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

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The biosimilars industry in the United States is still a nascent one. In 2015, FDA (Food and Drug Administration) approved the first biosimilar biological product, and several other approvals have followed, with more applications for other biosimilar biological products pending at FDA. 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.

Recent Publications

1. Kurt R Karst (2017) Patents and exclusivity (Ch. 17) Fundamentals of US Regulatory Affairs, 10th Ed. Regulatory Affairs Professionals Society.
2. Jan Berger, Jeffrey D Dunn, Margaret M Johnson, Kurt R Karst and W Chad Shear (2016) How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management. Am. J. Manag. Care. 22(16 Suppl):S487-S495.
3. Kurt R Karst (2015) FDA's Orange Book and ANDAs: Questioning the Policies and Precedents Surrounding RLD Patent Listings. Respiratory Drug Delivery. 1:59-66.
4. Kurt R Karst (2014) Jumping Legal Hurdles with the US FDA: The Generic Inhaler Challenge. Respiratory Drug Delivery. 1:151-158.
5. Kurt R Karst (2014) Letting the Devil Ride: Thirty Years of ANDA Suitability Petitions under the Hatch-Waxman Act. Wm. Mitchell L. Rev. 40(4):1260-1306.

Biography

Kurt R Karst provides regulatory counsel to pharmaceutical manufacturers on Hatch-Waxman patent and exclusivity, drug development, pediatric testing, and orphan drugs. He helps clients develop strategies for product lifecycle management, obtaining approval, managing post-marketing issues, and defining periods of exclusivity. As the Co-Founder and Primary Author of Hyman, Phelps & McNamara's FDA law blog, he often leads the response to new rules and regulations, sharing his interpretation with the broader legal community. He has co-authored and contributed to several text books, including "*Generic and Innovator Drugs: A Guide to FDA Approval Requirement's"; "Pharmaceutical, Biotechnology*, and *Chemical Inventions"; "Fundamentals of US Regulatory Affairs" and "FDLI's Drug and Biologic Approvals: The Complete Guide for Small Businesses-FDA Financial Assistance and Incentives"*.

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