



DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2020-0036]

Deferred-Fee Provisional Patent Application Pilot Program and Collaboration

Database to Encourage Inventions Related to COVID-19

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

ACTION: Notice.

SUMMARY: Patents and published patent applications provide a key source of free-flowing technical information among the world's brightest minds, thus promoting further innovation. The United States Patent and Trademark Office (USPTO or Office) recognizes that its charge to issue high-quality patents to inventors goes hand-in-hand with dissemination of this important information. Such information flow is now more important than ever in view of the urgent challenges posed by COVID-19. Therefore, the USPTO is implementing a deferred-fee provisional patent application pilot program (the program) to promote the expedited exchange of information about inventions designed to combat COVID-19. Under this program, the USPTO will permit applicants to defer payment of the provisional application filing fee until the filing of a corresponding nonprovisional application. In turn, applicants must agree that the technical subject matter disclosed in their provisional applications will be made available to the public via a searchable collaboration database maintained on the USPTO's website. To qualify for the program, the subject matter disclosed in the provisional application must concern a product or process related to COVID-19, and such product or process must be subject to

an applicable Food and Drug Administration (FDA) approval for COVID-19 use, whether such approval has been obtained, is pending, or will be sought prior to marketing the subject matter for COVID-19.

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 deferred-fee provisional patent application pilot program will accept certifications and requests for participation for a period of 12 months, beginning on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The USPTO may extend the pilot program (with or without modifications) or terminate it depending on the workload and resources needed to administer it, feedback from the public, and its effectiveness. Depending on feedback and public interest, the technological scope could also be expanded beyond COVID-19 to other areas that are the focus of pioneering or rapid innovation. If the pilot program is extended or terminated, the USPTO will notify the public. The USPTO may also make the program permanent via the rule-making process.

ADDRESSES: Comments should be sent by email addressed to Covid19ProvisionalApplication@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 below.

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.

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); or Kathleen Kahler Fonda, Senior Legal Advisor, Office of Patent Legal Administration (telephone at 571-272-7754, email at kathleen.fonda@uspto.gov).

SUPPLEMENTARY INFORMATION:

I. Background

The COVID-19 outbreak is a global crisis in urgent need of creative solutions. The American patent system has long facilitated creative solutions to important challenges by securing exclusive rights for inventors and disseminating technical information to the public to promote follow-on innovation. To disseminate information about inventions designed to combat COVID-19 on a more expedited basis while still securing rights for inventors, the USPTO is implementing a deferred-fee provisional patent application pilot program. The intent is to provide a cost-effective way for inventors to disclose their ideas to others quickly, but without losing their right to claim what is described and enabled by their disclosure. This expedited disclosure may allow the public to benefit from the efforts of inventors seeking to address the COVID-19 outbreak sooner than would otherwise be possible. Early public disclosure can facilitate collaborations, partnerships, or joint ventures, and, in turn, spur and expedite the development of critically needed

technologies.

II. Description of the Program

The program provides for early disclosure of the technical subject matter of provisional applications. Program participants will submit a technical disclosure as well as a provisional application cover sheet and a certification and request to participate in the program (form PTO/SB/452, titled “Certification and Request for COVID-19 Provisional Patent Application Program,” available at <https://www.uspto.gov/patent/forms/forms-patent-applications-filed-or-after-september-16-2012>). The Office will upload the technical disclosure and the form into a searchable public collaborative database and process the technical disclosure and the cover sheet as a filing of a provisional application. In exchange for the disclosure of the technical subject matter, program participants may defer payment of the provisional application filing fee until such time as a nonprovisional application claiming the benefit of the provisional application is filed. The basic filing fee need not be paid at all by those who desire publication of the technical subject matter in the collaborative database but do not make a benefit or priority claim in a corresponding later-filed application.

