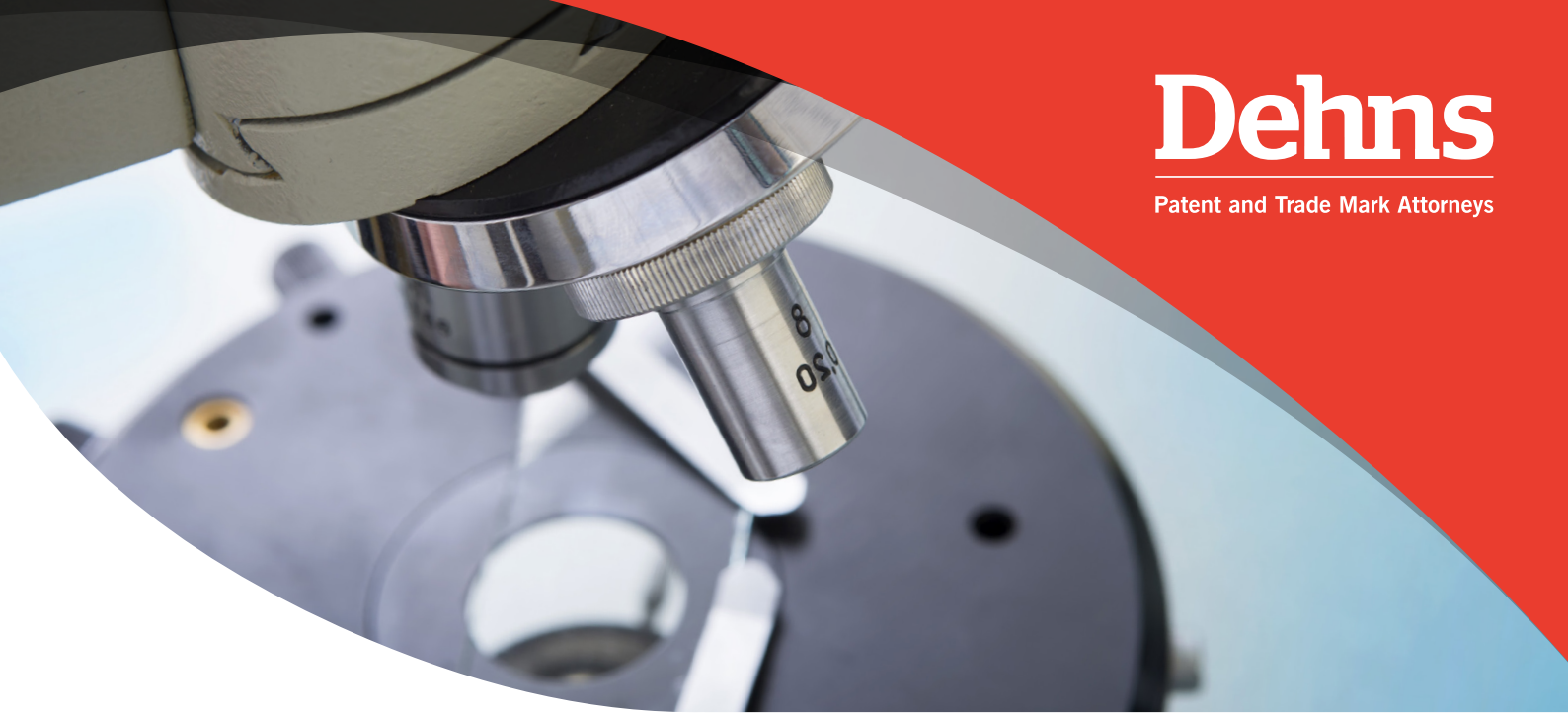

Dehns

Patent and Trade Mark Attorneys

Supplementary Protection Certificates

A Supplementary Protection Certificate (SPC) is a form of intellectual property that can extend the protection of patented active ingredients present in pharmaceutical or plant protection products by up to five years.

This briefing note provides basic information about SPCs. For a more in depth discussion, please refer to our additional **guidance discussing key case law.**

What are SPCs for?

SPCs were introduced to compensate patent holders for the effective loss in patent term through delays in receiving marketing authorisation.

The maximum term of a patent is generally 20 years. After expiry, the content of a patent falls into the public domain and will normally be available for use by anyone. However, some products in the fields of animal (including human) medicine and plant protection require regulatory approval before being able to be sold. Such approval almost always involves substantial and expensive trials and testing, and may take many years to obtain. This can significantly reduce the period available to the patentee to recoup his expenditure or gain additional benefit from his research.

In order not to prejudice research for new and more effective products in the pharmaceutical, veterinary or agrochemical areas, many European countries have provided for a form of patent term extension via Supplementary Protection Certificates (SPCs).

Where are SPCs available?

SPCs are national rights: there is currently no such thing as a pan-European SPC. Accordingly, individual SPCs must be sought in each of the countries of interest.

SPCs can be obtained in all member states of the EU. In addition, SPCs are available in certain non-EU states which are members of the European Economic Area (EEA), such as Norway and Iceland, as well as in some additional countries, including Switzerland and Serbia.

Similar types of right are also available in the USA, Japan and some other countries, though their nature and the applicable laws differ.

What is the term of an SPC?

The maximum term of an SPC is five years.

The aim of an SPC is to give a patentee up to a maximum of 15 years of protection for a particular product after he has obtained the necessary marketing authorisation. The last five years of protection can often be the most valuable in the lifetime of a commercial product, making SPCs one of the most important IP rights.

An SPC only enters into force once the basic patent expires. The term of an SPC is equal to the period of time between the filing date of the basic patent and the date of the first relevant marketing authorisation in the EEA, minus five years. However, the term is capped at a maximum of five years.

