Active Pharmaceutical Ingredients (APIs)

Securing strong patent protection for active pharmaceutical ingredients (APIs) – the biologically active ingredients in drugs) – is of key importance to the pharmaceutical industry.

In the European Patent Office (EPO) methods for treatment of the human or animal body are excluded from patentability under Article 53(c) EPC. Nevertheless, APIs used in such methods are themselves patentable. However, the form of the use claims is important. Patents for APIs may have claims to the active ingredient itself only if it is a truly novel compound. However, under Article 54(4) and (5) EPC, even if the API 'X' is known it is possible to protect it by first, second or even further medical use claims.

API is truly novel	can claim the API itself
First medical use	API X for use as a medicament
Second medical use	API X for use in treating disease Y
Further medical use	API X for use in treating disease Z

For further information on patenting the use of APIs in different circumstances please see our leaflet Patenting First and Second Medical Uses.

APIs may be the 'base' active substances, but their isomers, salts, esters and polymorphs may offer further scope for obtaining patent protection, in the same patent application as the 'base' API or in further patent applications.

It is also possible to protect APIs in several further ways, including when formulated as finished pharmaceutical products (FPPs) – these may include formulations, mixtures, delivery formats and different dosage regimes.

In all cases the patent claims must be novel and inventive to succeed, and the application as a whole must give sufficient information. The 'sufficient information' requirement can give rise to a difficult judgement call as to when to file a patent application for a particular API. Typically, the innovator companies feel that their interests are best served by filing patent applications as early as possible. However, in Eli Lilly v Janssen Alzheimer Immunotherapy [2013] EWHC 1737 (Pat), the UK High Court held the Janssen patent EP(UK) 1,994,937B1 to be invalid on the grounds that the patent application did not give sufficient information to make it plausible that the invention could to be worked across the whole scope of the claims. Further work and thought before filing the application could have been of value.

The innovator companies, who spend enormous sums researching and developing medicaments, are understandably keen to maintain their exclusivity in the market and keep out generics companies, whose unbranded equivalents would dilute their market share and erode their margins. There are many examples of patent proceedings being brought

between innovator companies and generics companies. For example, in Merck v Teva [2013] EWHC 1958 (Pat), an injunction was granted to prevent Teva from selling a generic drug which would infringe Merck's patent EP(UK) 0,582,455B1. In other cases the outcome has been that the generics company has succeeded in restricting or revoking the patent.

Patents are not the only defence that the innovator companies holds, for their APIs. In view of the long time it can take to obtain regulatory approval to put a drug onto the market some additional forms of protection are available to them. Firstly Supplementary Protection Certificates (SPCs) can be obtained giving 5 years of further protection for a regulated API. 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 leaflet 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). This is called 'data exclusivity'. For more information please see our leaflet Data Exclusivity.

Protecting APIs is a highly active and important area and it is vital to prepare sound patent filings which can withstand challenge in patent examination in 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.