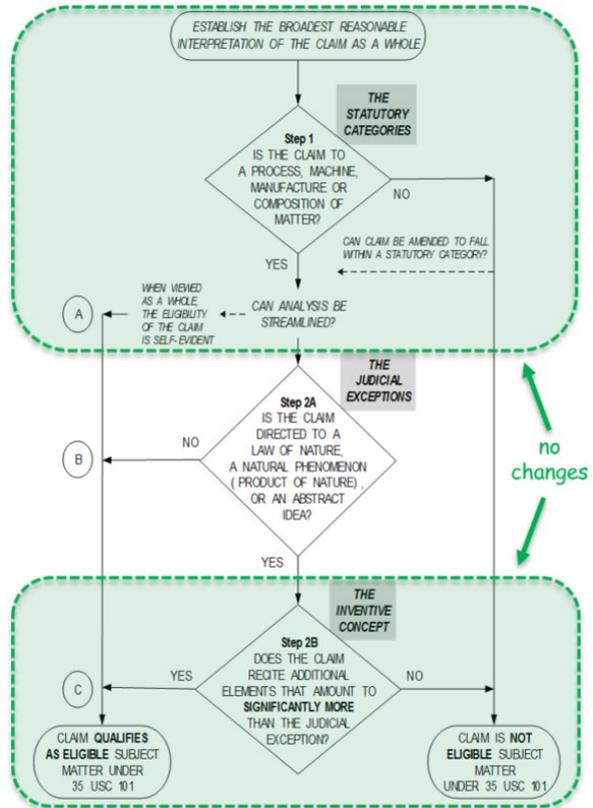
# ***Section 101 initiative: Revised Guidance***

- The 2019 Revised Patent Subject Matter Eligibility Guidance (hereinafter “2019 PEG”) published in January 2019.
- The guidance was revised for several reasons:
  - Increase clarity, predictability and consistency in how Section 101 is applied during examination.
  - Enable examiners to more readily determine if a claim does (or does not) recite an abstract idea.

# *Overview of 2019 PEG*

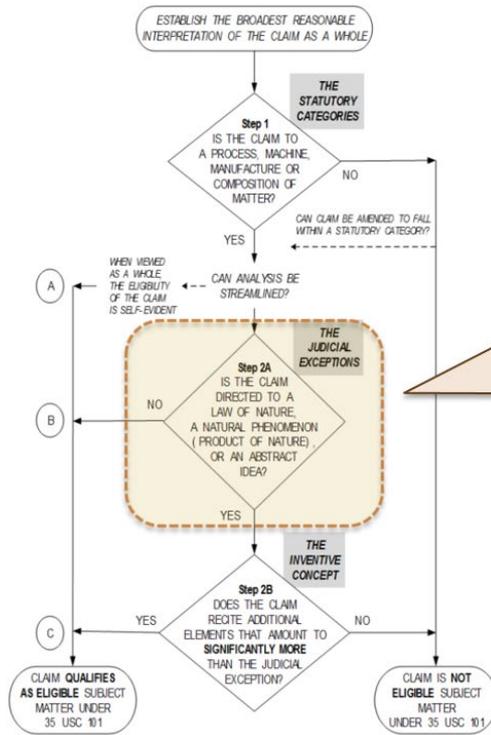
- Makes two changes in Step 2A:
  - Sets forth new procedure for Step 2A (called “**revised Step 2A**”) under which a claim is not “directed to” a judicial exception unless the claim satisfies a two-prong inquiry; and
  - Abstract ideas limited to: mathematical concepts; mental processes; certain methods of organizing human activity

