

Ralph Gabric, Eugene Goryunov, Judy He in Life Science Leader: 'Filing Considerations for PTAB Petitions on Biologic Patents Relating to COVID-19'

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PRACTICES Intellectual Property, Patents

As COVID-19 continues to impact our daily lives, it is hardly surprising that there is a surge in interest in and filings of patent applications related to biological products, such as messenger RNA (mRNA) vaccines, even when those products are still in early developmental and regulatory phases.

Of those applications that eventually issue as patents, it is important for applicants and patent owners to recognize there is no guarantee that all such patents will survive a validity challenge, even if they are related to COVID-19. Let's examine how the development of biological products and vaccines in response to COVID-19 may result in an increase of validity challenges at the Patent Trial and Appeal Board (PTAB), with a focus on biologic patents.

BPCIA Litigation: A Costly & Tedious Strategy

Biological products "are used to diagnose, prevent, treat, and cure diseases and medical conditions." Recent examples include therapeutic proteins, monoclonal antibodies, and vaccines. On Dec. 11, 2020, the U.S. FDA issued the first emergency use authorization of an mRNA vaccine (BNT162b2) against COVID-19 for individuals aged 16 or older, thereby marking a "significant milestone in battling" the pandemic.

In general, patents relating to biological products (including vaccines) can be litigated in U.S. district courts under the Biologics Price Competition and Innovation Act (BPCIA). While challengers can use the BPCIA to clear biologic patent rights, BPCIA litigation can be costly, and the "patent dance" framework provided in the BPCIA (i.e., where the parties undergo the exchange of confidential information before the filing of an infringement complaint) can be tedious for both sides. In view of these potential issues, another way to challenge patents relating to biological products may be at the PTAB.

Excerpted from *Life Sciences Leader*. To read the full article, click [here](#).