

## Intellectual property rights of biosimilars: Challenges and opportunities

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Product patents of many top-selling biopharmaceutical products including Enbrel, Herceptin, and Avastin are going to be off patent over the next five years, which paves a way to biosimilar players. Apart from the product patents, there are many potential defensive strategies followed by innovators including process patents, formulation patents, method of use patents, dosing regimen patents, and device patents, which may delay the entry of biosimilar products when the product patent expires. Moreover biosimilar approvals depend on many factors including the biosimilar regulatory guidelines in that geography, acceptance of biosimilars by medical professionals, medical reimbursement policies, etc. Most of the emerging markets including India, Mexico and Brazil developed their own biosimilar approval pathways.

Apart from proving biosimilarity with the innovator product, biosimilar players need to evaluate the potential non-infringement strategy with respect to process, formulation, method of use, dosing regimen and device patents/ applications filed by innovator as well as any third parties. Here we are going to describe some of the strategies that biosimilar players adopt to ensure that they do not-infringe the existing patents.

### Biography

Jayanthi Murthy is working as an Assistant Manager in Intellectual Property Management Department of Intas Biopharmaceuticals Ltd., (IBPL). She is a registered Patent Agent-India, and completed her post graduate diploma in Patents Law from Nalsar University, Hyderabad and having around 9 years of professional experience in biotech industry. She joined IBPL in 2004 and is associated with handling patent related issues of biotech products including recombinant proteins, mAbs and blood products.

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