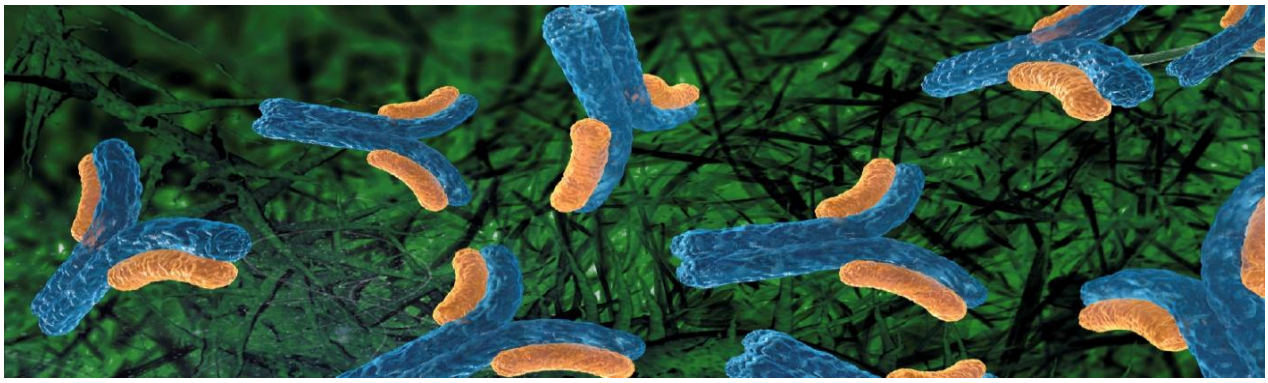
Biologics



Biologics are molecules of biological origin which can be used alongside or in place of more traditional chemically-derived small molecule medicines. Relative to the more traditional chemically-derived small molecule medicines, they can be better targeted, more effective, and more easily degraded by the body. Human insulin was arguably the first biopharmaceutical, or "biologic", to be commercialised. Typically, biologics now are at least partially produced in organisms using recombinant DNA technology. The biologics market has grown rapidly and developed sub-groups, discussed in AL Factsheet Biosimilars and Biobetters.

Biologics come in many forms, and examples include antibody drug conjugates, antibodies, antibody fragments, antigen fragments, insulins, coagulating factors, growth factors and nucleic acids. From a patent protection point of view, they are treated in a similar manner to more traditional pharmaceutical inventions. In the European Patent Office (EPO), methods for treatment of the human or animal body are excluded from patentability under Article 53(c) EPC. However, it is possible to obtain claims to new biologics, formulations, delivery methods, combination therapies, dosage regimes and preparative methods, as set out in AL Factsheet Active Pharmaceutical Ingredients (APIs), and claims to medical uses, as set out in AL Factsheet Patenting First and Second Medical Uses.

Increasingly, patents are being filed for biologics (and indeed traditional active pharmaceutical ingredients) which have efficacy within a particular population, or in patients having a known genotype. It is possible to protect these 'personalised medical use' inventions with second medical use type claims in the following format:

Biologic X for use in treating disease Y in an individual having genotype Z

Of course, patents relating to biologics must be novel, inventive, and provide sufficient information. Sufficiency in biologic patent applications can be an issue. A patent must 'sufficiently' disclose the invention so that the notional 'skilled addressee' can understand how the invention can be implemented across the full breadth of the patent claims. Increasingly, the EPO is requiring more data to support broad claims or is forcing the restriction of claim scope to cover only what has been exemplified in the description. Careful consideration needs to be given to how much data is available and the likely impact this will have on the scope of the patent claims, and whether additional experimentation will be required to secure broader protection.

Patents are not the only form of defence held by the biologics innovator companies. In view of the extensive time it can take to obtain regulatory approval to put a drug onto the market, additional forms of protection are available. Firstly, Supplementary Protection Certificates (SPCs) can be obtained, giving 5 years of further protection for a regulated biologic. The 5 year term (5.5 years in some special cases) starts on expiry of the patent upon which they are based. For more information, please see our AL Factsheet Supplementary Protection Certificates (SPCs). Secondly, the data the innovator companies file to obtain regulatory approval cannot be used to support launch of a generics product for

10 years from first approval in a European country (11 years in some special cases). For more information please see our AL Factsheet Data Exclusivity.

As European Patent Attorneys, the focus of our Factsheets is EPO patent practice but it should be noted that there are ongoing difficulties in the US regarding the patentability of biological inventions. For further information see our AL Factsheet US chem-bio patent issues?? (being written by Simon Bradbury)

Protecting biologics is an active, important area and it is vital for the preparation of sound patent filings which can withstand challenge in patent examination or litigation. We have explained the general principles 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.