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Kurt R Karst, J Develop Drugs 2016, 5:4(Suppl)
http://dx.doi.org/10.4172/2329-6631.C1.019

International Conference and Expo on

Generic Drug Market & Contract Manufacturing

November 07-09, 2016 Barcelona, Spain

Kurt R Karst

Hyman, Phelps and McNamara, P.C., USA

Biosimilars in the United States: A progress report and a peek in to the future

The biosimilars industry in the United States is still a nascent one, but hopefully not for long. In 2015, FDA approved the first biosimilars biological product, and several applications for other biosimilar biological products are pending at the agency. Although FDA and industry are tackling the scientific and data requirements for FDA to approve a so-called "Section 351(k) application" for a biosimilar biological product, legal issues abound. Whether it is the requirements or the contours of the "Patent Dance" for resolving patent disputes between biosimilars applicants and reference product sponsors, the availability and the scope of 12-year reference product exclusivity, or the appropriate naming convention for biological products, each issue is critical to the success of biosimilars in the United States and to the future of the industry. And with fast-paced litigation, the landscape for biosimilars seems to change on a monthly or weekly basis. This session will explore the ins and outs of current disputes involving the metes and bounds of the patent dance, non-patent exclusivity, naming and more, and explain what each dispute might mean for the future world of United States Biosimilars.

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