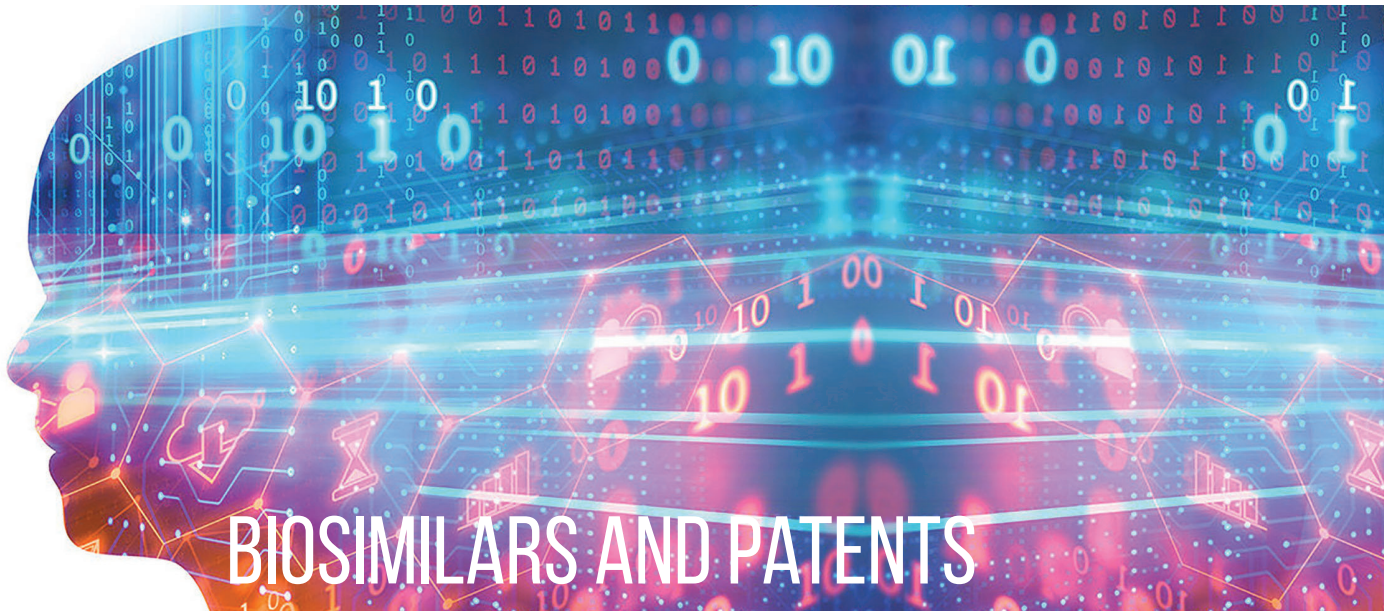

BIOSIMILARS AND PATENTS

The majority of the world's biggest selling medicines can be classified as "biologics" or "biopharmaceuticals". Such medicines contain one or more biologically active product produced from (or containing components of) living organisms as the active ingredients.

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Biosimilars are biological products which are highly similar in structure, biological activity, efficacy, safety and immunogenicity profile to another already approved biopharmaceutical (the 'reference product'). Traditionally, generic medicines contain the same active pharmaceutical ingredient(s) as the originally approved reference product upon which their marketing authorisation is based. In contrast, biosimilars do not contain active ingredient(s) identical to the originally approved biological product, but instead contain similar active ingredient(s). Therefore, a biosimilar cannot be regarded as a generic version of an already approved biological product since the natural variability and complex manufacturing process of biologics do not allow an exact replication of the original product.

HOW ARE BIOSIMILAR MEDICINES AUTHORISED FOR USE?

In the EU, marketing authorisation applications for biotechnology-derived medicines, including biosimilars, are reviewed centrally by the European Medicines Agency (EMA). Biosimilar medicines require distinct regulatory pathways from those applied to generic medicines as they are not exact replicates of the originator (reference) medicine.

For obtaining marketing authorization, developers of biosimilars must show through detailed comparative studies with the reference product that there are no clinically significant differences between the biosimilar and the reference product in terms of safety, quality and efficacy. Thus, although further clinical trials as already carried out for the reference product are not required, the regulatory approval process for biosimilars is far from trivial.

PATENTING BIOSIMILARS

Patents are granted only for inventions which meet certain legal requirements. For example, most Patent Offices require that the invention described and claimed in a patent application must (at least) be new, inventive (not simply an obvious modification of something that is already known) and capable of industrial application.

In order to obtain marketing approval for a biosimilar, it must be shown that the biosimilar is highly similar to the reference product. Yet, for a patent to be granted, the invention must be both new and inventive. Thus, patenting biosimilars becomes complicated as the very nature of biosimilars requires that they should be as close as possible to products that are already in the market.

Despite this, it may be possible to seek patent protection for inventions relating to a new process of preparing biosimilars, new formulations, combinations, mode of delivery, dosage regimen, and new medical uses including treatment of new patient groups using the biosimilar, as long as the improvement does not impart clinically significant differences. Thus, developers of biosimilars should check, prior to disclosing their biosimilar product, whether any feature of the product could be protected in its own right. Care should also be taken to ensure that any patentable differences over the reference medicine do not jeopardise an application for obtaining a marketing authorisation.

Biosimilars are often developed by companies as the patent protection of an original biopharmaceutical product approaches expiry of patent term (generally this period is 20 years from the filing date of the relevant patent application). Most innovators also depend on Supplementary Patent Protection (SPC) and Data Exclusivity to extend the protection term.

Recently, the European Commission (EC) issued a proposal to change the rules in relation to SPCs to include "export manufacturing waiver" for patented products to third parties in order to promote the competitiveness of the EU generic and biosimilar industries in global markets. This change may further encourage companies to develop more biosimilars.

If you have queries regarding this topic, or other pharmaceutical or biotechnological matters, please contact Leonita Paulraj at **ltp@aathornton.com** or visit our website **www.aathornton.com**

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