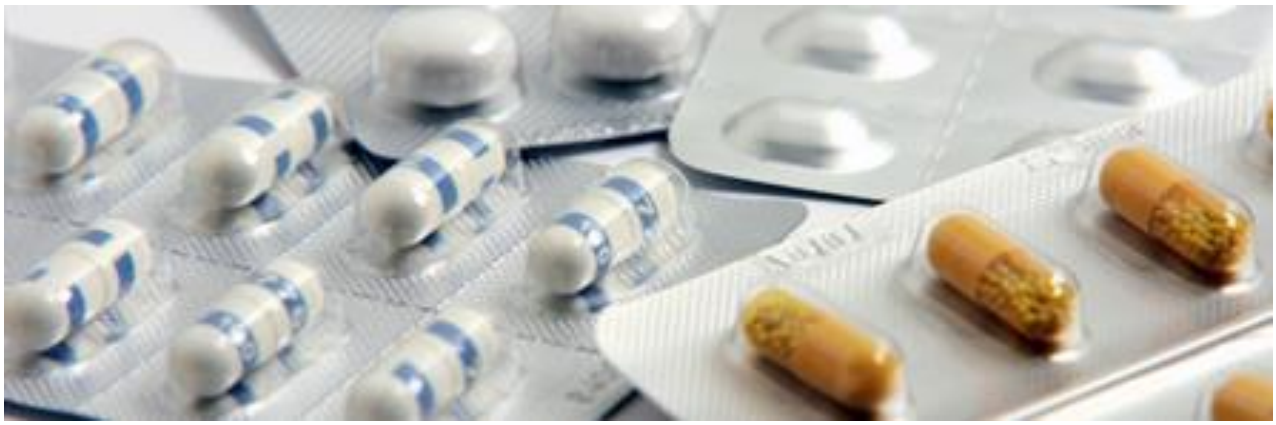
Supplementary Protection Certificates (SPCs)



Medicinal or plant protection products require regulatory approval, known as a marketing authorisation, to be sold. Obtaining marketing authorisation can significantly delay marketing and reduce the effective term of patents protecting the products. In order to compensate for this loss, a patent owner is given two benefits. First, the technical data submitted by the patent owner to obtain the marketing authorisation is protected from use by competitors (see our AL Factsheet Data Exclusivity). Second, the patent owner can obtain a Supplementary Protection Certificate (SPC). An SPC is an intellectual property right which can give up to 5 further years of exclusivity for a medicinal or plant protection product after the base patent has expired.

To obtain an SPC, it is necessary to have had a valid patent protecting the active ingredient and a marketing authorisation to place the active ingredient on the market as a medicinal or plant protection product. Renewal fees are payable to keep the SPC in force. If the base patent is declared invalid, the SPC is declared invalid therewith.

An SPC enters into force only when the relevant patent expires at the end of its 20 year life. It does not extend the patent. It protects only the active ingredient present in the medicinal or plant protection product.

If a patent covers several active ingredients which have been incorporated into different products for which marketing authorisations have been granted, it is necessary to apply for a separate SPC for each active ingredient.

SPCs are national rights that must be obtained country by country. It is not possible to obtain a Europe-wide SPC. An application for an SPC must be made at the national patent office of the country of interest within 6 months of the date on which the first authorisation to place the product on the market in that country is granted, or within 6 months of the date of grant of the relevant patent. Typically, it is the marketing authorisation which determines the deadline.

SPCs can be obtained in all European Union (EU) member states, as well as in Norway and Iceland by virtue of their membership of the European Economic Area (EEA). In addition, some other European countries which are not members of the EU or EEA, such as Switzerland, have their own system for granting SPCs.

The term of an SPC is equal to the period of time between the filing date of the patent and the date of the first marketing authorisation, minus 5 years; however, this is limited to a maximum term of 5 years. It is possible to extend an SPC for a medicinal product for a further 6 months when there is an agreed paediatric investigation plan (PIP) for the product.

There is fierce competition between rights holders and their generic competitors in this high-value area. Unsurprisingly, there is much litigation. The case law surrounding SPCs is highly complex and rapidly evolving. The highest body resolving disputes involving SPCs is the Court of Justice of the European Union (CJEU), Europe's highest court. There have been numerous decisions by the CJEU in recent years which have attempted to clarify the law surrounding SPCs but many uncertainties remain.

We have explained the general principles of protecting SPCs 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.