Dehns

Patent and Trade Mark Attorneys

Patenting of Biobetters

Once the patents on the reference biotherapeutic product have expired, competitors will often try to develop biosimilar and biobetter products. In contrast to biosimilars, biobetter therapeutic products will be structurally different from the reference biotherapeutic product. Does that make them patentable?

Any patent claims to biobetters will have to satisfy the standard criteria for patentability: the claimed biobetter will have to be novel and inventive over everything in the public domain at the filing date of the patent application to the biobetter, including everything which is in the public domain at that time about the reference product and any biosimilars.

By definition, biobetters will be structurally different from the reference biotherapeutic product and hence they might well be novel for this reason alone. For example, compared to the reference biotherapeutic product, the biobetter might:

- have a different amino acid sequence
- be a fragment of the reference product
- be a chimeric product
- have a different glycosylation pattern, or
- have different attachments, such as PEGylation.

The inventive step of the biobetter is likely to be judged on whether or not the differences (such as the above) over the reference product are not obvious, and whether the biobetter has surprising or unexpected properties compared to the reference product. Examples of such properties could, for example, be that the biobetter has a significantly longer half-life, an unexpectedly higher enzyme activity or surprisingly better efficacy.

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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