

The what million dollar question: Patent litigation and strategy under the Biologics Price Competition and Innovation Act

Bryan J. Vogel

Robins, Kaplan, Miller & Ciresi L.L.P., USA

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") has a regulatory and dispute resolution framework inspired by the framework set forth for small-molecule generics under the Hatch-Waxman Act. While similarities do exist, fundamental differences between the two regulatory frameworks will mean that the first originator and follow-on biosimilar manufacturers working their way through the process set forth in the BPCIA will be in uncharted and potentially time-consuming and costly waters. The proposed talk will review the fundamentals of the BPCIA regulatory framework and the system of disclosures and counter-disclosures required when an application to manufacturer a biosimilar raises the possibility of a claim for patent infringement. It will also highlight the areas where experience gained in prior patent litigation involving generics will likely apply and those areas where that experience may be inapplicable. Specific areas of consideration include patent portfolio management and protection under the BPCIA's evolving process, pre-litigation patent information disclosures, oversight and verification of required disclosures and validation, and the shared and specific patent-related challenges originator and biosimilar manufacturers will face.

Biography

Bryan J. Vogel is a partner in the New York office of the law firm of Robins, Kaplan, Miller, & Ciresi L.L.P. He is an Intellectual Property litigator with a practice emphasis in Life Sciences and Hatch-Waxman and biosimilars litigation and strategic counseling. He publishes frequently on general Intellectual Property topics, as well as matters specific to the Life Sciences community. He received his J.D. from George Washington University. In addition, he earned a B.S. in Chemical Engineering, with honors from Michigan State University, where he was also a member of Phi Beta Kappa and Tau Beta Pi (invited).