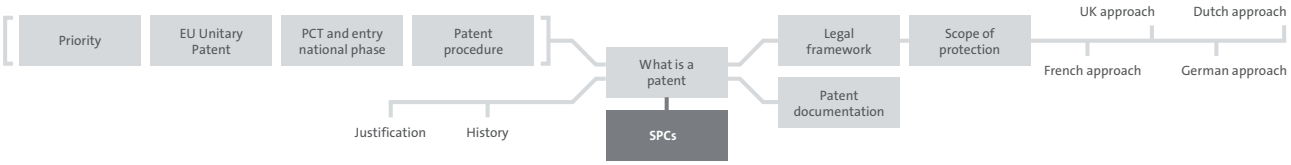
Supplementary protection certificates

Essentials: SPCs



Introduction

The term of protection of a patent is 20 years from the date of filing of the application. In the life sciences industry, however, the period of effective patent protection is significantly less than in other industry sectors, because of the need to satisfy certain regulatory requirements and obtain marketing authorisation before medicinal products (both human and veterinary) and plant protection products (such as pesticides or insecticides) can be placed on the market.

In order to satisfy the regulatory requirements for a new medicinal product, pre-clinical studies and clinical trials normally have to be carried out, in order to demonstrate the safety, efficacy and quality of the product. This can take a number of years (around 12 on average). It was recognised that the effect of these mandatory requirements would reduce the period of exclusive exploitation under a patent to just eight years, placing the European life sciences industry at a significant disadvantage compared with the US and Japan, where pharmaceutical patent term extensions have been available since the 1980s. So supplementary protection certificates (**SPCs**) were introduced in Europe to compensate, at least in part, for the investment made in these areas of life science research.

Article 63 EPC
Term of the European patent
(1) The term of the European patent shall be 20 years from the date of filing of the application.

(2) Nothing in the preceding paragraph shall limit the right of a Contracting State to extend the term of a European patent, or to grant corresponding protection which follows immediately on expiry of the term of the patent, under the same conditions as those applying to national patents:

[...]

(b) if the subject-matter of the European patent is a product or a process for manufacturing a product or a use of a product which has to undergo an administrative authorisation procedure required by law before it can be put on the market in that State.

In a communication of 28 October 2016 entitled "Upgrading the Single Market: More opportunities for people and business", the European Commission announced that it would explore the re-calibration of certain aspects of SPC protection following a review of the impact of the current system on the European pharmaceutical sector.

Legal framework – SPCs

Medicinal products – SPC Regulation

One of the key objectives of the legislature was to provide a uniform solution at Community level, thereby preventing the heterogeneous development of national laws which might affect the functioning of the internal market. Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning SPCs for medicinal products entered into force on 2 January 1993. It was subsequently amended and later codified and repealed by Regulation (EC) No. 469/2009 (**Medicinal SPC Regulation**), which entered into force across the European Union on 6 July 2009.

Iceland, Liechtenstein, Norway and Switzerland are members of the European Free Trade Association **(EFTA)** and are not bound by the Medicinal SPC Regulation. Instead, they are covered by Regulation (EEC) 1768/92, which entered into force (with certain amendments) on 1 July 1994 in those EFTA states which were a party to the European Economic Area Agreement (**EEA Agreement**).

Plant protection products – SPC Regulation

Regulation (EC) No. 1610/96 creating an SPC for plant protection products (**Plant SPC Regulation**) entered into force on 8 February 1997. Generally speaking, the Plant and Medicinal SPC Regulations contain broadly similar provisions. However, there are differences, some of which are highlighted below. It is also important to note that the Medicinal SPC Regulation is to be read and interpreted in the light of the following sections of the Plant SPC Regulation, since recital (17) Plant SPC Regulation states that:

> *"(17) Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) (c) and 17 of Council Regulation (EEC) No 1768/92."*

Together, the Medicinal SPC Regulation and Plant SPC Regulation are referred to in this publication as the **SPC Regulations**.

Explanatory Memorandum

Although it does not have binding effect, the **Explanatory Memorandum** to the proposal for Council Regulation (EEC) of 11 April 1990 (COM(90) 101 final) concerning the creation of a supplementary protection certificate for medicinal products is frequently referred to by the national patent offices, national courts and the Court of Justice of the European Union (**CJEU**) as a guide to the interpretation of the SPC Regulations.

The CJEU was formerly known as the European Court of Justice (**ECJ**). These two terms are used interchangeably in this module.

