

Patentability of Biosimilars

A biosimilar may be defined as “a biotherapeutic product which is similar in terms of quality, safety and efficacy to an already-licensed reference biotherapeutic product” (World Health Organisation). The reference biotherapeutic product will be one which has already passed the relevant clinical trials and a marketing authorisation will have been granted for it. After the patents on the reference biotherapeutic product have expired, other drug companies will often try to produce such biosimilars in order to exploit the market for that biotherapeutic product.

But will they be able to patent their biosimilars?

In order to be granted, any patent claims to biosimilars will have to satisfy the standard criteria for patentability: the claimed biosimilar will have to be novel and inventive over everything in the public domain at the filing date of the patent application to the biosimilar. Of course, at that time, all details of the reference product will be in the public domain.

The biosimilar is likely to be structurally identical (or at least extremely similar) to the reference biotherapeutic product. Hence any patent claims to the biosimilar are likely to lack novelty over the reference biotherapeutic product. For this reason, biosimilars are generally not patentable.

However, it might still be possible to patent one or more of the following:

- new formulations comprising the biosimilar
- new combinations comprising the biosimilar and other active agents
- new processes to make the biosimilar
- new methods of treatment using the biosimilar
- new modes of administration of the biosimilar
- new dosage regimes using the biosimilar
- the treatment of new patient groups using the biosimilar

Often the owner of the reference biotherapeutic product will file patent applications to one or more of the above in order to maximise their patent protection around their product. However, patent applications for the above can be filed by anyone.

Further advice

If you would like any further advice, please contact us at Dehns using the details below.

More detailed information on the above and other biotech inventions may be found in the Dehns' booklet on "Patenting of medical and biotech inventions" which is available from our website [here](#).



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