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Qualifying for the USPTO's COVID-19 Prioritized Examination Pilot Program

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When the USPTO launched its COVID-19 Prioritized Examination Pilot Program on May 14, 2020, a key focus was to shorten the timeline to patent protection of COVID-19 related innovations for small businesses and independent inventors, who already face the difficult task of getting important products to market with limited resources.[1] By implementing this pilot program, the USPTO is striving to minimize its impact on a product's barrier to entry and allow important and potentially life-saving products to get to market faster. As such, the USPTO has presented inventors with a beneficial and, quite frankly, necessary program in view of this global pandemic. However, as with many new programs, interpreting the requirements becomes important. As discussed below, the scope of the program and qualification standards may impact one's ability to take advantage of the program.

The COVID-19 Prioritized Examination Pilot Program is limited to applications with claims that cover "product or processes related to COVID-19."[2] More specifically, the product or process must be subject to U.S. Food and Drug Administration (FDA) approval for use in the prevention, diagnosis, or treatment of COVID-19. However, that does not mean, that applicants must have already sought or gained approval.[3] Applications also must not claim the benefit of more than one nonprovisional application or one prior international application designating the U.S. The program prioritizes independent inventors and small businesses by requiring that applicants qualify for small entity or micro entity status and, upon qualifying for the program, the prioritized examination fee and processing fees are waived and applicants can expect a final disposition in one year or less from the grant of prioritized examination. The USPTO is prioritizing expediency in light of the importance of these products, and its goal is to deliver a final disposition within six months from the grant of prioritized status assuming applicants respond to USPTO notices within 30 days. The pilot program is set to last until 500 requests for

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[1] The USPTO announced the COVID-19 Prioritized Examination Pilot Program on the USPTO.gov website on May 8, 2020. Press Release, USPTO, USPTO announces COVID-19 Prioritized Examination Pilot Program for small and micro entities (May 8, 2020), https://www.uspto.gov/about-us/news-updates/uspto-announces-covid-19-prioritized-examination-pilot-program-small-and. The program became effective on May 14, 2020 with publication of the notice in the Federal Register. *See* COVID-19 Prioritized Examination Pilot Program, 85 Fed. Reg. 28,932 (May 14, 2020).

[2] *Id*.

[3] *See* Presentation, USPTO, Faster at the USPTO: Expedited patent prosecution processes, slide 17 (Jul. 23, 2020), https://www.uspto.gov/sites/default/files/documents/20200721-PTAB-Boardside-Chat-7_23_2020.pdf.

prioritized examination under the program are granted. As of August 27, 2020, **282** applications have been filed under this program and **155** have been granted prioritized examination status, leaving **345** available slots.[4]

While the USPTO has made a significant effort to lower the barriers to patent protection for innovators working tirelessly to help us overcome this global pandemic, the scope of this program and its qualifying standards may still serve as barriers for those hoping to take advantage of its shortened timeline and reduced fees. Applicants will no longer be able to take advantage of the pilot program once the USPTO has granted 500 requests. With only 345 slots available and no indication of an extension of the program from the USPTO, those who qualify are encouraged to apply as soon as possible.[5]

However, assessing whether one's product qualifies for the program may present another barrier. It is unclear from the standards set by the USPTO what it means for a product or process to be "related to" COVID-19. In a comment to the USPTO on July 13, 2020, the Section of Intellectual Property Law of the American Bar Association stated that it was unclear whether the program covered claims to COVID-19 diagnostic products, pointing out that "for COVID-19 use" seems to mean use in treatment or diagnosis, but the regulatory filing examples do not include diagnostic applications such as in vitro diagnostics (IVD) or analyte specific reagents (ASR).[6] The regulatory examples cited by the USPTO include the following: Investigational Device Exemption (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an Emergency Use Authorization (EUA).

To illustrate this point, assume that a currently marketed product is an FDA approved 510(k) device that analyzes brain images, along with other data sources, to diagnose patients with Alzheimer's disease. Through data analysis, creators of this device determine that the same multi-modal analysis can be used to diagnose for COVID-19. Products that are used in the diagnosis of COVID-19 seem to qualify for the program given the USPTO's clarification that the product can be one used in the "prevention, diagnosis, or treatment of COVID-19."[7] However, the product must also be subject to FDA approval, and the USPTO does not clarify whether

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[4] *See* USPTO, *COVID-19 Prioritized Examination Pilot Program*, USPTO.GOV, https://www.uspto.gov/initiatives/covid-19-prioritized-examination-pilot (last visited Aug. 27, 2020).
[5] In a presentation by the USPTO on July 23, 2020, the following was stated with regards to the duration of the COVID-19 prioritized examination program: "The USPTO may extend, modify, or terminate the program depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program." *See* Presentation, USPTO, *supra* note 3, at slide 19.
[6] Letter from Mike Winkler, Section Director, ABA Section of Intellectual Property Law, to Andrei Iancu, Director of the USPTO (Jul. 13, 2020), https://www.uspto.gov/sites/default/files/documents/covidpep_a_aba-ipl_2020jul14.pdf.
[7] Presentation, USPTO, *supra* note 3.

"subject to approval" can apply generally to the product (i.e., FDA approval for Alzheimer's diagnosis is sufficient) or must apply to the product's diagnosis of COVID-19 specifically. If the latter is true, then the owner of the device will have to seek out additional resources for another FDA approval so it can certify that it is in fact "subject to approval" and qualifies for the program. Moreover, as discussed above by the ABA, the list of examples the USPTO cites does not clarify inclusivity of diagnostic applications, and does not include 510(k) approved devices.[8]

The COVID-19 Prioritized Examination Pilot Program is clearly a necessary program that seeks to address an acute and obvious public policy need. As with many new programs, some terms are still up for interpretation. Time will tell where the line is drawn between qualification and non-qualification. Regardless, those who believe they qualify should definitely apply while the program is still accepting applications, but also recognize that some of the requirements are, to date, still vague, and that qualification may not be a guarantee.

[8] In a comment to the USPTO on May 15, 2020, Jeff Goehring raised this exact question: whether or not "Class I and II medical devices through 510k submissions and/or through the *de novo* classification process" qualify. E-mail from Jeff Goehring to Robert Clarke & Covid19PrioritizedExamPilot@uspto.gov (May 15, 2020), https://www.uspto.gov/sites/default/files/documents/covidpep_f_goehring_2020may15.pdf. It does not appear as if the USPTO has addressed this question. *See* Presentation, USPTO, *supra* note 3, at slides 15-19.