



IPR Issue for Biosimilars

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ABSTRACT: Like generic pharmaceuticals, apart from serving the needs of the local population, India has the potential to become the world leaders in the development and manufacture of biosimilars. Innovation of biologics compared to small molecules itself is challenging, due to its several limitations. Further, biosimilar development is a landmine of complexities with respect to regulatory, IP activities, manufacturing, marketing aspects, while making it one of the most expensive development propositions in the pharmaceutical industry. Like generic pharmaceuticals, biosimilars enter the market with the aim of reducing healthcare cost, but entry to the biosimilar market carries higher costs, greater risks, more time and expertise in various fields of technology. Because of the higher stakes in this field, it is imperative to be focused on the IP, both for the innovators as well as the biosimilar biopharmaceuticals. Innovator companies develop various IP strategies to block the biosimilars through the patent filing. Biosimilar biopharmaceuticals have to sort out the weak blocking patents from innovator's patent portfolio and accordingly have to develop the strategies to overcome them and enter into the market, at the earliest. US has already streamlined the patent activities for generic entry for the generics through Hatch-Waxman act and the subsequent developments. Biosimilar, is however still in the infant stage, in spite of the specific provisions of the Biologics Price Competition and Innovation Act (BPCIA). In view of the above, the presentation will touch upon the patent aspects of biosimilars. © 2014 iGlobal Research and Publishing Foundation. All rights reserved.

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