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Patent issues for biologic and biosimilar products

William Simmons
Sughrue Mion PLLC, USA

Although there are recognized needs for the marketing of safe and effective follow-on biologics products in the U.S., significant intellectual property rights are inevitably involved in meeting these needs. The intricate US Pathway sets forth the law for the production, use and sale of follow-on biologic therapeutics in the U.S., including provisions designed for determining the outcome of intellectual property disputes. Sughrue has been at the forefront of this law and will discuss strategic options regarding all aspects of the complex intellectual property issues raised by the Approval Pathway for Biosimilar Biological Products.

Biography

William Simmons is a senior associate and his practice involves worldwide procurement, defense and enforcement or invalidation of patents in the biotechnology and related arts. He has extensive experience with monoclonal antibodies, fusion proteins, cytokines and genetic technologies, including experience working with multiple blockbuster drugs. He frequently speaks on developments in biosimilar (follow-on biologic) law. He works in all areas of patent law, and has in depth experience in interferences (e.g., Centocor, Inc. v. Abbott GmbH & Co., KG; Interference No. 105,592 and Institut National de la Recherche Agronomique v. BASF Plant Science GMBH, McGill University, and DNA Landmarks, Inc., Interference No. 105,682), reexaminations (e.g., Control. No. 90/010,039), oppositions (e.g., Amgen, Inc. v. ImmunoGen, Inc., Australia Appl. No. 2003241580), and the management of worldwide patent dossiers. He frequently prepares opinions regarding patentability and infringement and has performed and managed complex, extensive freedom-tooperate analyses. He is also conducts pre-suit investigations and provides litigation support.

wsimmons@sughrue.com