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USPTO Eligibility Guidance in the Life Sciences

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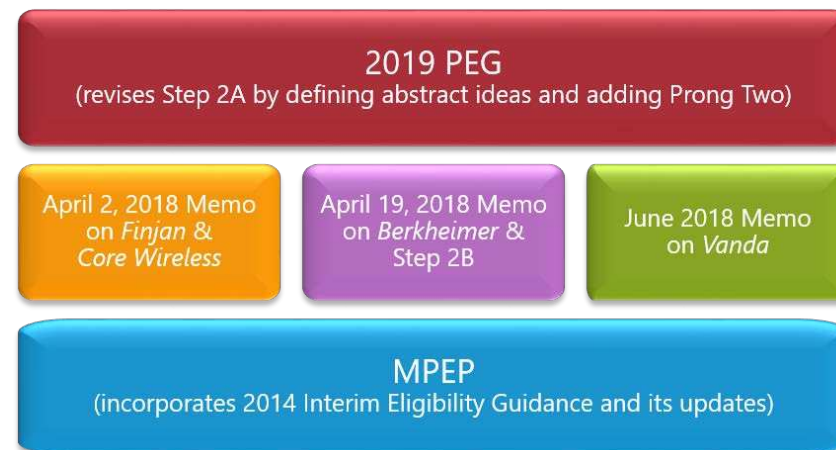
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Revised USPTO guidance

- 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.



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