



## American Intellectual Property Law Association

October 14, 2022

The Honorable Kathi Vidal  
Under Secretary of Commerce for Intellectual Property  
and Director of the United States Patent and Trademark Office  
600 Dulany Street  
Alexandria, VA 22314

Via Federal eRulemaking Portal at <https://www.regulations.gov>

**RE: Comments on USPTO Patent Subject Matter Eligibility Guidance**

Dear Director Vidal:

The American Intellectual Property Law Association (AIPLA) is pleased to have the opportunity to present comments on the Office's guidance on patent subject matter eligibility set forth in MPEP § 2106, as requested in the July 25, 2022 Director's Blog (<https://www.uspto.gov/blog/director/entry/providing-clear-guidance-on-patent>).

AIPLA is a national bar association of approximately 7,000 members that include professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

Subject matter eligibility under Section 101 of the Patent Act is a major concern for our members. AIPLA, like many others, believes that current patent eligibility jurisprudence is not only confusing and unpredictable, it excludes inventions that should be eligible subject matter. AIPLA has advocated for change in amicus briefs to the courts, and explored legislative solutions to the intractable problems that current law presents to new technology. In the absence of clear guidance from the courts, we believe that the only way to remedy the unfortunate situation is for Congress to provide greater clarity.

We recognize that, in the meantime, the U.S. Patent and Trademark Office must apply current law. We have worked with the Office in developing eligibility guidelines for prosecution as well as the pilot program for the eligibility analysis.<sup>1</sup> AIPLA thanks the Office for its continued focus on the eligibility examination procedures.

AIPLA recognizes that the Office must train examiners with practical guidance that they can understand and apply consistently to ensure uniform examination. This guidance must provide standards by which the Office can evaluate examiner performance and ensure consistency. At the same time, we recognize that it would be impossible for examination guidance and training to track all the qualitative nuances of judicial decisions now and in the future.

Current examination guidance appears to AIPLA to meet these requirements. The Office's quality metrics demonstrate that it can be consistently and correctly applied by examiners. It fits well with the current section 101 case law. Eligibility determinations during examination are largely in line with our members' expectations based on the current law.

In sum, AIPLA believes that the Office's eligibility guidance in MPEP § 2106 is appropriate under these challenging circumstances. We believe the guidance should be maintained, without substantial change at this time. We have several recommendations for improvements to various aspects of the guidance.

### **Recommendations for Improvement**

First, our members have found that, when examiners follow the guidance, subject matter eligibility decisions are more consistent with our members' expectations than before the Office issued the 2019 Revised Patent Subject Matter Eligibility Guidance, the October 2019 Patent

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<sup>1</sup> *Testimony of Barbara A. Fiocco, on behalf of AIPLA before Senate Judiciary Committee, June 5, 2019* [https://www.aipla.org/docs/default-source/advocacy/legislative/aipla-testimony-sjc-fiocco-testimony-060519.pdf?sfvrsn=700128fc\\_0](https://www.aipla.org/docs/default-source/advocacy/legislative/aipla-testimony-sjc-fiocco-testimony-060519.pdf?sfvrsn=700128fc_0). Joint AIPLA/IPO Legislative Proposal on Section 101. May 2018 [https://www.aipla.org/docs/default-source/uploadedfiles/documents/advocacy/congress/documents/aipla-ipo-joint-proposal.pdf?sfvrsn=a4067549\\_0](https://www.aipla.org/docs/default-source/uploadedfiles/documents/advocacy/congress/documents/aipla-ipo-joint-proposal.pdf?sfvrsn=a4067549_0). AIPLA Letter to USPTO on Patent Subject Matter Eligibility Study, October 15, 2021 [https://www.aipla.org/docs/default-source/news/aipla-comment-uspto-on-section-101-jurisprudence-final-101521.pdf?sfvrsn=68e37cc0\\_0](https://www.aipla.org/docs/default-source/news/aipla-comment-uspto-on-section-101-jurisprudence-final-101521.pdf?sfvrsn=68e37cc0_0). AIPLA Comments on 2019 Revised Patent Subject Matter Eligibility Guidance, March 8, 2019 [https://www.aipla.org/docs/default-source/advocacy/documents/aipla-comments-on-section-101-guidance-2019march08.pdf?sfvrsn=151cf880\\_0](https://www.aipla.org/docs/default-source/advocacy/documents/aipla-comments-on-section-101-guidance-2019march08.pdf?sfvrsn=151cf880_0). AIPLA Comments on Determining Whether a Claim Element is Well-Understood, Routine, Conventional for Purposes of Subject Matter Eligibility, August 13, 2018 [https://www.aipla.org/docs/default-source/advocacy/documents/aipla-comments-on-berkheimer-memo-2018aug13.pdf?sfvrsn=a374476c\\_0](https://www.aipla.org/docs/default-source/advocacy/documents/aipla-comments-on-berkheimer-memo-2018aug13.pdf?sfvrsn=a374476c_0). AIPLA Comments in Response to the Request for Comments on the "July 2015 Update on Subject Matter Eligibility," October 28, 2015 [https://www.aipla.org/docs/default-source/advocacy/documents/2015/aipla-comments-to-uspto-on-101-exam-guideupdate-10-28-2015.pdf?sfvrsn=693c03c6\\_4](https://www.aipla.org/docs/default-source/advocacy/documents/2015/aipla-comments-to-uspto-on-101-exam-guideupdate-10-28-2015.pdf?sfvrsn=693c03c6_4). AIPLA Comments on Deferred Subject Matter Eligibility Response Pilot Program, March 7, 2022 [https://www.aipla.org/docs/default-source/advocacy/aipla-comments-to-uspto-on-deferred-sme-response-pilot-030722-final.pdf?sfvrsn=f8168047\\_1](https://www.aipla.org/docs/default-source/advocacy/aipla-comments-to-uspto-on-deferred-sme-response-pilot-030722-final.pdf?sfvrsn=f8168047_1)

