Paul A Calvo, J Bioanal Biomed 2016, 8:3(Suppl)
http://dx.doi.org/10.4172/1948-593X.C1.020

An update on the legal landscape for biosimilars in the USA

Paul A Calvo
Sterne, Kessler, Goldstein & Fox P.L.L.C., USA

The past year has seen a great deal of activity related to the legal challenges for biosimilars in the United States. The legal landscape for biosimilars and the BPCIA is becoming clearer as decisions such as Amgen v. Sandoz are being handed down by the courts and an increasing number of biosimilar applications are being accepted by FDA. Legal challenges are also occurring at the US Patent and Trademark Office as biosimilar applicants attempt to obtain patent certainty in advance of submission of the biosimilar application to FDA. This presentation will outline the current status of the legal activity surrounding biosimilars in the US.

Biography

Paul A Calvo is the Director at Sterne, Kessler, Goldstein & Fox P.L.L.C., in Washington, DC, USA; where he spearheads the firm's biosimilars practice. He has experience in advising biopharmaceutical companies ranging in size from startups to industry-leading multinationals on complex legal issues related to the protection and enforcement of their intellectual property. He practices primarily in the fields of immunology and biotherapeutics with a particular focus on therapeutic antibodies.

pcalvo@skgf.com

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