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The USPTO and COVID-19: Innovation through adversity

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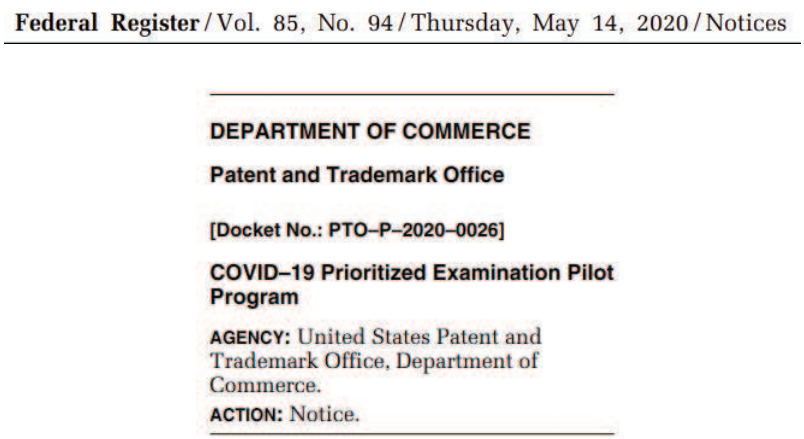
COVID-19 Pilot



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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.

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COVID-19 Prioritized Examination Pilot

- The USPTO considers the effects of the COVID-19 outbreak to be an "extraordinary situation," such that fees not required by statute may be waived.
- Accordingly, the USPTO is accepting requests for prioritized examination for applications that claim a product or process related to COVID–19 without the additional fee.
- The USPTO's goal is to provide a final disposition within *six months* of prioritized status being granted if applicants respond within 30 days to a notice from the USPTO.

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Program requirements

- Same requirements as Prioritized Examination (Track 1) except:
  - The prioritized examination fee is waived.
  - Open to small and micro entities only.
  - The application must be a non-continuing nonprovisional application or a continuing application claiming the benefit of one nonprovisional application or one prior international application designating the United States.
  - Applicants must certify claim(s) of the application must cover a product or process subject to an applicable FDA approval for COVID–19 use.
  - The request must include an Application Data Sheet (ADS).

"FDA Certification"

- Applicants must certify their applications claim products or processes that are subject to an applicable FDA approval, which 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).
- "Subject to . . . approval" does not mean approval has already been sought or granted, but rather that the product or process covered by the claim is subject to the FDA's jurisdiction before it can be marketed for use in prevention, diagnosis, or treatment of COVID-19.

Title search: The USPTO & COVID-19 – Innovation through Adversity

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