The statutory basis for provisional patent applications is 35 U.S.C. 111(b). In order to be entitled to a filing date, a provisional application must include a specification in accordance with 35 U.S.C. 112; see 37 CFR 1.53(c). Claims may also be included but are not required. Under 35 U.S.C. 111(b)(3), a fee is also required for a provisional application. Currently, the undiscounted fee is \$280; applicants who qualify for small

entity status pay \$140, and those who qualify for micro entity status pay \$70. See 37 CFR 1.16(d). Although payment of the fee is a statutory requirement, 35 U.S.C. 111(b)(3) authorizes the Director of the USPTO to permit payment after the filing date of the application. The filing requirements for provisional applications are discussed in MPEP 601.01(b).

A later-filed international, foreign or domestic nonprovisional application may be entitled to claim benefit or priority of the filing date of a provisional application. Domestic benefit under 35 U.S.C. 119(e)(1) and 37 CFR 1.78 requires that the provisional application be entitled to a filing date, and name the inventor or a joint inventor also named in the later-filed nonprovisional application. Furthermore, the basic filing fee set forth in 37 CFR 1.16(d) must be paid in order to rely on the provisional application in a later-filed nonprovisional application, although there is no requirement that the basic filing fee be paid in order for the technical subject matter to be posted in the program's collaborative database. See 37 CFR 1.78(a)(2). For more information about claiming the right of priority in an international application under the Patent Cooperation Treaty, see MPEP 1828. Regardless, the later-filed nonprovisional, international or foreign application should be filed not later than 12 months after the date on which the provisional application was filed if a benefit or priority claim to the provisional application is to be made.

Fee Deferral Under the Program

Under the program, payment of the basic filing fee for a provisional application may be deferred past the date on which the provisional application is filed, without imposition of a surcharge, provided that the fee is paid not later than the date on which a nonprovisional application that claims benefit or priority of the provisional application is filed. If the provisional application basic filing fee was not paid, a reminder will be sent 10 months after the provisional application filing date indicating that the basic filing fee must be paid not later than 12 months after the provisional application filing date, and in any case, the fee must be paid in order for an applicant to claim the benefit of the filing date of the provisional application in a nonprovisional application.¹

Certification of Eligibility for the Program

Consistent with the goal of encouraging information-sharing regarding inventions related to COVID-19, participation in the program requires a certification that the subject matter disclosed in the provisional patent application concerns a product or process related to COVID-19. The product or process must be 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

¹ Ordinarily, when the basic filing fee is not paid upon filing, the Office notifies the applicant that it must be paid within an extendable two-month time period from the date of the notice, and imposes a surcharge in accordance with 37 CFR 1.16(g). See MPEP 601.01(b). However, no notice requiring a basic filing fee or surcharge will be sent in an application submitted under the program.

(PMA), or an Emergency Use Authorization (EUA). Information on INDs, IDEs, NDAs, BLAs, PMAs, and EUAs may be obtained at www.fda.gov.

The subject matter requirement for participation in the program is the same as that for participation in the COVID-19 Prioritized Examination Pilot Program announced on May 8, 2020 (85 FR 28932). The requirement is broadly drafted to include any sort of FDA premarket regulatory review procedure. An applicant need not have obtained or sought FDA approval prior to requesting to participate in either the program or the prioritized examination pilot. However, the product or process disclosed in the application must require premarket regulatory review by the FDA prior to commercial marketing or use.

III. Prior Art Considerations

An inventor's technical disclosure published in the collaboration database cannot be used against the inventor's own corresponding later-filed nonprovisional application in the United States, provided that the later-filed application is filed within one year of the public disclosure. Regardless, applicant should consider filing a nonprovisional application making a proper benefit claim under 35 U.S.C. 119(e) and 37 CFR 1.78(a) no more than one year after filing of the provisional application. Special care should be taken where foreign patent protection is desired. Many foreign jurisdictions treat an inventor's public disclosure made within one year of filing as prior art against the inventor's own application unless that earlier disclosure is the subject of a proper priority claim in that jurisdiction. For this reason, applicants should be aware of the prior art

implications of their submissions. Making a submission under the program will result in a public disclosure of the technical subject matter via the Office's searchable collaboration database. Thus, such a public disclosure may be citable as prior art under 35 U.S.C. 102(a)(1) as of the date it publishes. In addition, the complete provisional patent application submitted under the program may become prior art under 35 U.S.C. 102(a)(2) as of the filing date, but only if there has been a proper benefit claim under 35 U.S.C. 119(e) in a later-filed nonprovisional application or international application and the later-filed application has been published or deemed published under 35 U.S.C. 122(b) or has issued as a U.S. patent.

