

Supplementary Protection Certificates (SPCs)

A Supplementary Protection Certificate (SPC) has the effect of extending the term of a patent relating to protection of a particular medicinal or plant protection product by a period of not more than five years. The aim is to “compensate” the patent owner for some “lost” patent protection caused by the length of time taken to obtain marketing authorisation for the product in question. An SPC is a national right, available in member states of the European Union (EU) by application to the national patent office of each state for which a certificate is desired. The SPC must be based on a patent but since an SPC is only granted in respect of a very specific active ingredient in a product, it is generally of rather more limited scope than the patent on which it is based.

How long does an SPC last?

The aim of an SPC is to restore 15 years of effective patent life between grant of the first marketing authorisation in the EU for the product to which the patent relates and expiry of the SPC. The term of the SPC is therefore equal to the period which has elapsed between the filing of the patent application and grant of the first EU marketing authorisation, less five years. The term of the SPC may not, generally, exceed five years. However, some EU legislation enacted in 2007, regarding paediatric medicines, provides for a six month extension of the basic SPC term in certain circumstances.

The SPC takes effect on expiry of the basic patent, but only if the annual renewal fees necessary to activate the SPC are paid prior to patent expiry.

When must an SPC application be filed?

In each country for which SPC protection is sought, a separate SPC application must be filed within six months of the grant of the first marketing authorisation in that country for the active ingredient(s) in question.

If the basic patent is not granted until after the marketing authorisation is given, then the SPC application must be filed within six months of the patent grant.

For what types of products are SPCs available?

An SPC may be granted in respect of a patented active ingredient, or mixture of active ingredients, of a medicinal or plant protection product.

However, the product must be one which must undergo a regulatory procedure (in accordance with certain EU directives) to obtain a “marketing authorisation” before it can be placed on the market in the EU.

A medicinal product may be one for the treatment of humans or animals.

Plant protection products include preparations which protect plants or plant products against harmful organisms or prevent the action of those organisms, as well as preparations which influence the life processes of plants or destroy undesirable plants or plant parts.

An SPC has the effect of extending the term of the patent in respect of the particular active ingredient only (or mixture of active ingredients) for which the SPC is granted.

Where a patent covers several active ingredients, which have been incorporated in different products each of which was the subject of a regulatory procedure, separate SPCs must be sought for each active ingredient for which extension of the term is required.

On what type of patent must an SPC be based?

An SPC may be based on any patent which protects:

- a) the active ingredient(s) of the authorised medicinal or plant protection product;
- b) a method of producing the active ingredient(s);
- c) an application of the active ingredients; or
- d) a preparation containing the active ingredient(s) (at least in the case of plant protection products).

The patent must be in force, in the country where the SPC is sought, at the time the SPC application is filed.

The patent may have been obtained either directly from a national patent office or from the European Patent Office (EPO).

If there is more than one relevant patent, the patentee has a free choice as to which of his patents an SPC is based on.

However, it should be kept in mind that no SPC will be available unless, as mentioned above, at least five years elapsed between the dates of filing of the chosen patent application and the grant of the first marketing authorisation in the EU for the active ingredient(s) specified in the SPC application.

On what marketing authorisation must an SPC be based?

An SPC application in a country must be based on the first marketing authorisation in that country for the product which incorporates the active ingredient (or mixture) for which SPC protection is sought.

A copy of this authorisation must be included in the SPC application and the authorisation must be valid at the time the SPC application is filed. In addition, the SPC application must give brief details of the first marketing authorisation in the EU, since the date of this determines the term of the SPC.

Where are SPCs available?

SPCs for medicinal products and for plant protection products can be obtained in all member states of the EU as well as in Norway and Iceland by virtue of those countries' membership of the European Economic Area (EEA). In addition, Switzerland, which is not a member of the EU or of the EEA, has its own national system for granting SPCs based on Swiss patents and authorisations.

Current member states of the EU are:

Austria	Greece	Portugal
Belgium	Hungary	Romania
Bulgaria	Irish Republic	Slovakia
Cyprus	Italy	Slovenia
Czech Republic	Latvia	Spain
Denmark	Lithuania	Sweden
Estonia	Luxembourg	United Kingdom
Finland	Malta	
France	Netherlands	
Germany	Poland	

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