Biosimilars Webinar: Prosecution and Litigation Trends and Takeaways from BPCIA Litigation



Michael Siekman, **Huiya Wu**, **Allegra Padula**, and **Riley Wyberg** will present their data-driven analyses of trends in BPCIA litigation and relevant takeaways.

With 10 years of litigation since the first BPCIA complaint on NEUPOGEN (filgrastim) was filed in 2014, trends are becoming apparent that should cause all biopharma companies to reassess how they protect biologics and plan for biosimilar launch.

Webinar Highlights:

- **Patents Being Asserted:** Learn which types of patents are being asserted to block biosimilar competition, how that has changed over time, differences for protein and antibody products, when those patents are being filed during drug development, and differences among Reference Product Sponsors.
- **Trends in BPCIA Litigation:** Learn how often and how much of aBLAs are being produced during the Patent Dance, which Biosimilar Manufacturers are producing them, how much the parties dance and who is engaging in the Patent Dance, when cases are settling, and how many asserted patents are carrying through to a final judgment.
- **Real-World Insights:** We will share practical recommendations for biologics and biosimilars companies based upon on our analysis and our experience with the BPCIA.

Please **RSVP** to confirm your attendance.

FDA Platform Technology Draft Guidance Highlights Utility of Obscure Patent Term Extension Provision

As discussed in a **prior Goodwin Alert**, the US Food and Drug Administration (FDA) recently released **Draft Guidance for designating a platform technology for drug development** pursuant to § 560k of the Federal Food, Drug, and Cosmetic Act. The platform technology program was included as part of the PREVENT Pandemics Act "to bring significant efficiencies to the drug development or manufacturing process." Specifically, a platform technology must have the "potential to be incorporated in, or utilized by, m**ore than one drug** without an adverse effect of quality, manufacturing or safety."

Read the full insight **here**.