Medicinal SPC Regulation

Key definitions

→ Certificates

SPCs (or certificates, as they are referred to in the legislation) are the mechanism by which industry is compensated, at least in part, for the erosion of the period of exclusivity under a patent as a result of the time which elapses between the filing of the patent application and the grant of marketing authorisation to place the product on the market.

SPCs are not strictly patent term extensions, but rather separate (or *sui generis*) rights that come into effect upon expiry of a patent for a maximum period of five years, which can themselves be extended if the criteria for a six-month paediatric extension are satisfied (see below).

SPC protection confers the same rights and obligations as the basic patent (the patent designated by the SPC applicant as the basis of its application). However, unlike the basic patent, an SPC does not extend the protection conferred across the entire scope of the patent claims, but will only protect the product covered by the authorisation to place the corresponding medicinal product (or plant protection product) on the market, and any use of that product as a medicinal product (or plant protection product) that has been authorised before expiry of the SPC.

Article 1(d) Medicinal SPC Regulation
'Certificate' means the supplementary protection certificate.

→ See Articles 4 and 5 Medicinal SPC Regulation and recital (10).

→ Article 1(a) – Medicinal product

Both SPC Regulations distinguish between the terms "medicinal product" and "plant protection product" on the one hand and "product" on the other. The definition of the former is based on the early regulatory directives which prescribed the requisite studies and trials that needed to be conducted in order to bring a medicinal product to the market, and referred to the restoration, correction or modification of physiological functions in humans or animals. It is the medicinal product that is the subject of the regulatory authorisations referred to in Article 3 (see below).

Article 1(a) Medicinal SPC Regulation
'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.

→ Article 1(b) – Product

The term "product" is defined as the "**active ingredient** or combination of active ingredients of a medicinal product". However, the term "active ingredient" is itself not defined in the Medicinal SPC Regulation, and its meaning has been the subject of a number of disputes that have resulted in preliminary rulings from the CJEU.

Article 1(b) Medicinal SPC Regulation
'Product' means the active ingredient or combination of active ingredients of a medicinal product.

→ See below for more information on the SPC application and examination process and an overview of preliminary rulings of the CJEU.

The CJEU confirmed its approach in C-210/13 *GlaxoSmithKline Biologicals v Comptroller-General of Patents* (***GSK***). This case concerned two SPC applications relating to an adjuvant used in combination with a particular influenza vaccine. The case turned on whether the adjuvant was an active ingredient and therefore capable of satisfying the "product" definition in the Medicinal SPC Regulation. With reference to its earlier judgment in C-431/04 *Massachusetts Institute of Technology* (***MIT***) and to the Explanatory Memorandum, the CJEU confirmed that the term "product" is to be understood as meaning an active substance in the strict sense. Accordingly, "a substance which does not have any **therapeutic effect of its own** and is used to obtain a certain pharmaceutical form of a medicinal product is not covered by the concept of 'active ingredient', which, in turn, is used to define the term 'product'."

→ **See *MIT*, sections 19, 21, 25–28; *GSK*, sections 29–35.**
In reaching this conclusion, the CJEU recognised that it is not unusual for a substance which does not have therapeutic effects of its own to *influence* the therapeutic efficacy of the active ingredient of a medicinal product.

In C-202/05 *Yissum Research and Development Company of the Hebrew University of Jerusalem v Comptroller-General of Patents* (***Yissum***), the CJEU relied *inter alia* on the finding in *MIT* that the concept of "product" in Article 1(b) must be interpreted strictly. The CJEU extended this to mean that the concept of "product" **cannot include the therapeutic use** of an active ingredient.

The CJEU also cited *Pharmacia*, described in more detail under Article 13.

→ See below for more information on the impact of this decision on compliance with Article 3(d).

In C-631/13 *Forsgren v Österreichisches Patentamt*, questions were referred to the CJEU to ascertain whether an SPC could be granted for an active ingredient (protein D) that is covalently bonded to other active ingredients in the medicinal product but nonetheless retains its own therapeutic effect. The CJEU observed that a substance is considered to be an active ingredient under Article 1(a) when it has an independent pharmacological, immunological or metabolic effect, regardless of whether it is bound to another active ingredient. However, Article 3(b) precludes the grant of an SPC for an active ingredient whose effect does not fall within the therapeutic indication covered by the relevant marketing authorisation.

