Introduction to Supplementary Protection Certificates for Medicinal Products

This document is intended to provide a brief introduction to Supplementary Protection Certificates (SPCs) for medicinal products. For more detailed information, please see our full briefing on this topic.

What are SPCs?

SPCs are intellectual property rights available for active ingredients of human and veterinary medicinal products requiring marketing authorisation. SPCs compensate patent holders for loss in effective patent term resulting from the time taken to receive marketing authorisation for such products.

Categories of product which are subject to regulatory delay but which cannot currently be the subject of an SPC include medical devices, and auxiliary substances in a medicinal product which enable or enhance therapeutic effect, but have no direct therapeutic effect on their own for the authorised indication (e.g. an adjuvant in a vaccine).

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. Please see our full briefing for additional information.
- 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)
- Albania, Bosnia & Herzegovina, Macedonia, and Serbia (national provisions)

Similar provisions exist in other countries worldwide.

What scope of protection is provided by the SPC?

The scope of an SPC is limited to the product 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 medical use, then the SPC will be similarly restricted.

Subject to the scope of the basic patent, an SPC for an active ingredient will cover:

- all subsequently authorised uses of the ingredient in a drug (provided SPC is still in force at time of authorisation)
- all subsequently authorised combinations which include that active ingredient (provided SPC is still in force at time of authorisation)
- therapeutically equivalent salts and esters of a small molecule

Are there any exceptions from infringement?

The EU/EEA has introduced a "manufacturing waiver" which came into effect on 1 July 2019. It allows manufacture of medicines protected by SPCs for the exclusive purpose of export to markets outside the EEA. Stockpiling for post-expiry use in the EU/EEA is permitted within the final 6 months of the SPC term.

The waiver does not apply to SPCs which were already in force on 1 July 2019. For SPCs which were applied for before 1 July 2019 but which come into force only after that date, the waiver will be applicable but only from 2 July 2022. The waiver will automatically apply to all SPCs applied for after 1 July 2019. An equivalent waiver has been transposed into UK law. No waiver presently exists in Switzerland.

More information is provided in our separate briefing on the manufacturing waiver, available here.

What additional term is provided by the SPC?

The effective maximum term is 5 years in addition to the term of the basic patent. For 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 determined by reference to the local marketing authorisation. A further 6 months term may be obtained by providing results obtained from an agreed paediatric investigation plan (PIP).

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 on the market is granted in that country; or
- 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 of the SPC Regulation.

- Article 3(a) requires that the product be "protected" by a basic patent.
- Articles 3(b) and 3(d) require that the SPC be based on the first valid authorisation to place the product on the market as a medicinal product.
- Article 3(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. Please ask your J A Kemp contact for more detailed advice.

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.

For more information, please contact:

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