# What remains the same



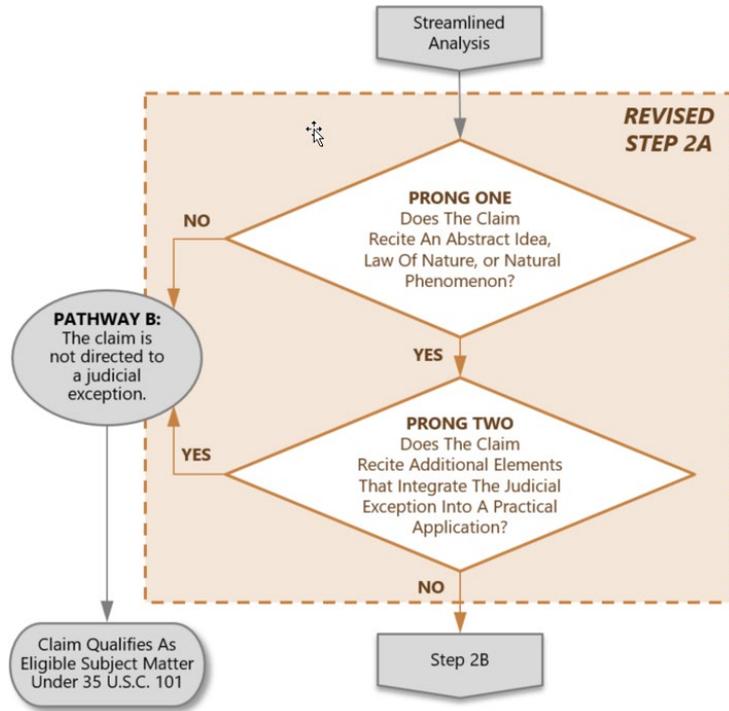
No changes to:  
Step 1 (statutory categories)  
Streamlined analysis  
Step 2B

# What has changed: revised Step 2A



2019 PEG revises Step 2A:  
Creates new two-prong inquiry for determining whether a claim is "directed to" an exception. Groups abstract ideas.

# What has changed: revised Step 2A



- This flowchart depicts revised Step 2A.
- Under this new two-prong inquiry, a claim is now eligible at revised Step 2A unless it:
  - Recites a judicial exception and
  - The exception is not integrated into a practical application of the exception.

# ***Revised Step 2A is a two-prong inquiry***

- Prong One: evaluate whether the claim recites a judicial exception (an abstract idea enumerated in the 2019 PEG, a law of nature, or a natural phenomenon).
  - If no exception is recited, the claim is **eligible**. This concludes the eligibility analysis.
  - If claim recites an exception, go to Prong Two.
- Prong Two: evaluate whether the claim recites additional elements that integrate the exception into a practical application of the exception.
  - If the recited exception is integrated into a practical application, then the claim is **eligible**. This concludes the eligibility analysis.
  - If the exception is not integrated into a practical application, then the claim is “directed to” the exception. Go to Step 2B for further analysis.

# Prong two considerations: details

Limitations that are indicative of integration into a practical application:

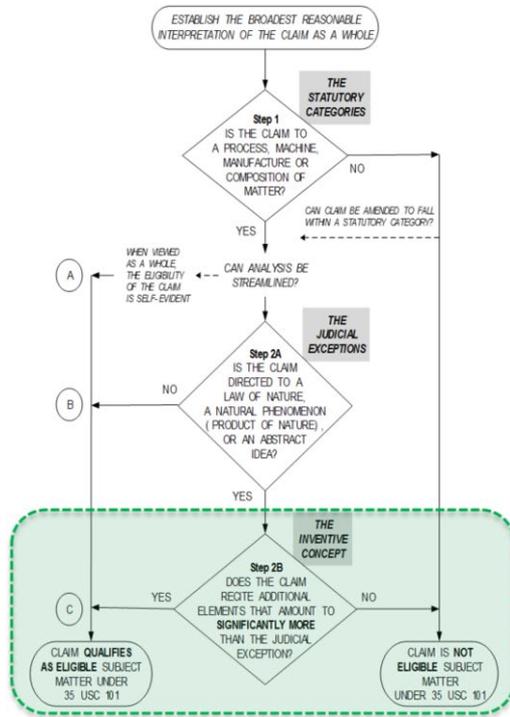
- Improvements to the functioning of a computer, or to any other technology or technical field
- Applying or using a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition – see *Vanda Memo*;
- *Vanda Pharm. Inc. v. West-Ward Pharm.*, 887 F.3d 1117 (2018)
- Applying the judicial exception with, or by use of, a particular machine -
- Effecting a transformation or reduction of a particular article to a different state or thing -

Limitations that are **not** indicative of integration into a practical application:

- Adding the words “apply it” (or an equivalent) with the judicial exception, or mere instructions to implement an abstract idea on a computer, or merely uses a computer as a tool to perform an abstract idea -
- Adding insignificant extra-solution activity to the judicial exception -
- Generally linking the use of the judicial exception to a particular technological environment or field of use –

Whether claim elements represent only well-understood, routine, conventional activity is considered at Step 2B and is not a consideration at Step 2A.

