

Introduction to Supplementary Protection Certificates for Plant Protection Products

This document is intended to provide a brief introduction to Supplementary Protection Certificates (SPCs) for plant protection products. For more detailed information, please speak to your usual J A Kemp contact.

What is a Plant Protection Product?

Plant protection products protect crops or desirable or useful plants. They are primarily used in the agricultural sector, but also in forestry, horticulture, amenity areas and in home gardens. Plant protection products are defined as active substances, or preparations containing one or more such active substances, put up in the form in which they are supplied to the user, which are intended to:

- protect plants or plant products against harmful organisms or prevent the action of such organisms
- influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators)
- preserve plant products
- destroy or prevent growth of undesirable plants or parts of plants

Before a plant protection product can be placed on the market, it must obtain a marketing authorisation. This is a two stage process.

The first stage is approval of the active substance. This may be a chemical element or compound (occurring naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process) or a micro-organism, including a virus, having general or specific action against harmful organisms (plant pests and pathogens) on plants, parts of plants or plant products. For the EU/EEA, the active substance is assessed by a rapporteur member state and included in the EU's "approved list" of active substances. A similar process of active substance approval applies nationally in the UK and Switzerland.

The second stage is approval of the plant protection product including the active substance in its final formulation (with all other components). The plant protection product must be assessed for a national marketing authorisation in each EU/EEA member state. This is the first marketing authorisation for SPC purposes (see calculation of term and filing deadlines below). Marketing authorisations then arise in other member states via mutual recognition. The UK and Switzerland issue their own national marketing authorisations.

What are SPCs for Plant Protection Products?

SPCs are intellectual property rights available for active

substances of plant protection products. SPCs compensate patent holders for loss in effective patent term resulting from the time taken to receive marketing authorisation for such products.

Where are SPCs available?

SPCs are national rights: at present there is no such thing as a Europe-wide SPC. Accordingly, individual applications must be made to national patent offices in countries where SPC protection is desired, although a national SPC application may be based on a European Unitary Patent in those countries in which the Unitary Patent takes effect. Additional information on the Unitary Patent is available [here](#), with a guide to participating member states [here](#).

SPC protection is available in all EU member states, namely:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain and Sweden.

SPC protection is also available in the following non-EU States which may nonetheless be covered by a European patent application granted by the EPO:

- United Kingdom SPCs in the UK are available on effectively the same terms as the EU SPC Regulation, which was transposed into national law at the end of the Brexit implementation period (31 December 2020). The EU SPC Regulation continues to apply directly to SPCs which were pending or granted prior to this date. Similarly, CJEU case law prior to this date is applicable to SPCs in the UK, but deviation has become possible.
- Norway and Iceland (EEA member states, apply the EU regulation)
- Switzerland (national law based on the EU regulation)
- Liechtenstein (SPC issued in Switzerland automatically takes effect)

What scope of protection is provided by the SPC?

The scope of an SPC is limited to the product (active substance or combination of active substances) of the relevant marketing authorisation. It protects that product to the same extent as the patent on which the SPC is based ("the basic patent"). For example, if the basic patent covers the product only for a specific use, then the SPC will be similarly restricted.

Subject to the scope of the basic patent, an SPC for an active

substance will cover:

- all subsequently authorised uses of the substance in a plant protection product
- all subsequently authorised combinations which include that active substance
- derivatives (salts and esters) of a small molecule

What additional term is provided by the SPC?

The effective maximum term is 5 years in addition to the term of the basic patent. In EU/EEA member states, the SPC will expire at whichever is the earlier of:

- 15 years from the first Marketing Authorisation in the EU/EEA
- 5 years from the expiry of the basic patent

For non-EU/EEA member states, the term is usually determined by reference to the local marketing authorisation. However, as currently transposed from the EU Regulation, the law in the UK is such that term will be calculated based on the first authorisation for the product in either the EU/EEA or the UK.

For the purposes of calculating term a so-called “provisional authorisation” in an EU/EEA member state is taken into account only if it is directly followed by a definitive authorisation.

Who should apply for the SPC?

The Applicant for the SPC must own the basic patent, but need not hold the relevant marketing authorisation. Thus, it is possible to secure an SPC based on a marketing authorisation held by a third party.

When should the SPC application be filed?

An application for an SPC must be filed with the national Patent Office of the country concerned within the later of:

- 6 months from the date on which the first authorisation to place the product (active substance or combination of active substances) on the market as a plant protection product is granted in that country; or

For more information, please contact:

Graham Lewis – glewis@jakemp.com

Ravi Srinivasan – rsrinivasan@jakemp.com

- 6 months from the date of grant of the basic patent

What are the substantive requirements for obtaining SPCs?

The requirements for grant of an SPC are set out in Article 3(1) of the SPC Regulation (with equivalent provisions appearing in the national laws of non-EU/EEA states UK and Switzerland).

- Article 3(1)(a) requires that the product (active substance or combination of active substances) be “protected” by a basic patent
- Articles 3(1)(b) and 3(1)(d) require that the SPC be based on the first valid authorisation to place the product on the market as a plant protection product
- Article 3(1)(c) requires that the product has not already been the subject of an SPC

Although these requirements may appear relatively simple, each has been subject to multiple referrals to the CJEU - primarily in connection with the closely-related regulation for SPCs for medicinal products. Please ask your J A Kemp contact for more detailed advice.

Article 3(2) prohibits the holder of more than one patent for the same product from receiving more than one certificate for that product. However, it also explicitly provides that where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, a certificate for the product may be issued to each of these holders.

Is it possible for a third party to challenge the grant of the SPC?

Most national patent offices will consider observations filed by a third party against a pending application for an SPC. After grant, the validity of an SPC may be challenged in the national courts. In both instances challenges to validity of the SPC should focus on compliance with the substantive requirements of the SPC Regulation. Validity of the basic patent should be challenged separately.

Chris Milton – cmilton@jakemp.com