

USPTO Introduces Prioritized Examination Pilot Program for Patent Applications Related to COVID-19

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In an effort to support ongoing research and development efforts related to treatments and diagnostic tools for COVID-19, the United States Patent and Trademark Office (“USPTO”) has announced a prioritized examination pilot program (“the Pilot Program”) directed specifically to patent applications claiming products or processes related to COVID-19.[1] Under the Pilot Program, the USPTO will advance out of turn certain patent applications relating to COVID-19.[2] Additionally, certain fees normally associated with prioritized examination, will be waived.[3] Table 1 provides a summary of the requirements to participate in the Pilot Program.

Qualifying technologies	Claimed products or processes related to COVID-19
Regulatory requirements	Claimed product or process must be subject to an applicable FDA approval for COVID-19 use (e.g., an Investigational Device Exception (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an Emergency Use Authorization (EUA))
Qualifying applicants	Applicant must qualify as a micro-entity or small-entity
Procedural requirements	Applicant must file a Certification and Request for COVID-19 Prioritized Examination Pilot Program
Qualifying patent applications	<ol style="list-style-type: none"> 1. Non-continuing and original non-provisional patent applications (plant or utility patent applications) 2. Plant or utility non-provisional applications that claim the benefit of only one earlier-filed non-provisional patent application (e.g., an earlier U.S. non-provisional application, or an international application designating the United States) 3. Pending utility or plant patent applications where a request for prioritized examination is filed with or after the filing of a Request for Continued Examination (RCE)
Effect	Final disposition within twelve months of prioritized examination being granted (e.g., a Notice of Allowance or a Final Office Action)
Fees	None. Fees waived
Pilot program size	Up to 500 qualifying patent applications

Table 1. Summary of the requirements to participate in the Prioritized Examination Pilot Program for COVID-19 Related Patent Applications.

I. Background

The USPTO normally examines patent applications in the order of their U.S. filing dates. Under normal examination procedures, it is common for a new patent application to be pending in excess of 12 months before receiving an initial action on the merits from a patent examiner. Current USPTO procedures allow applicants to request prioritized examination[4]; however, to do so, applicants must pay a prioritized examination fee[5] and a processing fee.[6]

II. Pilot Program Size

The USPTO will accept up to 500 qualifying patent applications for prioritized examination.[7]

III. Pilot Program Requirements

a. Effective Date

The Pilot Program goes into effect on May 14, 2020.[8]

b. Entity Size

The Pilot Program is currently limited to those applicants who qualify for micro-entity or small-entity status.[9] Applicants filing under large-entity status are not currently eligible for the Pilot Program.[10]

c. Timing of Request

The USPTO specifies three scenarios where a request for prioritized examination under the Pilot Program will be considered. The form PTO/SB/450 titled “Certification and Request for COVID-19 Prioritized Examination Pilot Program Under 35 C.F.R. 1.102(e)” is recommended by the USPTO to request participation in the Pilot Program.[11]

(1) A request for prioritized examination will be considered if included with the filing of a non-continuing, original non-provisional patent application. Such a patent application could be either a plant or a utility patent application.[12]

(2) A request for prioritized examination will be considered if included with the filing of an original plant or utility non-provisional application that claims the benefit of one earlier-filed application. The earlier-filed application may be an earlier U.S. non-provisional application or a prior international application designating the United States.[13] Those applications claiming priority to two or more earlier-filed applications are not eligible for participation in the Pilot Program; however, claiming the benefit of one or more provisional applications or the inclusion of one or more foreign priority claims will not cause a non-provisional application to be ineligible for the Pilot Program.[14]

(3) A request for prioritized examination will be considered if filed with or after the filing of a Request for Continued Examination (RCE) in a plant or utility non-provisional application or in a national stage of an international application.[15]

d. Relation to COVID-19

To qualify for the Pilot Program, an application must contain one or more claims to a product or process related to COVID-19.[16] Additionally, the claimed product or process must be subject to an applicable FDA approval for COVID-19 use.[17] Such an FDA approval could be an Investigational Device Exception (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an Emergency Use Authorization (EUA).[18]

IV. Pilot Program Benefits

The Pilot Program waives the prioritized examination fee and the processing fee normally assessed by the USPTO for prioritized examination.[19] Once prioritized examination is granted, a patent application will be prioritized and examined out of turn.[20] It is anticipated that an application will receive a final disposition within twelve months of prioritized examination being granted.[21] Under USPTO procedures, a final disposition is one of (1) the mailing of a Notice of Allowance; (2) the mailing of a Final Office Action; (3) the filing of a Request for Examination (RCE); (4) abandonment of the application; or (5) the filing of a Notice of Appeal.[22]

V. Conclusion

Participation in the Pilot Program affords those applicants who are addressing the COVID-19 pandemic the opportunity for rapid disposition of their patent applications. While the Pilot Program is currently limited to 500 applications, the Pilot Program may be extended or terminated based on USPTO resource allocation and feedback from the public.[23] Thus, urgent consideration and action is necessary for those applicants who meet the requirement for participation.

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- [1] United States Patent and Trademark Office, “COVID-19 Prioritized Examination Pilot Program,” 85 Fed. Reg. 28932 (May 14, 2020).
- [2] *Id.* at 28933.
- [3] *Id.*
- [4] See 37 C.F.R. § 1.102(e).
- [5] 37 C.F.R. § 1.17 (c) (\$1,000 for micro entity, \$2,000 for small entity).
- [6] 37 C.F.R. § 1.17 (i)(1) (\$35 for micro entity, \$70 for small entity).
- [7] May 18, 2020 USPTO press release entitled “COVID-19 Prioritized Examination Pilot Program” (hereinafter “May 18 Press Release”).
- [8] May 18 Press Release.
- [9] *Id.* at 28933.
- [10] May 18 Press Release
- [11] 85 Fed. Reg. 28933.
- [12] *Id.*
- [13] *Id.*
- [14] *Id.*
- [15] *Id.*
- [16] May 18 Press Release.
- [17] 85 Fed. Reg. at 28933.
- [18] May 18 Press Release.
- [19] 85 Fed. Reg. 28933.
- [20] *Id.*
- [21] 85 Fed. Reg. at 28934.
- [22] *Id.*
- [23][23] May 18 Press Release.