



Insights: Perspectives

Takeaways | Making the Most of COVID Regulatory Changes

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3 KEY TAKEAWAYS

Making the Most of COVID Regulatory Changes

[Nicki Kennedy](#) -- a [Kilpatrick Townsend](#) partner who is a registered patent attorney concentrating her practice on patent-related matters with a focus on client counseling, patent prosecution, domestic and international patent portfolio development and management, and post grant proceedings -- recently moderated a panel discussing "Making the Most of COVID Regulatory Changes."

Three key takeaways from the presentation, include:

1

Emergency Use Authorization Leads to Expansive Product Development: Since the January 30, 2020 Declaration by the Secretary of Health & Human Services, the FDA has issued emergency use authorizations for PPE, and over 400 in-vitro diagnostics. More than 630 drug development programs are in the planning stages. Filing for patent protection early is key, as the market is fast moving and competitive. Inventors can also take advantage of fast-track programs at the U.S. Patent and Trademark Office, as well as in other jurisdictions. Such speed can especially help small companies since they can obtain patent rights and leverage those rights in the marketplace through sales, partnerships, and/or licensing.

FDA Guidance: While there are no new FDA regulations related to the epidemic, the FDA has issued more than 58 guidance documents. These documents are issued as final, without the opportunity for public comment, and reflect the non-binding thinking of the FDA. Following this guidance, particularly trends shown in the guidance, is helpful in presenting new applications for products. The guidance can be found [here](#).

2

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Immunity Provisions for Qualified Persons: The Public Readiness and Emergency Preparedness Act (PREP Act) provides liability immunity to "covered persons" for certain activities related to "covered countermeasures" during a public health emergency declared by HHS (PHS Act § 319F-3, 42 U.S.C. § 247d-6d). Covered persons include manufacturers, distributors, program planners, and qualified persons, and their officials, agents and employees, and the US government. Liability protections is currently in place until October 1, 2024. A recent decision, *Garcia v. Welltower OpCo Group LLC et al.* (2021 WL 492581 (C.D. Cal. Feb. 10, 2021)), affirmed the broad applicability of the PREP Act when the defendant's actions relate to limiting the spread of COVID-19. This case suggests that even nursing home operators can remove claims related to such actions to federal court and seek immunity under the PREP Act.

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