



3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-P-2020-0026]

COVID-19 Prioritized Examination Pilot Program

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is implementing a pilot program to provide prioritized examination of certain patent applications. To qualify, the claim(s) of an application must cover a product or process related to COVID-19, and such product or process must be subject to an applicable FDA approval for COVID-19 use.

Under this pilot program, the USPTO will grant qualified requests for prioritized examination without payment of certain fees associated with prioritized examination for applicants that qualify for small or micro entity status. The goal of prioritized examination is to provide a final disposition within 12 months, on average, from the date the prioritized status has been granted. Furthermore, the USPTO believes it can achieve final disposition in six months if applicants provide more timely responses to notices and actions from the USPTO, as compared to those required by prioritized examination. This notice outlines the conditions, eligibility requirements, and guidelines of the pilot program.

DATES: Comments must be received by [INSERT DATE 60 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER] to ensure consideration.

Pilot Duration: The COVID-19 Prioritized Examination Pilot Program will accept requests for prioritized examination beginning [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] until such time as the USPTO has accepted a total of 500 requests. The USPTO may extend the pilot program (with or without modifications) or terminate it depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program. If the pilot program is extended or terminated, the USPTO will notify the public.

ADDRESSES: Comments should be sent by email addressed to Covid19PrioritizedExamPilot@uspto.gov. If submission of comments by email is not feasible due to, e.g., a lack of access to a computer and/or the internet, please contact the USPTO for special instructions using the contact information provided in the Further Information section of this notice.

Comments will be available for viewing via the USPTO's website (<https://www.uspto.gov>). Because the comments will be made available for public viewing, information the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION, CONTACT: Robert A. Clarke, Editor of the Manual of Patent Examining Procedure (MPEP) (telephone at 571-272-7735; email at robert.clarke@uspto.gov).

SUPPLEMENTARY INFORMATION: New patent applications are normally taken up for examination in the order of their U.S. filing dates. See section 708 of the MPEP (9th ed., Rev. 08.2017, 2018). The USPTO has procedures under which an application will be advanced out of turn (accorded special status) for examination if the applicant files a petition to make special under 37 CFR 1.102(c) and (d) with the appropriate showing. See 37 CFR 1.102(c) and (d) and MPEP 708.02 and 708.02(a).

In addition, an application can be advanced out of turn (accorded special status) for examination if the applicant files a grantable request for prioritized examination under 37 CFR 1.102(e). Section 11(h) of the Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284 (2011), effective September 26, 2011, provides for prioritized examination whereby an applicant may request prioritized examination upon payment of appropriate fees and compliance with certain requirements. See MPEP 708.02(b). 35 U.S.C. 2(b)(2)(G) authorizes the USPTO to provide for prioritization of examination of applications for products, processes, or technologies that are important to the national economy or national competitiveness without requiring the prioritized examination fee.

In an extraordinary situation, 37 CFR 1.183 permits the USPTO to suspend or waive *sua sponte* any requirement of its regulations that is not a requirement of the patent statutes. The USPTO considers the effects of the COVID-19 outbreak that began in approximately January 2020 to be an “extraordinary situation” within the meaning of 37 CFR 1.183 for affected patent applicants and innovators. Consistent with this determination and the provisions of 35 U.S.C. 2(b)(2)(G), the USPTO has decided to implement a pilot program to provide prioritized examination without payment of the additional fees for prioritized examination for certain applications that claim products or processes that are subject to an applicable FDA approval for COVID-19 use. Such approvals may include, but are not limited to, an Investigational New Drug (IND) application, an Investigational Device Exemption (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an Emergency Use Authorization (EUA). Information on INDs, IDEs, NDAs, BLAs, PMAs, and EUAs may be obtained at www.fda.gov. To focus the USPTO’s resources on those applicants that may be more resource constrained, the pilot is limited to applicants that qualify for either small or micro entity status. The USPTO will periodically evaluate the pilot program to determine whether and to what extent its coverage should be expanded or limited.