It is important to note, for the purpose of understanding prior art implications, that the Office does not consider adding the technical subject matter disclosed in submissions to the Office's collaboration database under the program to constitute publication of the provisional application under 35 U.S.C. 122(b).² Rather, by way of submission of form PTO/SB/452 and in accordance with the confidentiality waiver provision of 35 U.S.C. 122(a), the program participant specifically authorizes the database to publish the technical subject matter disclosed as well as any contact information the participant wishes to include. The database will also publish the name of the inventor or the first named joint inventor, the provisional application filing date, and the date the submission was placed in the database. However, the database will not publish the cover sheet, which is a requirement for a provisional application. Furthermore, the basic filing fee need not

² Provisional applications are generally maintained in confidence and not published under 35 U.S.C. 122(b). See 35 U.S.C. 122(b)(2)(A)(iii).

have been paid at the time of publication in the database. For these reasons, the disclosure in the database is not a complete provisional patent application under 35 U.S.C. 111(b).

IV. Requirements to Participate in the Program

1) The certification and request for participation in the program must be by way of a completed form PTO/SB/452, titled “Certification and Request for COVID-19 Provisional Patent Application Program.” Form PTO/SB/452 is available at <https://www.uspto.gov/patent/forms/forms-patent-applications-filed-or-after-september-16-2012>. The form must be submitted with a specification upon filing of the application. Form PTO/SB/452 cannot be used to request that a provisional application that had previously received a filing date be included in the program; such a request will be denied. Form PTO/SB/452 contains the necessary certification regarding the need for the product or process disclosed to obtain FDA approval prior to marketing for a COVID-19 use, as well as a statement authorizing publication of the technical subject matter of the program submission. It includes a field for the name of the sole inventor or the first joint inventor. (Program participants should note, as discussed below, that the provisional application cover sheet required by 37 CFR 1.51(c)(1), and not form PTO/SB/452, will be used to establish the inventorship of the provisional application.) Form PTO/SB/452 also allows the program participant to provide any desired contact information to be included in the database. Form PTO/SB/452 must be signed in compliance with 37 CFR 1.33(b). This requires that the form be signed by: (1) a patent practitioner of record; (2) a

patent practitioner not of record who acts in a representative capacity under the provisions of 37 CFR 1.34; or (3) the applicant (37 CFR 1.42), if the applicant is not a juristic entity. If the applicant is the inventor (as defined in 35 U.S.C. 100(f)), and the inventor is not represented by a patent practitioner, then all individuals who constitute the inventive entity must sign; limited exceptions are provided in 35 U.S.C. 117. Use of form PTO/SB/452 will enable the USPTO to identify the provisional application as a program submission and to process the certification and request in a timely manner.

The program is reserved for provisional patent applications filed under 35 U.S.C. 111(b). No nonprovisional patent application or international application designating the United States is eligible for participation.

2) The program submission must be in the English language.

3) The program submission must include the provisional application cover sheet required by 37 CFR 1.51(c)(1). In accordance with 37 CFR 1.51(c)(1)(ii), this cover sheet will be used to establish the inventorship of the provisional application. Although form PTO/SB/452 provides a field to indicate the first named inventor for inclusion in the searchable online database, the entry in that field will not override the inventorship established in the required cover sheet. If the applicant is a juristic entity, the applicant must be identified on an application data sheet (ADS) included with the program submission; in that circumstance, form PTO/SB/452 must be signed by a registered

practitioner. See 36 CFR 1.46(b). The ADS may serve as the required cover sheet. See 37 CFR 1.53(c)(1) and MPEP 601.01(b).

4) The provisional application specification including any drawings, claims and/or abstract, cover sheet (which may be an ADS), and form PTO/SB/452 must be filed electronically via Patent Center. The specification must be filed in DOCX format to facilitate making the material text searchable. Requests for assistance with electronic filing should be directed to the Patent Electronic Business Center at EBC@uspto.gov.

