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LEGAL UPDATES

USPTO Implements COVID-19 Prioritized Examination Pilot Program

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On May 8, 2020, the United States Patent and Trademark Office (USPTO) introduced a pilot program to provide prioritized patent examination for certain patent applications that claim products or processes subject to an applicable FDA approval for COVID-19 use.

The pilot program is limited to applicants that qualify for either small or micro entity status. For eligible applications, the USPTO will grant qualified requests for prioritized examination, similar to the USPTO's existing Track One Prioritized Examination program, except **without** payment of the fees normally required for prioritized examination. Current fees for the Track One program cost \$2,000 for small entities and \$1,000 for micro entities. The processing fee for requesting prioritized examination (\$70 for small entity; \$35 for micro entity) is also waived. Thus, this pilot program could greatly benefit innovative small companies and nonprofit research groups working on COVID-19-related technologies.

The goal of the pilot program is to provide a final disposition (i.e., allowance or refusal) for a new qualifying application within 12 months, on average, from the date prioritized status has been granted. Further, final disposition could be achieved in a shorter timeframe, even as short as six months, if applicants proactively respond to notices and actions more quickly than required under normal prioritized examination procedures.

The USPTO began accepting requests for prioritized examination on May 14, 2020, and the pilot program will initially be limited to 500 requests. However, the USPTO has indicated that the program may be extended depending on a number of factors, including effectiveness of the program and feedback from the public.

As noted, to qualify for the pilot program, the claim(s) of an application must cover a product or process related to COVID-19, and such a product or process must be 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

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Emergency Use Authorization (EUA). The FDA has similar programs in place for expedited COVID-19-related review.

Public Notice of the USPTO COVID-19 pilot program, and specific details on eligibility for the program are provided here: <https://www.federalregister.gov/documents/2020/05/14/2020-10372/covid-19-prioritized-examination-pilot-program>

Lathrop GPM has been actively assisting clients with COVID-19-related patent matters. For more information, please contact [Tucker Griffith](#) or your regular Lathrop GPM contact.