The USPTO currently provides for prioritized examination of utility and plant original applications if certain requirements are met. See 37 CFR 1.102(e) and MPEP 708.02(b). Upon filing a request for prioritized examination, an applicant must pay certain fees, including a prioritized examination fee set forth in 37 CFR 1.17(c) and a processing fee

set forth in 37 CFR 1.17(i)(1). The requirement to pay these two fees will be waived under this pilot program if the requirements are met. The remaining fees listed in 37 CFR 1.102(e) and MPEP 708.02(b), subsection I. A. 2., that are not currently set to \$0 must be paid by all applicants, and the requirement to pay those fees by the time the request for prioritized examination is made is not waived under this pilot program.

Part I. Requirements to Participate

1) The request for prioritized examination under the pilot program must be made:

a) with the filing of a non-continuing original utility or plant nonprovisional application;

b) with the filing of an original utility or plant nonprovisional application claiming the benefit of an earlier filing date under 35 U.S.C. 120, 121, or 365(c) of one prior nonprovisional application or one prior international application designating the United States;

or

c) with or after the filing of a request for continued examination (RCE) of such plant or utility application or of a national stage of an international application.

Consistent with 37 CFR 1.102(e)(2), only a single request for prioritized examination filed with or after filing an RCE may be granted in an application.

The pilot program is reserved for the above nonprovisional applications. Any application that claims the benefit of the filing date of two or more prior filed nonprovisional U.S. applications or international applications designating the United States under 35 U.S.C. 120, 121, or 365(c) is not eligible for participation under the pilot program, but the applicant may request prioritized examination under 37 CFR 1.102(e). Claiming the benefit under 35 U.S.C. 119(e) of one or more prior provisional applications or claiming a right of foreign priority under 35 U.S.C. 119(a)-(d) or (f) to one or more foreign applications will not cause a nonprovisional application to be ineligible for the pilot program.

The USPTO encourages the use of form PTO/SB/450, titled “Certification and Request for COVID-19 Prioritized Examination Pilot Program under 37 CFR 1.102(e),” to make the request for prioritized examination under the pilot. Form PTO/SB/450 is available at <https://www.uspto.gov/patent/forms/forms-patent-applications-filed-or-after-september-16-2012>. Form PTO/SB/450 contains the necessary certifications for qualification to participate in the pilot. Use of form PTO/SB/450 will also enable the USPTO to quickly identify and timely process the request.

2) The applicant must certify 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. Form PTO/SB/450 contains this certification.

3) The request must include a certification that the applicant qualifies for either small entity (37 CFR 1.27) or micro entity (37 CFR 1.29) status when the request is made.

Form PTO/SB/450 contains this certification.

4) The request must include an executed application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i).

Part II. Internal Processing of the Request under the Pilot Program

Requests complying with the four requirements above will be further reviewed to determine if the other requirements for prioritized examination are met, e.g., the requirements of 37 CFR 1.102(e) other than payment of the fees set forth in 37 CFR 1.17(c) and 1.17(i)(1). These requirements include: filing the application and request for prioritized examination under the pilot program via the USPTO's patent electronic filing systems (EFS-Web or Patent Center) if the application is a utility application; presenting no more than four independent claims and 30 total claims, and no multiple dependent claims; and paying the other required fees (e.g., the basic filing fee, search fee, and examination fee). In addition, obtaining an extension of time to a notice before the request has been acted upon will result in the request being denied. See MPEP 708.02(b), subsection I, for a discussion of the requirements.

Part III. Office Actions and Replies under the Pilot Program

The time periods set for reply in Office actions for applications undergoing prioritized examination under the pilot program will be the same as those for other applications undergoing prioritized examination and are set forth in MPEP 710.02(b). If an applicant files a petition for an extension of time to file a reply or a request for suspension of action, the petition or request will be acted upon, but the prioritized examination of the application under the pilot program will be terminated, as is the case with other applications undergoing prioritized examination. In addition, in order to maintain special status, filing an amendment to the application that results in more than four independent claims, more than 30 total claims, or a multiple dependent claim will terminate the prioritized examination, as is the case with other applications undergoing prioritized examination. Upon termination of prioritized examination, the application will be removed from the examiner's special docket and placed on the examiner's regular docket in accordance with its stage of prosecution, as is the case with other applications undergoing prioritized examination.

