

**From:** [Winkler, Mike](#)  
**To:** [Covid19PrioritizedExamPilot](#)  
**Subject:** Comments from the ABA-IPL Section on COVID–19 Prioritized Examination Pilot Program  
**Date:** Tuesday, July 14, 2020 9:49:16 AM  
**Attachments:** [ABA-IPL Comments on COVID19 Exam Pilot.pdf](#)

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Please see the attached letter from the ABA Section of Intellectual Property Law responding to the request from the United States Patent and Trademark Office for public comment regarding the COVID–19 Prioritized Examination Pilot Program (Federal Register, Vol. 85, No. 94, p. 28932, PTO-P-2020-0026, May 14, 2020).

Thank you.

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July 13, 2020

The Honorable Andrei Iancu  
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Director of the United States Patent and Trademark Office  
Mail Stop: Comments—Patents, Commissioner for Patents  
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Via email to: Covid19PrioritizedExamPilot@uspto.gov

Re: Comments in Response to *Request for Public Comment re COVID–19 Prioritized Examination Pilot Program* (Federal Register, Vol. 85, No. 94, p. 28932, May 14, 2020)

Dear Director Iancu:

As Chair of the Section of Intellectual Property Law of the American Bar Association (the “Section” or “ABA-IPL Section”), I write on behalf of the Section to provide comments responding to the request from the United States Patent and Trademark Office (the “Office”) for public comment regarding the COVID–19 Prioritized Examination Pilot Program (Federal Register, Vol. 85, No. 94, p. 28932, PTO-P-2020-0026, May 14, 2020) (“COVID-19 Notice” or “Notice”). The views expressed herein are presented on behalf of the Section, have not been approved by the House of Delegates or the Board of Governors of the American Bar Association, and accordingly should not be construed as representing the positions of the Association.

Since 1894, the ABA-IPL Section has advanced the development and improvement of intellectual property laws and their fair and just administration. As the forum for myriad perspectives and balanced insight on the full spectrum of intellectual property law, the Section serves the ABA as a highly respected voice within the intellectual property profession, before policy makers, and with the public. In that capacity, the Section applauds the Office’s efforts to promote COVID-19 related innovation from small and non-profit inventors through the COVID-19 pilot program. As discussed below, the Section also urges the Office to make certain clarifying changes to the pilot program.

The COVID-19 Notice sets forth the conditions for participation in a pilot program to offer expedited examination of patent applications from qualifying small and non-profit organizations claiming COVID-19 innovations. The COVID-19 Notice outlines four requirements to qualify for the program, namely 1) an appropriate non-provisional patent application; 2) certification that

at least one of the pending claims covers a product or process related to COVID-19 and that such product or process is subject to an applicable FDA approval for COVID-19 use; 3) certification of small or micro-entity status at the time of request; and 4) an application data sheet meeting the conditions specified in 37 C.F.R. 1.53(f)(3)(i).

The ABA-IPL Section recommends clarifying the requirement to certify that at least one of the pending claims cover an FDA approved product or process to participate in the pilot program. The Section is concerned that the wording of the Notice will discourage applicants that may benefit from the program, including those at early stages of the FDA regulatory process and applicants of qualifying COVID-19 device inventions. The requirement that the application must claim an invention that “is subject to an applicable FDA approval for COVID-19 use” implies that at least one claimed invention in the application must already be the subject of an accepted Investigational New Drug (IND) filing prior to participating in the pilot program. Patent applicants, and particularly small entity applicants, may not yet have accumulated sufficient regulatory information to merit an accepted IND at the time when a patent application is ready for filing, but would otherwise benefit from a speedily granted patent under the stated objectives of the pilot program. Consequently, applicants may not be properly incentivized to utilize the program to timely prosecute life-saving innovations that are patentable prior to any of the regulatory acts currently identified by the COVID-19 Notice. The Section therefore suggests that the Office clarify whether an applicant may qualify for the pilot program by certifying that a claimed invention “is or will be subject to” such an FDA approval.

Further, it is unclear whether the pilot program is intended to apply to patent applications with claims to COVID-19 diagnostic products. The phrase “for COVID-19 use” implies use in treatment or diagnosis. Yet, based on the regulatory filing examples in the Notice, the program appears to omit claims to COVID-19 diagnostic products. If the Office intends the pilot program to apply to claims covering COVID-19 diagnostic products, then the Section suggests expanding the regulatory examples to include COVID-19 diagnostic applications subject to FDA approval such as in vitro diagnostics (IVD) or analyte specific reagents (ASR).

Lastly, the Section recognizes that prioritization of a class of patent applications may result in a net delay in the examination of other patent applications. Accordingly, the Section supports clearer qualification guidelines to ensure only appropriate patent applications are accepted for the pilot program. Clarification of the qualifying inventions would help further the USPTO's goal of expediting COVID-19 patent applications of small and non-profit organizations during this crisis.

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The ABA-IPL Section appreciates the opportunity to provide feedback to the Office regarding the COVID-19 Prioritized Examination Pilot Program. If you have any questions regarding the above comments, please feel free to contact me.

Sincerely,



George W. Jordan III  
Chair, ABA Section of Intellectual Property Law