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

The United States Patent and Trademark Office (USPTO) is accepting requests for prioritized examination or "fast track" of patent applications that claim a product or process subject to FDA approval for COVID-19 use, without the payment of additional fees. The USPTO will advance accepted patent applications out of turn, aiming to reach a final disposition within one year of granting prioritized status. Up to 500 patent applications will be accepted under the pilot program. As of July 9, 2020, 66 requests had been granted, with 434 acceptances still available.

Details regarding the pilot program were published in the Federal Register (**85 Fed. Reg. 28932**). The Federal Register Notice indicates that FDA 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).

To qualify for consideration under the pilot program, a **request** for prioritized examination must be made with the filing of a new utility or plant nonprovisional application or with the filing of a utility or plant nonprovisional application claiming priority to only one prior nonprovisional or international patent application. In addition, a request for prioritized examination may be filed with or after filing a Request for Continued Examination (RCE) of an existing utility or plant nonprovisional application, but only one such request may be granted in an application. The Applicant also must certify that they qualify for small or micro entity status. Other requirements include the submission of an Application Data Sheet with the application, and limiting the number of claims to 4 independent claims and 30 total claims.

The USPTO has announced that it will periodically evaluate whether the program should be expanded.