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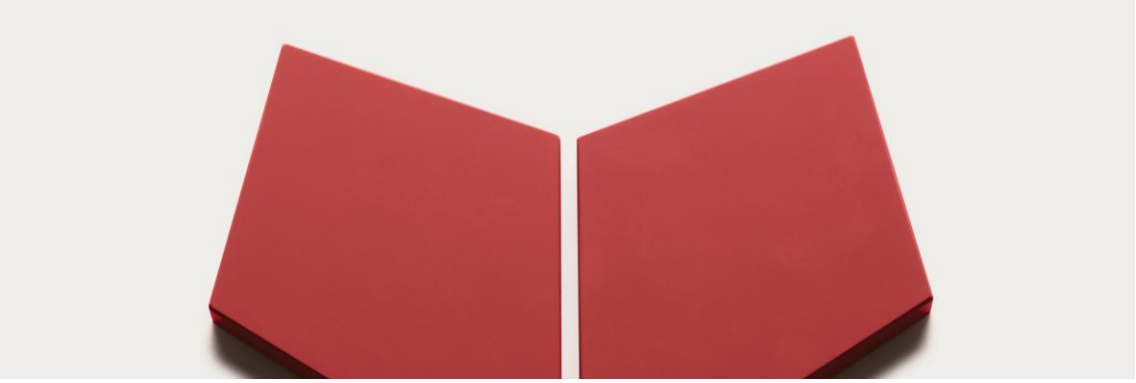
BRIEFING



SUPPLEMENTARY PROTECTION CERTIFICATES FOR MEDICINAL PRODUCTS

A Supplementary Protection Certificate (SPC) is an Intellectual Property right which can give up to five extra years of exclusivity after a patent has expired. SPCs are available in many European jurisdictions for active ingredients of human and veterinary medicinal products requiring marketing authorisation. SPCs are also available for active substances in plant protection products. The SPC regime was instigated to compensate patent holders whose effective patent term was eroded by delays in receiving marketing authorisation.

SPCs are national rights: 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. To qualify for SPC protection, an active ingredient of a medicinal product must be protected by a patent in force in the country of interest, and there must be a valid marketing authorisation in that country to place the product on the market.

The highest tribunal hearing disputes involving SPCs is the Court of Justice of the European Union (CJ-EU). Recently there have been a number of key CJ-EU Decisions which are highlighted in the discussion below.

Availability

In the countries of the European Union (EU), SPC protection is governed by consolidated EC Regulation 469/2009 ("the SPC Regulation"). SPC protection is available under this Regulation in 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, Sweden and the United Kingdom. SPC protection is also available under this Regulation in Norway and Iceland, which are members of the European Economic Area (EEA), but not of the EU.

Switzerland, which is neither an EU nor EEA member, has its own SPC provisions in its national law. Swiss national law in this regard is, however, based on the EU SPC Regulation. Patents of Switzerland extend to Liechtenstein (which joined the EEA in 1 May 1995) and similarly Swiss marketing authorisations and SPCs take effect in Liechtenstein.

SPCs are also available under the national law in the non-EU/EEA countries Albania, Bosnia and Herzegovina, Macedonia, and Serbia.

SPCs are granted for products. A product is defined as the active ingredient or combination of active ingredients of an authorised medicinal product. The medicinal product may be authorised for human or veterinary use. The Applicant for the SPC must own the basic patent, but need not hold the relevant marketing authorisation. Thus, it is in principle possible to secure an SPC based on a marketing authorisation held by a third party.

This definition of the product in the SPC Regulation as an "active ingredient" has been held to exclude the possibility for SPCs for substances having no therapeutic effect of their own on the human or animal body but enabling or enhancing the activity of the ingredient having the therapeutic effect in a medicinal product. That is perhaps unfortunate, because the development of such substances can require clinical testing leading to significant regulatory delay. However, the CJ-EU has on two occasions held that despite this potential for regulatory delay, SPCs are not available for such substances.[1]

Scope of an SPC[2]

An SPC confers the same rights as are conferred by the patent on which it is based ("the basic patent"), insofar as the patent relates to the specific product which is the subject of the relevant marketing authorisation. For example, if the basic patent covers the product *per se*, the SPC will also cover the product *per se*. If the basic patent only covers a method of manufacturing or using the product, then the SPC will be similarly restricted.

Although Article 2 of the SPC Regulation indicates that the subject of the SPC must be the "product" approved in the marketing authorisation, it has long been established than an SPC may extend to derivatives in particular salts and esters of the active product (provided of course that they are covered by the basic patent). When the active ingredient is a biologic, however, it is less clear to what extent an SPC can cover variants of the biologic (for example similar proteins with different glycosylation patterns).

