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Intellectual property issues in global biosimilar programs

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In addition to development, manufacturing and commercial challenges, patent legal issues have a major impact on the success of a global biosimilar program. The multidimensional complexity of the patent landscape relating to a biosimilar candidate is due to the variety of categories of patent rights, encompassing, e.g., compound, process, formulation, indication, dosage and device patents; to the territorial diversity in scope and term of patent protection; to the technical complexity of biopharmaceutical production; and to the rapidly evolving, often controversial case law in this field. All these aspects need to be addressed when it comes to freedom-to-operate analysis and clearance of biosimilar projects, but is also relevant for securing one's own IP position by filing and prosecuting applications on, e.g., improved process, formulation or device features. The talk will discuss challenges and chances along those lines and will give relevant examples. An update will be provided on some recent developments in patent law which will have an impact on future biologics and biosimilars patent landscapes in major markets, such as the Unitary Patent in Europe and the evolving biosimilars legislation in the US.

Biography

Christoph Volpers earned a PhD in Molecular Biology from the University of Mainz, Germany, and an MBA from Bradford University, UK, both with Distinction. He has almost fifteen years of experience in Intellectual Property and Licensing. Before he joined the patent law firm Michalski Hüttermann & Partners, Dusseldorf/Munich, as Senior Patent Consultant in early 2015, he was Director IP Biologics of the Teva Pharmaceutical Industries/ratiopharm group for six years with global responsibility for innovative biologics and biosimilar products. He is founder of a biopharmaceutical consultancy firm, author of more than 20 publications and a member of the Licensing Executive Society.

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