Eligibility Guidance, and the *Berkheimer* Memo. AIPLA suggests that the Office continue to stress to examiners that the guidance should be closely followed, when applicable. It may be useful to analyze application of the guidance across the examination corps on a unit-by-unit basis to assess where reliance on and compliance with the guidance is lower; additional training could be focused on these units. We believe that increased examiner reliance on the guidance will lead to greater predictability in subject matter eligibility decisions, thereby improving the quality and efficiency of patent examination.

Second, we have found that examiners often refer to PEG examples 1-46, which the Office issued from 2014 to 2019.<sup>2</sup> Examiners often analogize to these examples in subject matter eligibility analysis. Our members will often cite the examples when responding to examiners' decisions. Further examples of how to apply the guidance, using more recent court decisions, would be beneficial. In general, the more examples of how to apply the guidance, the better.

While our members have found the PEG examples helpful when claims are readily analogizable to the examples, we have noted issues in cases where there are significant differences between claims and the examples. For example, when the claims at issue are directed to a different technology than the example, the example may not be useful in the subject matter eligibility analysis. We believe that the Office should emphasize to examiners that, while the PEG examples can sometimes be useful, they are merely examples and there may not be any example applicable to a particular case.

Third, the guidance should be updated to clarify how claims directed to functional improvements in technological fields other than computers could integrate an abstract idea into a practical application of the exception under Step 2A, prong two, of the subject matter eligibility test. This is briefly discussed in MPEP § 2106.04(d).

Fourth, our members have noted that, for certain technologies, subject matter eligibility decisions are more unpredictable, and our members more often disagree with an examiner's determinations in these technologies. Some of our members have identified issues involving technologies such as simulation, modeling, forecasting, medical diagnostics, live cultures, and probiotics. There are few, if any, judicial opinions on which to base examples for these

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<sup>2</sup> [https://www.uspto.gov/sites/default/files/documents/101\\_examples\\_1to36.pdf](https://www.uspto.gov/sites/default/files/documents/101_examples_1to36.pdf);  
[https://www.uspto.gov/sites/default/files/documents/101\\_examples\\_37to42\\_20190107.pdf](https://www.uspto.gov/sites/default/files/documents/101_examples_37to42_20190107.pdf);  
[https://www.uspto.gov/sites/default/files/documents/peg\\_oct\\_2019\\_app1.pdf](https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_app1.pdf)

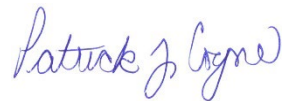
technologies. The Office should develop examples of how to apply the guidance in these technical areas.

Fifth, sometimes the applicant and examiner reasonably disagree how the claims should be interpreted in the context of a rejection based on ineligibility. Issues of claim interpretation also arise in rejections under sections 102, 103, and 112. There may be value in providing additional guidance or training on claim interpretation in the context of a section 101 analysis, to ensure that claim limitations are not being read out of the claim.

Finally, the Office should continue to emphasize that subject matter eligibility must be evaluated on a claim-by-claim basis.

We appreciate the opportunity to provide these comments and would be happy to further discuss our views on these issues with the Office. Please do not hesitate to contact us for further information or clarification.

Sincerely,

A handwritten signature in blue ink that reads "Patrick J. Coyne". The signature is written in a cursive, flowing style.

Patrick J. Coyne  
President  
American Intellectual Property Law Association