As regards the field of use, an SPC for a given drug will cover any use of that drug which is authorised before the SPC expires (subject of course to the scope of the basic patent). Subsequent marketing authorisations made after grant of an SPC will extend the scope of the SPC, even when the later marketing authorisation is

[1] C-431/04 MIT (a bioerodible matrix for an intracranial stent) & C-210/13 Glaxosmithkline (an adjuvant for an antigen in a vaccine)
[2] Governed by Articles 2, 4 & 5 of the SPC Regulation – see Annex 1

obtained by an entity unconnected with the owner of the SPC. The CJ-EU has also confirmed that an SPC for a product will, subject to the scope of the basic patent, cover all subsequently authorised combinations of active ingredients containing the product at issue.[3]

Term of an SPC

An SPC takes effect at the end of the normal expiry term of the patent on which it is based. The term of protection is established by the date of the earliest marketing authorisation in any EU/EEA country. The term of an SPC is equal to the period of time between the filing date of the basic patent and the date of first EU/EEA marketing authorisation, minus five years, but subject to a maximum term of five years. Given a patent term of 20 years from the filing date of the basic patent, any SPC will therefore expire at the earlier of 15 years from the first EU/EEA marketing authorisation or 5 years from expiry of the basic patent.

Recent guidance from the UK Intellectual Property Office (IPO) indicates that for the purposes of calculating the term of an SPC in the UK, the relevant date for an EU marketing authorisation is the date of notification of the marketing authorisation to the authorisation holder, and not the date of the Commission Decision granting the authorisation, generally a difference of a few days[4]. This will mean that some UK SPCs will have a slightly longer term than previously thought.

The term of a Swiss SPC is determined by reference to the date of the Swiss marketing authorisation using a calculation analogous to that set out above. Thus where the Swiss marketing authorisation is later than the first marketing authorisation in the EC/EEA, the Swiss SPC for a medicinal product may have a longer term than the SPCs in the EU/EEA countries.

It should be noted that although Switzerland is not an EEA country, 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 EU/EEA. Until 1 June 2005 Swiss authorisations were automatically recognised in Liechtenstein. From 1 June 2005 Liechtenstein has maintained a list of medicinal products whose authorisations are not automatically recognised: those authorisations will generally take effect in Liechtenstein 12 months after the Swiss authorisation.

With effect from 26 January 2007, it has been possible to extend the term of an SPC by six months by providing clinical results obtained from an agreed paediatric investigation plan. Further information is provided in our briefing note on the Paediatric Products Regulation, available on request.

Time limits for applying for an SPC

An application for an SPC must be filed with the national Patent Office of the country concerned within six months of the date on which the first authorisation to place the product on the market is granted in that country. Where authorisation is obtained

[3] C-322/10 Medeva, C-422/10 Georgetown and C442/11 Novartis v. Actavis
[4] Decision BL O/418/13 of the UK Intellectual Property Office

before the basic patent is granted, however, the application for an SPC must be filed within six months from the date of grant of the basic patent.

If the basic patent expires before marketing authorisation is achieved, it may not be possible to secure an SPC. Under such circumstances, it may be worthwhile filing an application for an SPC before expiry of the patent, and following up with the marketing authorisation when it is available. However, the chances of persuading Patent Offices to grant an SPC under such circumstances would be uncertain, at best.

Substantive requirements for obtaining an SPC[5]

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.

All of these criteria have been subject to comment from the CJ-EU. They are discussed in more detail below.

What is meant by "protected" by a basic patent?

Perhaps surprisingly, to fulfil this requirement it is **not** sufficient simply that the claims of the basic patent embrace the product at issue. Regrettably, however, it is not entirely clear exactly what is required.

In 2010 the CJ-EU held that an SPC may not be granted for active ingredients which are not "specified in the wording of the claims of the basic patent".[6] This arose in the context of a patent claim to A, which would prevent an unauthorised third party from manufacturing and selling a medicinal product containing A and another active ingredient, B, but would not support an SPC for the product A+B as B was not specified in any way in the wording of the claim. There has been much debate about whether and if so how the requirement should be applied to single active ingredients and what, if any, degree of specificity is required. Clearly, this criteria will be satisfied if the basic patent contains a claim which mentions specifically the product at issue. The situation is less clear, though, when the claims of the basic patent embrace the product at issue without mentioning it specifically. We do, however, have the following further judicial guidance.

- A patent which claims product A and does not mention combination therapies cannot support an SPC for combinations of active ingredients containing A (eg an SPC for A+B).[7]

[5] The relevant provisions (Article 3) of the SPC Regulation are provided in Annex 1
[6] C-322/10 Medeva and C-422/10 Georgetown
[7] Medeva BV v Comptroller General of Patents [2012] EWCA Civ 523 – NB this is a ruling of the Court of Appeal of England and Wales, and it is not impossible that courts in other EU states may take a different view

- A patent which claims a combination of A+B cannot be the basic patent for an SPC for A alone, despite the fact that sale of A may well, under some circumstances, infringe the patent under the "contributory infringement" provisions. This remains true even where the marketing authorisation is for a medicine comprising A and includes an indication that A may or should be used together with B.[8]

