

Produced by the United States Patent and Trademark Office; no copyright is claimed by the United States in this presentation or associated materials.

**UNITED STATES
PATENT AND TRADEMARK OFFICE**



USPTO Eligibility Guidance in the Life Sciences

June E. Cohan

Senior Legal Advisor, Office of Patent Examination Policy

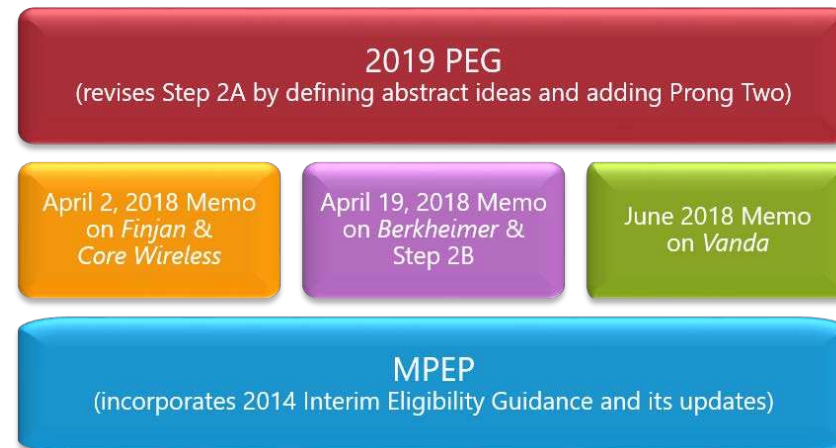
March 21, 2019

UNITED STATES
PATENT AND TRADEMARK OFFICE

uspto

Revised USPTO guidance

- The 2019 Revised Patent Subject Matter Eligibility Guidance (“2019 PEG”) revises existing guidance to:
 - 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.
- Current universe of USPTO guidance on subject matter eligibility is shown in diagram to the right.



Guidance overview

- MPEP 2106 discusses the two criteria for eligibility (statutory category + eligible subject matter) and the overall framework.
- MPEP 2106.03 discusses Step 1 (four categories of patentable subject matter.)
- MPEP 2106.04 + 2019 PEG introduce the judicial exceptions, and provide guidance on how to evaluate Step 2A.
- MPEP 2106.05 explains the significantly more (aka “inventive concept”) inquiry, and provides guidance on how to evaluate Step 2B.
- MPEP 2106.06 discusses the streamlined analysis.
- MPEP 2106.07 + *Berkheimer* Memo discuss how examiners should formulate and support subject matter eligibility rejections.

A chart of MPEP sections affected by the 2019 PEG is posted on the USPTO’s eligibility webpage.



Find the full text of this and thousands of other resources from leading experts in dozens of legal practice areas in the [UT Law CLE eLibrary \(utcle.org/elibrary\)](https://utcle.org/elibrary)

Title search: USPTO Eligibility Guidance in the Life Sciences

Also available as part of the eCourse

[2019 Advanced Patent Law \(USPTO\) eConference](#)

First appeared as part of the conference materials for the

14th Annual Advanced Patent Law Institute session

"Section 101 Updates: Lifesciences"