SAUL EWING ARNSTEIN & LEHR LLP

ALERT

Intellectual Property Practice

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USPTO COVID-19 Prioritized Examination Pilot Program for Small and Micro Entities

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On May 8, 2020, the United States Patent and Trademark Office (USPTO) announced a COVID-19 Prioritized Examination Pilot Program, which will allow for prioritized examination of patent applications that contain at least one claim that covers a product or process related to COVID-19 where such product or process is subject to an applicable FDA approval for COVID-19 use. The goal of prioritized examination is to provide a final disposition within 12 months, on average, from the date the prioritized status is granted. Applicant certification of this request is required, and the program is presently set to accept 500 total requests beginning on May 14, 2020. An accepted application under this program will have the processing and prioritized examination fees waived. Applicant must also qualify for small- or micro-entity status.

Qualifying Patent Applications

A variety of patent applications qualify for this program, all of which must be non-provisional. In order to qualify for this program, the applicant must file a request to participate in this program with:

(1) an original utility or plant non-provisional application that claims the benefit of priority to no more than one prior non-provisional application or one prior international application designating the United States; or

(2) filing or after filing a Request for Continued Examination (RCE) of the aforementioned plant, utility, or national stage of an international application. Only a single request for prioritized examination filed with or after filing an RCE may be granted in an application.

Priority claims to provisional applications and foreign applications do not affect eligibility for this program.

Continuing applications of applications in the prioritized program are not automatically given prioritized status; each application must, on its own, meet all requirements for prioritized examination under the pilot program.

Applications processed under this program are subject to the standard prioritized examination rules that are otherwise available to all applicants under the regular Track I program.

FDA Regulatory Requirement

In addition to the above requirements in the filing of patent applications themselves, the claims in the application must 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).

This alert was written by Dennis Ostrovsky, Ph.D., a member of the Firm's Intellectual Property Practice. Dennis can be reached at (202) 295-6627 or at Dennis.Ostrovsky@saul.com. This information has been prepared for information purposes only.

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