

Supplementary Protection Certificates (SPC)

In European Union member countries, a Supplementary Protection Certificate (SPC) is a unique right that provides an additional monopoly that comes into force after expiry of a patent upon which it is based.

This type of right is available for various regulated, biologically active agents, namely human or veterinary medicaments and plant protection products (e.g. insecticides, and herbicides).

Purpose

Supplementary Protection Certificates were introduced in order to encourage innovation by compensating for the long time needed to obtain regulatory approval of these products (i.e. authorization to put these products on the market) compared to the standard 20 year patent term.

Legislative Background

The relevant EU legislation is:

- For medicinal products, Council Regulation (EEC) No. 1768/92.
- For plant protection products, Regulation (EC) No. 1609/96.
- For medicinal products tested for paediatric use, Regulation (EC) No. 1901/2006.

The above regulations apply directly in all EU member states. However, the Supplementary Protection Certificates themselves and their extensions have effect only in the individual EU member state in which they are granted.

In the United Kingdom, the patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007 give effect to the above EU regulations, by inserting Section 128B and Schedule 4a into the Patents Act 1977 as amended.

Requirements for Supplementary Protection Certificate Protection

According to the Art. 3 EC Regulation 1768/92, the conditions for obtaining a Supplementary Protection Certificate are:

1. The product is covered by a patent which is in force.
2. A valid authorization to place the product on the market has been granted.
3. The product has not yet been the subject of a Supplementary Protection Certificate.
4. The authorization referred to in (2) is the first authorization to place the product on the market.

The basic patent can be a European Patent or a national patent issued by a European national state. The basic patent may protect the product as such, a process to obtain the product, or an application of the product. For a plant protection product, it may specifically protect a “preparation” defined as a mixture or solution composed of two or more substances, of which at least one is an active substance.

The term “active ingredient” or “active substance” will generally be interpreted as including any closely related derivative, in particular a salt or ester, which has obtained an authorisation to be placed on the market, and is protected by the basic patent, unless the derivative in question can be regarded as a new active ingredient.

Apart from the case of such derivatives, a Supplementary Protection Certificate can only cover a single product. Different products will need to be the subject of different certificates, even if they are protected by the same basic patent.

Applications for Supplementary Protection Certificates can only be granted to the holder of the basic patent, or their successor in title. The same applies to any paediatric extensions of a Supplementary Protection Certificate.

The Term of a Supplementary Protection Certificate

A Supplementary Protection Certificate takes effect at the end of the maximum term of the basic patent (20 years from filing).

The term of an Supplementary Protection Certificate depends on the date of issuance of the first Market Authorization (MA) within the European Economic Area (EEA) and can be determined by the equation:

Term = date of 1st Market Authorization in the EEA – Filing date of patent - 5 years

Under normal circumstances, this means the following:

- No Supplementary Protection Certificate term is available if less than 5 years have elapsed between the date of filing of the corresponding patent and the date of issuance of the first Market Authorization in the European Economic Area.
- If the first Market Authorization is issued more than five years but less than ten years after the filing date of the corresponding patent, a Supplementary Protection Certificate is granted for a term corresponding to the period elapsed between the five-year point and the Market Authorization issuance date.
- If the first Market Authorization is issued more than ten years after the filing date of the corresponding patent, an Supplementary Protection Certificate is granted for a full five-year term.

Annual renewal fees need to be paid for a Supplementary Protection Certificate, just the same as for a normal patent.

Pediatric Supplementary Protection Certificates

Article 36 of Regulation 1901/2006 provides for a 6-month extension to the Supplementary Protection Certificate term. The extension is available only under certain conditions, the most notable being the requirement for the submission of a new Market Authorization application containing data from all trials conducted in accordance with an agreed Paediatric Investigation Plan (PIP).

A consequence of the 6-month Supplementary Protection Certificate extension is that the maximum term of a Supplementary Protection Certificate can now be up to 5.5 years.

Supplementary Protection Certificate Application

Although all countries in the European Union are required to provide supplementary protection certificates, no unified cross-recognition exists. Applications must be filed and approved on a country-by-country basis.

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