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Freedom to operate issues and patent litigation considerations for biosimilars

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Abstract

This presentation will provide an overview of litigation under the Biologics Price Competition and Innovation Act of 2009 ("Biologics Act"). An analysis of the intellectual property considerations and hurdles that must be overcome in preparation for litigation under the Biologics Act and launch of a biosimilar product in the United States. This includes a discussion on the types of patents that exist covering a biologic product, patent protection for biosimilars and trade secret issues that must be considered.

Biography

Sailesh K. Patel is a partner at Schiff Hardin, a U.S. based law firm with over 400 attorneys. He leads Schiff Hardin's Pharmaceuticals and Biologics team and focuses on intellectual property litigation with an emphasis in pharmaceutical patent litigation. Mr. Patel has extensive experience representing pharmaceutical companies in highly complex Hatch-Waxman patent litigation involving prescription drugs and other matters in federal courts throughout the United States. Mr. Patel has served as lead counsel on numerous patent infringement litigation matters, including high-profile Hatch-Waxman pharmaceutical litigation matters. His experience extends from pre-litigation counseling up and through trial and appeal, including several successful trials through verdict in the past few years. Mr. Patel is registered to practice before the United States Patent and Trademark Office and has a background in chemical and biomedical engineering. He is a frequent author and speaker on IP issues and is an adjunct professor of Pharmaceutical Patent Law at the Chicago-Kent College of Law.