

10 Things to Know About Supplementary Protection Certificates in Europe

A Supplementary Protection Certificate (SPC) is a unique intellectual property right that can give up to 5 years additional protection for a medicinal or veterinary product or a plant protection product (herein after referred to as a “product”) covered by a patent after the patent term has expired. A SPC compensates a patent holder for the delay in his/her ability to market a medicinal/veterinary/plant protection because of the need to obtain marketing approval.



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The SPC regulations are complex, and there is a multitude of case law relating to SPCs. Below are 10 facts about SPCs in Europe that provide an introduction to SPC law and practice in Europe:

1. SPCs are national rights: there is no pan-European SPC. You must apply for an SPC in each country for which you want SPC protection (at the national patent office). They can be applied for in all EU countries and the EEA countries Norway and Iceland.

2. Some non-EU European countries (such as Switzerland, Albania, Bosnia and Herzegovina, Macedonia, and Serbia) have their own, separate SPC systems, which are closely modelled on the EU system.

3. To apply for an SPC, you must have a valid marketing authorisation for the product in the country where you are applying: the marketing authorisation can be from an EU or EAA national regulatory authority; or it may be an EU marketing authorisation granted by the European Medicines Agency (EMA). The marketing authorisation must be the first marketing authorisation to place that product on the market in the EU or EAA.

4. To apply for an SPC, you must also have a granted patent that covers the product, and that patent must be in

force in the country where you are applying.

The claims of the patent do not need to cover the product *per se*, but could cover the product for a particular use (e.g. the treatment of a particular disease) or a method of making the product. If the product in the marketing authorisation includes two active ingredients, A + B, a patent having claims covering A only can be used to obtain an SPC but only under particular circumstances.

5. Only one patent covering the product can be extended by each patent holder. If a patentee has more than one patent that covers the product, he/she can choose which patent to use to obtain the SPC. He/she cannot obtain an SPC for the same product on both patents. On the other hand, if two patents cover the product and are owned by different parties, both patent holders can obtain an SPC on their own patent (each party does not need their own marketing authorisation, they can both apply using the same marketing authorisation).

6. The deadline for filing an SPC application in a particular country is whichever is the later of:

- a. within 6 months of the date of notification of the first marketing

authorisation of the product in that country; and

- b. within 6 months of the date of grant of the patent in that country.

If the marketing authorisation in that country is not granted before the patent term expires, it is not possible to obtain a SPC.

7. The maximum duration of an SPC is 5 years after the patent term has expired. The duration of an SPC is calculated as follows:

$$\text{SPC term}^* = ((\text{date first marketing authorisation for the product}) - (\text{date of filing of patent})) - 5 \text{ years}$$

*If the resulting SPC term is more than 5 years, it is capped at 5 years.

The SPC duration is always calculated using the date of notification of the first marketing authorisation for the product anywhere in the EU, EEA or

Switzerland (as a Swiss marketing Authorisation also covers the EU state Lichtenstein).

8. It is possible to extend the term of an SPC by 6 months by obtaining a "Paediatric Extension" to the SPC. A Paediatric Extension is always 6 months and is independent of the length of the SPC. If an SPC has the maximum 5 year term, then after a Paediatric Extension the term will be 5 years and 6 months.

To qualify for a Paediatric Extension, results from an agreed Paediatric Investigation Plan (PIP) on the product must have been provided to the EMA.

9. A SPC does not extend the life of the actual patent on which it is based. It only offers protection for the product that is the subject of the marketing authorisation. However, the protection offered for the product is equivalent to the protection that the patent offered the product: if the

patent claims the product itself, the SPC will protect the product; if the patent covers only the product *for use* in a particular purpose, then the SPC will only protect the product *for use* in that purpose.

10. An SPC comes into force after the end of the patent term, i.e. 20 years from the filing date. The patent must be granted and in force at the end of the patent term for the SPC to take effect. To keep the SPC in force, renewal fees must be paid. In some countries these are due annually, and in others they are due as a single, combined fee.

If you would like more information regarding SPCs, or any of the points raised above, please do not hesitate to get in touch with your usual Abel & Imray contact, or send an email to ai@abelimray.com, and a member of our specialist SPC team will be pleased to help.

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