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Challenges for biosimilar generics

Vivek Kashyap

Lex Orbis IP Practice, India

Biosimilars are recombinantly produced drugs and are similar to reference biologic. Although, defined, specific and well planned guidelines for Biosimilars are available world-wide, yet the biosimilar drugs face lot of challenge from the patenting strategies from their innovator competitors. Interestingly, most of the innovators not only protect their Biopharmaceuticals in form of product patents but also in form of formulations, delivery systems, preparing methods and their use. However, the biosimilar generics face even a greater challenge from innovator's devising strategies for developing better and enhanced efficacious Biopharmaceuticals than the existing ones, as the new and improved versions of Biopharmaceuticals can be of concern for biosimilar generics. Therefore it is pertinent for biosimilar generics to understand the patenting strategies of the innovators for Biopharmaceuticals they have developed. In addition, the biosimilar generics need also undertake a comprehensive review of the prosecution strategies of the innovators, which can provide them a good insight to prevent any legal issues.

Biography

Vivek Kashyap, is a Patent Attorney and a registered Patent Agent. He holds PhD and LLB degrees. Dr. Kashyap is presently working as a Senior Associate with Lex Orbis IP Practice, New Delhi. Dr. Kashyap regularly advises national and international clients on patent strategies in India. He was working as an In-House patent attorney with a leading multi-national pharmaceutical company before moving to LexOrbis.

vivek@lexorbis.com