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# IP checklist for similar biologics

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Various blockbuster Biologics go off patent by 2020 creating a huge opportunity for the Biopharma Industry. To capitalize on this opportunity and improve access to such Biologics, innovators as well as generic companies are developing molecules called similar Biologics, more commonly referred to as "Biosimilars".

Intellectual Property ("IP") challenges faced by developers planning to launch Biosimilars in India and other jurisdictions are far more complex than those faced by their counterparts developing generic small molecules. Besides the molecule itself and its manufacturing process clones, promoters, vectors, plasmids, sequences, and downstream processes can also be separately patented. Therefore, an in-depth study of the IP landscape revolving around a specific product of interest has become a pre-requisite. A well thought out IP strategy would go a long way in ensuring an encumbrance free and effective launch of biosimilar products. Creation of a stepwise IP checklist is a good start for devising and implementing a cost effective IP strategy. An effective stepwise IP checklist aligned to various steps of development and launch should include –

- CDA;
- FTO - carried out at the final stages for the innovator product is required to be carried out early on in case of similar biologics;
- Study of Patent family, file wrappers;
- Claim scope;
- Litigations in jurisdictions of interest;
- R&D considerations –assignments, lab notebooks, research material IP status e.g. of clones, plasmids, phages, etc.
- Due diligence of materials to be In-licensed;
- Patentability and creating own IP;
- Complimentary FTO

## Biography

Mita Sheikh has Masters Degree in Plant Physiology from the I.Sc. Mumbai. She is a Patent Agent and Sr. Associate with the Life Sciences and Chemistry Department of Krishna & Saurastri Associates. She has been providing counseling for protection and management of patent estate in global geography for Life Sciences inventions. She has assisted clients with inventions relating to stem cells, recombinant proteins, vaccines, diagnostics, industrial biotechnology, etc. She has over fifteen years of experience in the field of intellectual property management and around six years of research experience from prominent pharmaceutical and biotechnology organizations of India.

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