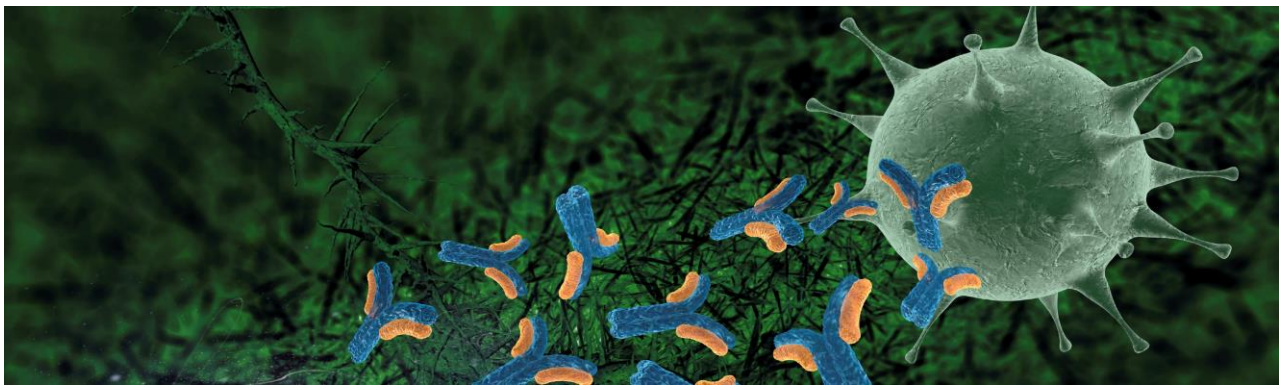
Biosimilars and Biobetters



"Biosimilars" are biopharmaceuticals or "biologics" which are designed to have similar properties to proteins that have already obtained regulatory approval. As the number of approved biologics grows and revenues increase, it was only a matter of time before generic versions of these biologics were investigated and developed.

Often the precise biological process which is utilised to produce a biologic by a manufacturer is unknown. Therefore, even when a biosimilar is being developed, the end protein may have slightly different properties and *in vivo* action. For a biosimilar to receive regulatory approval, it must be proven to the regulators that it has bioequivalence to the biologic already having regulatory approval.

If the biosimilar company develops a new or different manufacturing process to produce the biologic the new process may be patentable in its own right. The biosimilar company could obtain protection which prevents the original biologic company or competitor biosimilar companies from using the improved process.

During the development of a biosimilar, proteins similar to the original biologic may be developed which have greater efficacy, bioavailability and stability for example. Such "biobetters" can be protected by EP patents, provided the differences can be characterised and the inventions meet the criteria for patentability. The improved products can be launched when the original biologic is no longer protected or can be used as a negotiating lever in seeking an early licensing or cross-licensing deal with the biologics company.

Our AL Factsheet Biologics provides further information on patenting biologics and applies also to biosimilars and biobetters.

Companies wishing to manufacture and launch biosimilar or biobetter products need to adopt a "generics" pharmaceutical approach and mind-set with their patent strategy. Prospective launch of a biosimilar or biobetter will require much preparatory patent work, including a comprehensive Freedom to Operate (FTO) analysis to determine when the original biologic is no longer covered by any patents, Supplementary Protection Certificates or data protection (discussed in our AL Factsheets Supplementary Protection Certificates and Data Protection), in all scheduled and future launch markets.

We have explained the general principles of protecting biobetters and biobetters in this AL Factsheet but it is only an introduction, and any live situation will need individual assessment. Please contact us if you need more detailed information.