A reply to an Office action must be fully responsive to the rejections, objections, and requirements made by the examiner. Any amendment filed in reply to a non-final Office action will be treated as not fully responsive if it attempts to: (1) add claims that would result in more than four independent claims or more than 30 total claims pending in the application; or (2) add any multiple dependent claim. If a reply to a non-final Office action is not fully responsive because it does not comply with the pilot program

requirements but is a *bona fide* attempt to advance the application to final action, the examiner may, at his or her discretion, provide one month or 30 days, whichever is longer, for the applicant to supply a fully responsive reply, in which case prioritized examination would not be terminated. Submission of a petition for extension of time under 37 CFR 1.136(a) to the notice of nonresponsive amendment will result in termination of special status. Any further nonresponsive amendment will not be treated as *bona fide*, and the time period set in the prior notice will continue to run.

Part IV. After-Final and Appeal Procedures

The mailing of a final Office action or the filing of a Notice of Appeal, whichever is earlier, is a final disposition for purposes of the 12-month goal for the pilot program. During the appeal process, the application will be treated in accordance with the normal appeal procedure (see MPEP chapter 1200). Any amendment, affidavit, or other evidence submitted after a final Office action and prior to appeal must comply with 37 CFR 1.116. The filing of an RCE for an application in the pilot program is a final disposition for purposes of the 12-month goal for the program. The application will not retain its special status after the filing of a proper RCE.

Part V. Proceedings Outside the Normal Examination Process

If an application becomes involved in proceedings outside the normal examination process (e.g., a secrecy order or petitions under 37 CFR 1.181-1.183), the USPTO will place the application in special status under the pilot program before and after such proceedings. During those proceedings, however, the application will not be under special status. For example, while under a secrecy order, the application will be treated in accordance with the normal secrecy order procedures and will not be in special status under the pilot program. Once the proceeding outside the normal examination process is completed, the application will continue in special status until it reaches a final disposition, which may occur later than 12 months from the grant of special status under the pilot program.

Part VI. First Action Interview (FAI) Pilot Program is not Available

Applications accepted into the FAI Pilot Program are not eligible for this pilot program. In addition, applications accepted into this pilot program will not be eligible to participate in the FAI Pilot Program. However, standard interview practices and procedures applicable to regular *ex parte* prosecution will still be available. See MPEP 713.02. For more information about the FAI Pilot Program, please visit <https://www.uspto.gov/patent/initiatives/first-action-interview/full-first-action-interview-pilot-program>.

Part VII. Actions Resulting in Termination from the Pilot Program

There is no provision for withdrawal from special status under the pilot program.

However, the filing of a petition for any extension of time under 37 CFR 1.136(a) will result in the termination of special status under the pilot program. Presenting more than one benefit claim to previously filed nonprovisional U.S. applications or international applications designating the United States under 35 U.S.C. 120, 121, or 365(c) will also result in the termination of special status under the pilot program.

An applicant may abandon the application that has been granted special status under the pilot program in favor of a continuing application. However, a continuing application will not automatically be given prioritized examination status based on the request filed in the parent application. Each application (including each continuing application) must, on its own, meet all requirements for prioritized examination under the pilot program.

Part VIII. Twelve-Month Goal

The objective of the pilot program is to complete, on average, the examination of an application within 12 months of special status being granted (i.e., within 12 months from the mailing date of the decision granting the petition to make special). The 12-month goal is successfully achieved when one of the following final dispositions occurs within 12 months from the grant of special status under the pilot program: (1) the mailing of a notice of allowance; (2) the mailing of a final Office action; (3) the filing of an RCE; (4)

the abandonment of the application; or (5) the filing of a Notice of Appeal. The final disposition of an application, however, may occur later than the 12-month time frame in certain situations (e.g., when the applicant filed a petition under 37 CFR 1.181). In any event, however, the 12-month time frame is a goal. Any failure to meet the 12-month goal, or other issues related to this goal that arise, are neither petitionable nor appealable matters.

Applicants may shorten the overall pendency of an application in the pilot program by replying to Office actions and notices earlier than required by the USPTO. For example, the USPTO will endeavor to reduce pendency, from approval of the request for prioritized examination to final disposition, to six months if all replies occur within 30 days of a notice by the USPTO. This goal depends on additional factors, including the demands placed on specific examiners by multiple co-pending applications under the pilot program. Current statistics for prioritized examination are available at <https://www.uspto.gov/corda/dashboards/patents/main.dashxml?CTNAVID=1007>.

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Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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