



IP Counsel Exchange for Biosimilar Applicants & Sponsors

January 23–24, 2014

Katten is pleased to sponsor the IP Counsel Exchange for Biosimilar Applicants & Sponsors, a forum for IP counsel within the pharmaceutical, biopharmaceutical and biotechnology space that will provide participants with best practices and proven strategies for positioning biosimilar/biobetter products to obtain market exclusivity.

Associate Christopher Ferenc will participate in the roundtable discussion “The Evolving Biosimilar Landscape” at 4:45 p.m. on Thursday, January 23. Senior IP counsel will discuss the changing generic drug landscape being ushered in by the anticipated approval of biosimilars in the United States. Topics will include interchangeable exclusions, market exclusivity and alternative monetization strategies for an IP portfolio should a company choose not to enter the biosimilar market.

Partner Stephen Benson will present “Understanding the Biosimilar Landscape: Addressing Emerging Regulatory and Legal Issues” at 11:00 a.m. on Friday, January 24. The session will address the emergent regulatory and legal issues that are expected to arise from the Biologics Price Competition and Innovation Act (BPCI Act) and its implementation. Starting with a review of regulatory and legal issues that arose from the passing of the Hatch-Waxman Act that came to define the landscape for the introduction of generic versions of small molecules, Stephen will explore the regulatory and statutory provisions of the BPCI Act that are expected to similarly evolve as the FDA implements the BPCI Act and as the courts are asked to interpret the legal operation of the law. He will also discuss emerging, real-world examples to demonstrate the current clarification and implementation of the law. The presentation will conclude with a discussion of potential strategies for companies navigating the regulatory and legal framework created by the BPCI Act.

Also on Friday, associate Rachel Schweers, PhD, will moderate the interactive roundtable discussions “Looking Beyond Year 12 – How to Ensure Your Patent Strategies Are Adding Value Beyond the Statutory Period of Exclusivity” and “Distinguishing Regulatory Pathways for Biosimilar Products – ‘Biobetter’ vs. Biosimilars and Considering the Impact Your Regulatory Choice Will Have on Your IP Strategy” at 3:00 p.m.

CONTACTS

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