5) In order for the technical subject matter of a program submission to be posted in the Office's collaboration database, the submission must meet the requirements for a provisional application as indicated in 35 U.S.C. 111(b)(1) and 37 CFR 1.53(c), with the exception that payment of the basic filing fee may be deferred until the filing of a nonprovisional application that is entitled to claim benefit of the provisional application. However, there is no requirement that an applicant must file a later application that claims benefit or priority of a provisional application filed under the program.

V. Internal Processing of the Certification and Request Under the Program

1) A provisional patent application number will be assigned to an application filed by a program participant in accordance with 37 CFR 1.53(a).

2) A program submission that includes a legible specification in DOCX format, with or without claims, will be given a provisional application filing date under 37 CFR 1.53(c). The program participant will be notified of the filing date.

A submission that fails to include a legible specification in DOCX format will not be treated as a program submission, even if it is accompanied by form PTO/SB/452. The submission will be handled as a provisional application, and a notice will be sent pursuant to 37 CFR 1.53(g), including a requirement for payment of the basic filing fee ordinarily within two months of the date of the notice. See MPEP 601.01(b).

3) If a program submission is otherwise complete but does not include a cover sheet as required for a provisional application by 37 CFR 1.51(c)(1), or any necessary application size fee as required by 37 CFR 1.51(c)(4), the applicant will be notified and given an extendable two-month time period from the date of the notice to submit the missing items in accordance with 37 CFR 1.53(g). However, the applicant may continue to defer payment of the basic filing fee until a nonprovisional application claiming benefit of the provisional application is filed. Even if the notice sets a due date for the basic filing fee that is earlier than 12 months after the date the provisional application was filed, the fee will be considered timely if paid not later than the date on which a nonprovisional application that is entitled to claim benefit of the provisional application is filed. A reply to an Office notice that purports to require payment of the basic filing fee earlier than 12 months after the date the provisional application was filed will be considered complete, as to the fee payment issue, if it refers to this Federal Register notice as the basis for

deferring payment or includes a copy of this notice. Failure to draw the Office's attention to this Federal Register notice will result in the application being processed as if the fee were due in response to the Office notice, and substantial processing delays may occur.

4) When all the requirements for a provisional application have been met, with the exception that the basic filing fee set forth in 37 CFR 1.16(d) can be deferred, the specification and form PTO/SB/452 will be placed in a text-searchable online collaboration database that is available to the public and maintained by the Office. The collaboration database will also include the first named inventor, any contact information provided on form PTO/SB/452, the provisional application filing date, and the date the information is posted in the database. The cover sheet, as required for a provisional application by 37 CFR 1.51(c)(1), will not be posted in the database. The Office will notify the program participant of the posting date of the information.

5) If the basic filing fee set forth in 37 CFR 1.16(d) has not been paid by 10 months after the provisional application filing date, the Office will notify the applicant that the fee must be paid not later than 12 months after the provisional application filing date, and in any case, the fee is required in order to claim 35 U.S.C. 119(e) benefit of the provisional application in a corresponding nonprovisional application.

The mere absence of the basic filing fee, without any other defects in the submission, will not trigger a notification regarding payment earlier than the 10-month notice. If, however, the Office inadvertently sends such a notice requiring payment of the basic filing fee

prior to the date a corresponding nonprovisional application is filed, a participant may respond by drawing attention to this Federal Register notice. Deferring payment until filing of a corresponding nonprovisional application is permitted under the program, even if a notice setting an earlier payment date is inadvertently sent.

VI. Actions Resulting in Termination From the Program

There is no provision for withdrawal from the program. Once the technical subject matter of a program submission is made available to the public in the searchable collaboration database on the USPTO's website, that public availability cannot be revoked. This is in keeping with the goal of providing a publicly available repository of information relevant to technologies that may help to combat the COVID-19 pandemic. However, there is no requirement that an applicant must file a later application that claims benefit or priority of a provisional application filed under the program.

Andrei Iancu,

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

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