# What remains the same: Step 2B



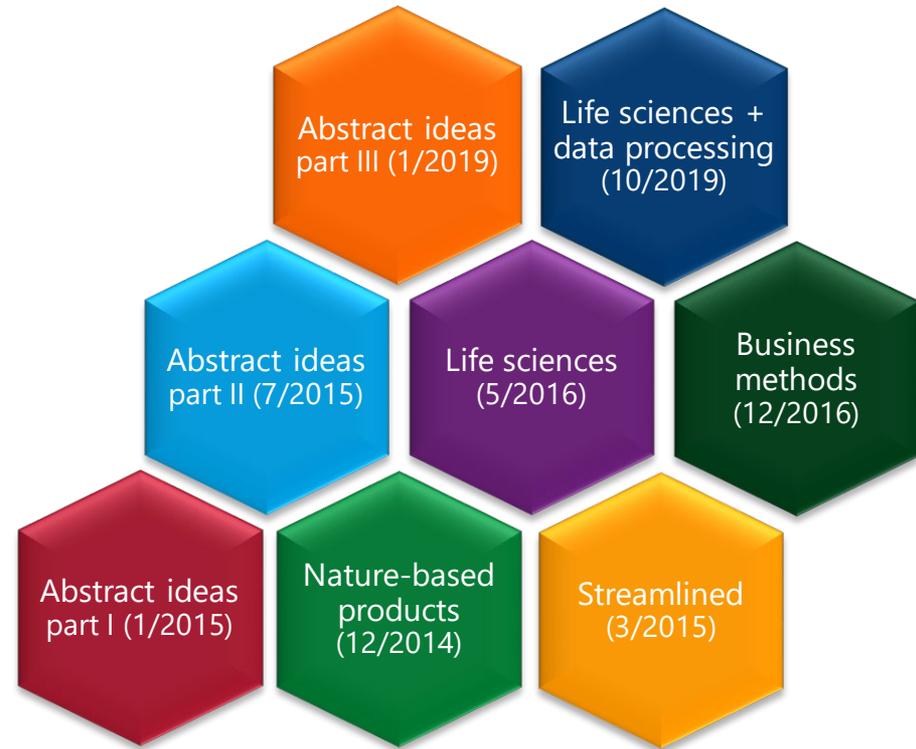
Still analyze inventive concept (aka "significantly more") in 2B  
Even if claim ends up in Step 2B, it may still be eligible  
E.g., claim recites an element or combination of elements that is unconventional

# ***Still analyze for inventive concept in Step 2B***

- In Step 2B, evaluate whether the claim recites additional elements that amount to an inventive concept (aka “significantly more”) than the recited judicial exception.
  - If the claim as a whole amounts to significantly more than the exception itself (there is an inventive concept in the claim), the claim is **eligible**.
  - If the claim as a whole does not amount to significantly more (there is no inventive concept in the claim), the claim is **ineligible**.
- Same procedure as in prior guidance:
  - Identifying whether there are any additional elements recited in the claim beyond the judicial exception(s), and
  - Evaluating those additional elements individually and in combination to determine whether they amount to significantly more, using the considerations discussed on the following slides.

