The USPTO has authorized an initiative to prioritize examination of patent applications having COVID-19 uses that would require FDA approval.

A pilot program only for small and micro entities has been implemented effective from May 14, 2020 to prioritize examination of applications having one or more claims related to COVID-19.[1] The pilot program waives the associated petition fee, which would otherwise be $2000 for a small entity. The program is currently scheduled to last until 500 such requests have been approved. As of June 18, 2020, 35 requests have been approved. [2]

Although some of the requirements may appear stringent, the USPTO likely loosens their interpretations under this program.[3] In particular, the requirements stipulate that the application must contain one or more claims to a product or process related to COVID-19, which must be subject to an applicable FDA approval process. In practice, as long as the application at the time of filing contains one or more claims related to COVID-19, the application would likely fit the criteria of the program. Even if an applicant later amends the claims or elects a subset of claims following a restriction requirement such that the amended or elected claims are no longer related to COVID-19 or subject to FDA approval, the application would still be likely to remain in prioritized examination. Additionally, an applicant need not have submitted to the FDA at the time the prioritized examination is requested.
Moreover, the applicable FDA approval processes also include a 510(k), although not explicitly listed in the requirements.

However, applicants should note that the prioritized status of the application will be terminated if an extension of time is taken to respond to an Office action or a request for suspension of action is filed. Additionally, the mailing of a final Office action, a filing of a Notice of Appeal, abandonment of the application, or a notice of allowance will also remove the application from its prioritized status.

In particular, the program is available for an original or a continuing nonprovisional utility or plant patent application, as long as the application does not claim the benefit of previous filing dates from two or more non-provisional U.S. applications or international applications designating the United States. However, an application claiming a benefit to numerous prior provisional applications or foreign applications would still be eligible under this program. Additionally, a request to participate in this program may be filed with or after a RCE, as long as no prior RCE was granted prioritized examination.

As you are aware, things are changing quickly and the current guidelines may be subject to further revision by the USPTO. This article represents our best understanding and interpretation based on where things currently stand.

FOOTNOTES


[4] See 35 U.S.C. § 120, § 121, or § 365(c)

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