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New patent reform litigation options for biosimilars

Biosimilar patent litigation is sure to be an area where the parties will be constantly adapting to the changing legal landscape in order to gain a competitive advantage. The America Invents Act (AIA) has introduced the most significant changes to patent law in over fifty years. The new inter partes proceedings instituted by AIA, which are dealt with at the US Patent and Trademark Office, may provide earlier resolution for originator and biosimilar conflicts through expedited validity determinations, as well as bring about settlements that could avoid more costly litigation altogether. This presentation will outline the new inter partes patent proceedings and highlight their applicability to biosimilar patent challenges.

Biography

Paul A. Calvo, Ph.D. is a Director at the intellectual property specialty law firm of Sterne, Kessler, Goldstein & Fox P.L.L.C. in Washington, D.C. Dr. Calvo is a member of the firm's Biotechnology/Chemical Group, and he represents a diverse group of U.S. and international companies innovating in the biotechnology and pharmaceuticals industries. He provides counsel with regard to global patent portfolio strategy, licensing, patent validity, infringement, and design around strategies. Dr. Calvo is experienced in U.S. and international patent procurement and enforcement matters (particularly patent prosecution and oppositions), FDA/ANDA practice, technology transfer, invalidity, noninfringement, freedom-to-operate and patentability opinions, and due diligence investigations. Dr. Calvo has extensive technical expertise in the areas of vaccines, therapeutic antibodies, cellular immunology, cell and molecular biology, proteomics, signal transduction, stem cells, and biotherapeutics. His graduate studies focused on immune responses directed to malarial antigens. During a postdoctoral fellowship at the University of Pennsylvania, Dr. Calvo was awarded a National Research Service Award, sponsored by the National Institutes of Health. That research entailed the examination of cellular biological aspects integral to antigen processing and presentation. Dr. Calvo continued his postdoctoral training in the Laboratory of Viral Diseases in the National Institute of Allergy and Infectious Diseases at the NIH, where he undertook further studies on the cell biological aspects of immune responses and the cellular biology of influenza viruses.

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