- A generic disclosure such as a functional definition in the claims of the basic patent which embraces a marketed product can in principle support the grant of an SPC. However, the CJ-EU have held that in order for an SPC to be granted in those circumstances the claims when construed in the context of the description must relate "implicitly but necessarily and specifically to the active ingredient in question".[9]

    - Regrettably, it is far from clear how to determine whether a claim "implicitly but necessarily and specifically" relates to an active ingredient, and little guidance has been given by the CJ-EU in this regard. However, the referring UK Court has now interpreted the CJ-EU's decision[10]. The UK Court suggested that any general claim language which covers a single active agent, including a functional definition, will satisfy the requirements of Article 3(a) for an SPC directed to that active agent. This remains the case even if there is no "individualised description" of the active ingredient elsewhere in the patent. However, claims which embrace active ingredients only by virtue of open-ended language, such as "comprises", would not satisfy Article 3(a). This first instance decision has been appealed, and further judicial guidance is therefore expected in due course.

What is meant by "a valid authorisation to place the product on the market as a medicinal product"?

The CJ-EU has confirmed that an SPC for a given product can be based on any marketing authorisation for a combination therapy which includes the product. Thus, for example, an SPC for product A can be based on a patent claiming A and a marketing authorisation for a medicinal product containing A+B.[11] This may be important for vaccine products, where marketing authorisations often relate to combinations of multiple active ingredients.

An SPC granted under such circumstances will cover all products containing product A approved before the SPC expires.

How many SPCs may be granted for a given product or patent?

Although Article 3(c) of the SPC Regulation suggests that only one SPC can be granted for a given product, it has long been the case that if two basic patents are owned by

[8] C-518/10 Yeda
[9] C-493/12 Eli Lilly
[10] [2014] EWHC 2404 (Pat) Eli Lilly
[11] C-322/10 Medeva and C-422/10 Georgetown

different Patentees, each Patentee can secure an SPC. Under such circumstances, both SPCs can be based on the same marketing authorisation.

If two patents which cover a given product are held by a single Patentee, only one SPC is available. The Patentee must choose which patent to use to support the SPC. Considerations which may apply when determining which patent to choose will include the relative vulnerability of the patents to any validity challenge and the duration of the SPC available from each patent. If, however, the two patents are held by different entities, each patent can support a separate SPC.

The question of whether a single patent which covers multiple products can support several SPCs based on different marketing authorisations was considered by the CJ-EU in **C-484/12 Georgetown**. In that judgement the CJ-EU explained that it is, in principle, possible to have multiple SPCs granted for multiple different products on the basis of the same basic patent, provided that each product is protected by the basic patent (reason 30 of the decision).

However, in an exception to the general position set out in C-484/12, the CJ-EU held in **C-443/12 Actavis v Sanofi** that where an SPC had been granted for an active ingredient (irbesartan), a subsequent SPC, in that case having a later expiry date, could not be granted on the basis of the same patent for a combination containing that active ingredient (irbesartan and hydrochlorothiazide).

Which Marketing Authorisation is the first Marketing Authorisation?

Article 3(d) of the SPC Regulation requires that an SPC be based on the first authorisation to place a drug on the market as a medicinal product (the earliest marketing authorisation). The proper identification of the earliest marketing authorisation may be an issue when a patent protecting a second or subsequent medical use of a particular drug is used as the basis for an SPC application.

Historically it had been thought that a patent to a new medical use of a drug could form the basis of an SPC, but that SPC had to be based on the earliest marketing authorisation for that drug, even if the earliest authorisation was for a different disease or condition from that specified in the patent.[12] In practice, reference to the earliest marketing authorisation often meant that any resultant SPC would have a zero term, because of the maximum SPC term of 15 years from first marketing authorisation in the EU.

More recent guidance from the CJ-EU, however, suggests that in certain circumstances it may be possible to base an SPC application on an authorisation which is not the first marketing authorisation to place a particular drug on the market.[13] Thus, it may be possible for Patentees to obtain SPCs on the basis of (a) a patent to a downstream development of a known drug, for example a patent for a new medical use or a new formulation of a known active ingredient, and (b) a second or subsequent marketing authorisation for a medicinal product containing the active ingredient at issue.

[12] C-202/05 Yissum
[13] C-130/11 Neurim

Such SPCs may be granted if: (i) the downstream patent does not cover the medicinal product specified in the original marketing authorisation; and (ii) the second or subsequent marketing authorisation is the first authorisation for a medicinal product which is protected by the downstream patent. Further information on SPCs based on patents for downstream developments of a known drug can be found in our briefing on the **Neurim** decision, available on request.

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Annex 1

Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 (selected provisions)

Article 1

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'medicinal product' means 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 in humans or in animals;

(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product; […]

Article 2

Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

Article 3

Conditions for Obtaining a Certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorization to place the product on the market as a medicinal product.

Article 4

Subject matter of protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

Article 5

Effects of the certificate

Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

[…]