Reinhart

Patent Office Pilot Program to Encourage COVID-19 Related Inventions (expanded)

On September 17, 2020, the U.S. Patent and Trademark Office (Patent Office) launched a new pilot program in an effort to incentivize inventors to find solutions to COVID-19. Under the new pilot program, filing fees for provisional patent applications may be deferred and, in some cases, need not be paid at all if certain conditions relating to COVID-19 are met. The pilot program is reserved for provisional patent applications filed under 35 U.S.C. 111(b). Nonprovisional patent applications or international applications designating the United States are not eligible for participation.

Currently, inventors enjoy the economic advantage provided by the patenting right of exclusion. In exchange for the right of exclusion, the patent application is laid open to the public so that its technical subject matter becomes part of the total available information in the field of the invention. This information sharing permits others to improve upon the invention and even to practice the invention once the patent term expires.

The Patent Office recognizes that COVID-19 requires creative solutions. The intent of its new pilot program is to further incentivize inventors by providing a cost-effective means to disclose their ideas without losing their right to claim what is described and enabled by their disclosure. The Patent Office believes the public may benefit from the efforts of inventors seeking to address the COVID-19 outbreak sooner than would otherwise be possible. The belief is that early public disclosure will facilitate collaborations, partnerships or joint ventures and will speed up the development of important solutions to COVID-19.

How to Qualify

To qualify for the pilot program, the subject matter disclosed in the provisional patent application must concern a product or process related to COVID-19, and the product or process must require Food and Drug Administration (FDA) approval for COVID-19 use, whether the approval has been obtained, is pending or will be sought prior to marketing the subject matter for COVID-19.

Participants in the pilot program are required to submit a technical disclosure, a provisional application cover sheet and a certification and request form to participate in the pilot program. The Patent Office will upload the technical

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disclosure and the certification and request form into a searchable public collaborative database, and will 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, the pilot program participants may defer payment of the provisional application filing fee until a nonprovisional application claiming the benefit of the provisional application is filed. The basic filing fee does not need to be paid 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.

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.

Under the pilot program, payment of the basic filing fee for a provisional application may be deferred and without payment of a surcharge as long as 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. 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. 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.

Participation in the pilot 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. The approvals may include, among other possibilities, 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). Visit www.fda.gov for more information on these approvals.

FDA approval or seeking FDA approval prior to requesting to participate in the pilot program is not required. However, the product or process disclosed in the application must require premarket regulatory review by the FDA prior to commercial marketing or use.

Regarding 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, so long as the later-filed application is filed within one year of the public disclosure. Nevertheless, applicants 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. Where foreign protection is desired, further attention is required. An inventor's public disclosure made within one year of filing is considered in many foreign jurisdictions as prior art against the inventor's own application unless that earlier disclosure is the subject of a proper priority claim in that jurisdiction. Therefore, applicants are advised to take into consideration 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 Patent Office's searchable collaboration database. That is, a public disclosure may be citable as prior art under 35 U.S.C. 102(a)(1) as of the date it publishes. Moreover, the complete provisional patent application submitted under the pilot 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.

The Patent Office does not consider adding the technical subject matter disclosed in submissions to the Patent Office's collaboration database under the program to constitute publication of the provisional application under 35 U.S.C. 122(b). By submitting form PTO/SB/452, titled “Certification and Request for COVID-19 Provisional Patent Application Program” and in accordance with the confidentiality waiver provision of 35 U.S.C. 122(a), the applicant specifically authorizes the database to publish the technical subject matter disclosed as well as any contact information the participant desires 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. The database will not publish the cover sheet, which is a requirement for a provisional application. The basic filing fee does not need to have been paid at the time of publication in the database. Therefore, according to the Patent Office, the disclosure in the database is not a complete provisional patent application under 35 U.S.C. 111(b).

The requirements to participate in the pilot program are:

1. The certification and request for participation in the pilot program must be by way of the completed form PTO/SB/452. The form must be submitted

with a specification upon filing of the application. The form cannot be used to request that a provisional application that had previously received a filing date be included in the program and such a request will be denied. The form 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. The form includes a field for the name of the sole inventor or the first joint inventor. 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 pilot program participant to provide any desired contact information to be included in the database. Form PTO/SB/452 must be signed by: (i) A patent practitioner of record; (ii) a patent practitioner not of record who acts in a representative capacity under the provisions of 37 CFR 1.34; or (iii) 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 Patent Office to identify the provisional application as a pilot program submission and to process the certification and request in a timely manner.

2. The pilot program submission must be in the English language.
3. The pilot 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), the cover sheet establishes the inventorship of the provisional application. Form PTO/SB/452 provides a field to indicate the first named inventor for inclusion in the searchable online database but 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 pilot program submission; in that circumstance, form PTO/SB/452 must be signed by a registered practitioner.
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.
5. In order for the technical subject matter of a program submission to be posted in the Patent 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. Currently, the undiscounted basic filing fee is $280; applicants who qualify for small entity status pay $140, and those who qualify for micro entity status pay $70. 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.

If you would like to take advantage of the new pilot program or have questions in general, please contact Tim Naill, another member of Reinhart's Intellectual Property Practice or your Reinhart attorney.