# 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.



# Training

## Current training

- Step 1  
(Sept. 2015)
- 2019 PEG: Introductory Module  
(Jan. 2019)
- 2019 PEG: Advanced Module  
(Jan. 2019)
- Well-Understood, Routine Activity after the *Berkheimer* Memo  
(May 2018)

Training issued  
under prior guidance

## General training

- Overview of Entire Analysis  
(Mar. 2015)
- Formulating Rejections & Evaluating Responses  
aka Workshop III  
(Jun. 2016)
- Exploring Subject Matter Eligibility: Abstract Ideas  
(Feb. 2018)

## Technology-Specific training

- Abstract Ideas Workshop I  
(May 2015)
- Nature-Based Product Training  
(Jul. 2015)
- Abstract Ideas Workshop II  
(Feb. 2016)
- Life Sciences Workshop  
(Jun. 2016)

**Disclosure requirement under  
35 U.S.C. § 112(a)**

# ***35 U.S.C. § 112(a)***

- § 112(a) - The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as **to enable** any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth **the best mode** contemplated by the inventor or joint inventor of carrying out the invention.

# ***The Enablement Requirement***

- For enablement, the critical inquiry is:

*Does the specification provide enough information so that one of ordinary skill in the art can make and/or use the **full scope** of the claimed invention without "undue experimentation"?*

- A conclusion of lack of enablement means that, based on the evidence of record, the specification, at the time the application was filed, would not have taught one of ordinary skill in the art how to make and/or use the full scope of the claimed invention without undue experimentation
- The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date

# ***Enablement Requirement (continued)***

- The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art, as well as the predictability in the art
  - The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation
  - The test of enablement is not whether any experimentation is necessary, but whether, if it is necessary, it is undue

# ***Enablement Requirement (continued)***

- Factors to be weighed when evaluating whether a disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue”; *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). (“Wands” factors):
  - Breadth of the claims;
  - Nature of the invention;
  - State of the prior art;
  - Level of one of ordinary skill;
  - Level of predictability in the art;
  - Amount of direction provided by the inventor;
  - Existence of working examples; and
  - Quantity of experimentation needed to make or use the invention based on the content of the disclosure

# *The Written Description prong*

- This requirement is separate and distinct from the enablement requirement (*Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1355 (Fed. Cir. 2010)(*en banc*)).
- depends on whether one of skill in the art would recognize possession was achieved at the time of filing
- attributes or features possessed by the members of the genus.
- generally, in an unpredictable art, adequate written description of a genus
- which embraces widely variant species cannot be achieved by disclosing only
- one species within the genus

# *Written Description continued*

## *Amgen v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017)*

- "knowledge of the chemical structure of an antigen [does not give] the required kind of structure-identifying information about the corresponding antibodies"
- disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository does not, without more, provide an adequate written description of an antibody claimed by its binding affinity to that antigen, even when preparation of such an antibody is routine and conventional

# *Written Description Continued*

- Adequacy under 35 U.S.C. § 112(a) requires disclosing either a representative number of species falling within the scope of the claimed genus, or structural features common to the members of the genus such that an ordinarily skilled person would be able to visualize or recognize the members of the genus.

# ***Best Mode prong***

- Best Mode: Two-Step Test
- First Step (Subjective):
  - – Did the inventor(s) have a best mode of practicing the invention at the time of filing?
- Second Step (Objective):
  - – If there was a best mode, was it disclosed in sufficient detail
  - to allow one skilled in the art to practice it?

# USPTO resources

- Eligibility webpage:  
[www.uspto.gov/PatentEligibility](http://www.uspto.gov/PatentEligibility)
  - Includes guidance documents, example, training materials, and information about case law
  - Includes links to public comments
- MPEP webpage:  
[www.uspto.gov/MPEP](http://www.uspto.gov/MPEP)
  - Includes current and archived versions of MPEP
  - “Change Summary” document explains changes since last version
  - MPEP 2106 discusses the overall analysis for subject matter eligibility
- Public comments:  
[www.regulations.gov/document?D=PTO-P-2019-0034-0001](http://www.regulations.gov/document?D=PTO-P-2019-0034-0001)
- External chats:  
[www.uspto.gov/patent/initiatives/patent-quality-chat](http://www.uspto.gov/patent/initiatives/patent-quality-chat)
  - January 2019 event discussed the 2019 PEG
  - May 2018 event discussed the Berkheimer Memorandum





# Thank you!

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