At least in EU member states, the date of the first relevant marketing authorisation is not the date of the marketing authorisation decision, but instead the date of the notification of the marketing authorisation.

It is possible effectively to extend the term of an SPC by obtaining a Paediatric Extension. A Paediatric Extension is always 6 months starting from the end of the normal SPC term, and is independent of the length of the SPC term. Because a Paediatric Extension must be based on an SPC, it can be important to obtain an SPC even if the SPC itself has a negative term.

What are the applicable laws?

In EU member states, as well as EEA members Norway, Liechtenstein and Iceland, SPCs are governed by EU **Regulation (EC) No 469/2009** for pharmaceutical or veterinary products and **EU Regulation (EC) No 1610/96** for plant protection products, plus any associated enabling national patent legislation.

Countries that are neither EU nor EEA members, such as Switzerland, have their own SPC provisions, but they are closely based on the EU Regulations.

Unfortunately, the EU Regulations are very unclear, so the Court of Justice of the EU (Europe's highest court) frequently has been, and continues to be, called upon to clarify certain points of law. Consequently, there is a wealth of case law in the SPC field.

The information provided herein is based on the EU SPC Regulations and certain relevant case law. For a more detailed summary of case law concerning areas of SPC law that continue to develop, please refer to our **separate briefing note.**

What are the basic requirements?

The wording of the EU Regulation is deceptively simple, setting out just a few basic requirements. To qualify for SPC protection, an active ingredient of a medicinal or plant protection product must be protected by a basic patent that is in force in the relevant country; and a valid marketing authorisation to place the product on the market in that country must exist.

Important further details regarding each of these requirements are provided later in this briefing.

What products can be protected?

SPCs are only available for active ingredients of authorized medicinal or plant protection products.

A "medicinal product" is defined as any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions.

"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.

The product must be one which needs to undergo a regulatory procedure to obtain a marketing authorisation before it can be placed on the market.

The active ingredient may be a combination of active ingredients. Substances which have no therapeutic effect on their own, such as adjuvants, cannot form the basis of an SPC application. Medical devices are also not eligible for SPCs.

The product must be 'protected' by the patent on which the SPC application is based. This requirement has proven to be difficult to assess, particularly with regard to combination products, so the CJEU has repeatedly been asked to issue guidance. Please refer to our **separate briefing note** in this regard.

Which patents can be used to obtain an SPC?

The patent on which an SPC application is based must be owned by the SPC applicant and be in force in the country of interest. It can be a European patent or a national patent.

The patent can cover an active agent as such, a process for obtaining the agent, or an application of the agent, e.g. a medical use. It may cover a combination of two or more agent. For a plant protection product, it may protect a "preparation" defined as a mixture or solution composed of two or more substances, of which at least one is an active substance.

If a patentee holds more than one relevant patent relating to a product of interest, he can nevertheless only obtain a single SPC for that product, so it is important to choose carefully which patent to base the SPC application on. Considerations which may apply in this regard include the scope of the different patents (e.g. a product patent

versus a medical use patent), the duration of the SPC available from each patent, and the relative vulnerability of the patents to any validity challenge.

Also important is the case law that has developed regarding the grant of multiple SPCs based on a single patent. It is possible to base more than one SPC on a single patent, provided that the SPCs are directed to different products that are each protected as such by the basis patent. However, where an SPC has been granted for an active ingredient, this precludes the grant of a subsequent SPC for a combination containing that active ingredient.

If two patents are owned by different parties then each patent holder can obtain an SPC based on their own patent.

The patent must 'protect' the relevant product. This requirement has proven to be difficult to assess, particularly with regard to combination products, so the CJEU has repeatedly been asked to issue guidance. Please refer to our **separate briefing note** in this regard.

What is the relevant marketing authorisation?

An SPC application must rely on a valid marketing authorisation in the country where the SPC is sought.

However, for the purpose of calculating the SPC term, the relevant marketing authorisation is the first one anywhere within the EEA, which may well have an earlier date than the one relied on for the SPC application. In this regard, it is important to note that any marketing authorisation obtained in Switzerland will also take effect in Liechtenstein and must therefore be taken into account in identifying the earliest marketing authorisation in the EEA.

In the UK, the marketing authorisation may be obtained via a national procedure; via the EU's centralized or decentralized procedure; or via the EU's mutual recognition procedure.

Ownership of the marketing authorisation is irrelevant, so, somewhat controversially, a patentee may obtain an SPC based on a third party's marketing authorisation.

What is the scope of SPC?

A SPC does not extend the life of the patent on which it is based. It only confers the same rights as the patent insofar as the patent relates to the specific product which is the subject of the relevant marketing authorisation. However, this is another area that continuously develops through case law, so please refer to our separate briefing note for further information.

The protection offered by an SPC for a product is equivalent to the protection that the patent offered for that product: if the patent claims the product itself, the SPC will protect the product; whereas if the patent is, for example, use limited, then the SPC will equally be use-limited.

Where and when should you apply for an SPC?

SPCs are national rights, so individual applications must be filed with the national patent offices.

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

a) 6 months of the date of notification of the first marketing authorisation of the product in that country; and
b) 6 months of the date of grant of the patent in that country.

For the situation where the patent term expires before a marketing authorisation in that country is granted, please refer to our **separate briefing note**.

SPCs are examined and granted (or, as the case may be, refused) by national patent offices. Once SPCs are granted and come into force, renewal fees are payable on them in a manner similar to national patents. They can be enforced and/or revoked before the relevant national courts.

Further advice

The Dehns Pharmaceutical and Life Sciences teams have significant expertise in obtaining and advising on SPCs. Please contact using the details below.

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