3rd International Conference and Exhibition on Bio-waivers, Biologics and Biosimilars

PATENTING OF BIO-SIMILARS IN INDIA AND RELATED ISSUES

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“Biotechnology can transform humanity – provided humanity wishes to be transformed”

– Geoffrey Carr

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Bio similars

Biological products manufactured after the expiry of the patent of the innovator biophramaceuticals and these are called as Biosimilars.

Biosimilars are also called – **Similar Biologics**, **Follow on Biologics**, **Follow on Protein products**, **Subsequent entry Biologics**.

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Patentability Requirements in India

- Basic Requirements (Harmonious with International laws)
- Novelty
- Utility
- Non-Obviousness

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Regulatory Requirements for Marketing authorization in India

- Similar biologics are developed through a sequential process designed to demonstrate the similarity, by extensive characterization studies, of the molecular and quality attributes of the similar biologic with a reference biologic.
- The extent of the testing of the similar biologic is likely to be less than that required for a reference biologic; however, it is essential that the testing of the similar biologic be sufficient to ensure that the product meet acceptable levels of safety, efficacy and quality to ensure public health.
- Generally, a reduction in data requirements is possible for preclinical and or clinical components of the development program by demonstrating comparability of the product (to the reference biologic) and consistency in the production process.
- If any significant differences in safety, efficacy and quality between the similar biologic and the reference biologic are identified, more extensive preclinical and clinical evaluation will be necessary.
- It is quite likely in this instance that the product may not qualify as a similar biologic.

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In Contrast Bio similars…..

- An applicant for marketing authorization must demonstrate that -
  - Highly Similar to the reference product notwithstanding minor differences in clinically inactive components.
  - “No clinically meaningful differences between the biological product and the reference product in terms of safety, Purity and potency.

- If a bio similar drug is highly similar to and has no clinically significant differences over a reference biologic/innovator product – there will be nothing to patent.

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Patenting Bio similars

- Products with improved formulation properties such as:-
  - Storage stability
  - Flowability
  - Change of excipients
  - Solubility

- Improved methods or manufacturing processes
  - Different Cell line
  - Altered nucleic acids (DNA/RNA)
  - Altered Culture conditions
  - Improved purification
  - Improved sterilization

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Bio-Betters

- Bio-betters offer benefits over the first-generation products that current biosimilars simply attempt to imitate.

- Biosimilar companies also now need to formulate strategies to develop bio betters, as these are likely to be accepted more readily by end-users, and could match–or even exceed–originator products in terms of revenue-earning potential.

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Second Generation Bio similars

- Other improved bio similar products might be considered as second-generation biologicals and could obtain patent protection and premium pricing.

- The current development period for a first-generation bio similar ranges from seven to 10 years, which is not vastly shorter than that for a biopharmaceutical product.

- Improved bio similars, which will need to be approved via the same pathways as innovator drugs, will not require the same extensive investment as an innovator drug, nor will they carry the same level of risk.

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Section 3 (d)

- Section 3 (d) – Excludes
  - Mere discovery of new form of a known substance
  - Mere discovery of a new property or new use
  - Mere new use of a known process
  - which does not result in the **enhancement of the known efficacy of that substance.**
  - **Unless such known process results in a new product or employs at least one new reactant.**

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Other provisions of Patent Act

- Section 3 (e) –Admixture resulting only in aggregation
- Section 3 (j) – Plant and Animals whole or any part other than micro-oganisms
- Section 3 (p) – Traditional Knowledge
- Section 10 (4) (d) (ii) – A to D – Disclosure of Biological materials, their deposit, identified characteristics, Geographical Source
- Section 19 - Reference to earlier patent in case of potential infringement.
- Section 25 – Opposition to the patent (Pre grant and post grant)

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Section 107(A)

Act not considered as Infringement of Patent:-

Any act of making, constructing, (using, selling or importing) solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in any country other than India that regulate the manufacture, construction, use, sale or import of any product.

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It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is the most adaptable to change.”

-Charles Darwin

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Importance of Patent Watch

Need to look into the following:-

- Has entered into Indian Market or not
  - Paris Convention
  - PCT Treaty
- Patent Validity
  - Oppositions
  - Renewals
  - Revocation
  - Litigation
- Disclosure and claims
  - What is disclosed; and
  - What is claimed
- Landscape Analysis
  - FTO Analysis
  - White space

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Q & A

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Thank You

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