→ See also the *Bayer* case concerning the meaning of "active substances" in the context of plant protection products.

→ Article 1(c) – Basic patent

SPCs are granted in respect of a basic patent, which is a patent which protects:

(a) a product as such,
(b) a process to obtain a product, or
(c) an application of a product.

The basic patent can be either a national patent or a European patent designating the member state in which the SPC application is lodged.

Article 1(c) Medicinal SPC Regulation
"Basic patent" means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate.

Whilst the unitary patent will be capable of being a basic patent for the purposes of Article 1(c), individual national applications will have to be made in the same way as for existing European patents. There is currently no available mechanism for the grant of a single, unitary SPC.

Overview of the SPC examination process

The SPC Regulations are intended to provide a Community-wide solution and have direct effect across the member states of the EU. However, whilst SPCs are examined on the basis of the same conditions, as prescribed by the SPC Regulations, they are granted by the competent intellectual property offices of individual member states and have effect only in those member states in which they are granted.

This has in the past led to divergent approaches being adopted across Europe as to how the SPC Regulations should be applied in practice. If a dispute arises between an applicant and the national patent office and either party appeals, the relevant national court can (and frequently does) refer questions of interpretation to the CJEU, seeking a preliminary ruling on a point of interpretation for the national court to apply to the particular facts of that case.

Some national patent offices conduct a substantive examination of SPC applications, while the procedure in other jurisdictions is closer to a formalities examination.

Under Article 267 Treaty on the Functioning of the European Union, the court may request a preliminary ruling from the CJEU if it considers that a decision on the question is “necessary” to enable it to give judgment.

Questions of interpretation arising from any of the EFTA states are referred to the EFTA Court for a preliminary ruling or “advisory opinion” on the basis of a very similar procedure.

Overview of the SPC application process

Generally speaking, SPC applications should be lodged with the competent intellectual property office of the member state which granted the basic patent and in which the authorisation referred to in **Article 3(b)** was obtained (see **Article 9 Medicinal SPC Regulation**).

Under **Article 7**, the general rule is that applications for SPCs must be lodged within **six months** of either:

(a) the date on which the **marketing authorisation** to place the product on the market was granted in the member state in which the application was filed, or

(b) the date on which the **basic patent** was granted (if later).

Article 19 Regulation (EEC) No. 1768/92 (now repealed) previously provided for exceptions to this general rule in the form of transitional provisions. Article 19 is not considered further in this module, except to note that certain case law concerning Article 19 is relevant to the assessment of SPC duration and is covered under Article 13 below.

Article 8 Medicinal SPC Regulation sets out the content of the SPC application, which is based on limited documentation and objective criteria that are, in principle, easy to verify, consistent with the objective of providing a "simple, transparent system". These requirements include:

(a) the number of the basic patent;

(b) a copy of the authorisation to place the product on the market as referred to in Article 3(b), i.e. in the **member state** in which the SPC application is lodged (see right-hand column and below); and

(c) if the authorisation in (b) above is not the first authorisation to place the product on the market as a medicinal product in the **Community**, the number and date of that authorisation.

Where the authorisation referred to in (b) above is held by a different entity to the patentee/SPC applicant (e.g. a licensee), and the SPC applicant is unable to provide a copy, the ECJ held in C-181/95 *Biogen v SmithKline Beecham Biologicals* (***Biogen***) that the application must not be refused on that ground alone. The ECJ recognised that, by simple co-operation, the national authority granting the SPC can itself obtain a copy of the authorisation from the relevant authority which issued it.

Article 9 Medicinal SPC Regulation
(1) The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

Article 7(1) and (2) Medicinal SPC Regulation
1. The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

Article 19 Regulation (EEC) No. 1768/92
Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.

In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

→ See section 16 Explanatory Memorandum on the provision of a "simple, transparent system".

Article 3(b) Medicinal SPC Regulation
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:
[...]

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

→ Article 2 – Scope of the Regulation

According to Article 2 Medicinal SPC Regulation (and subject to it satisfying the other terms and conditions for obtaining a certificate), any product that satisfies the following criteria may be the subject of a certificate:

(a) the product is protected by a patent; and

(b) the product was subject to an administrative authorisation procedure as laid down in Directive 2001/83/EC (concerning medicinal products for human use) or Directive 2001/82/EC (concerning medicinal products for veterinary use) *prior to* being placed on the market as a medicinal product.

Article 2 Medicinal SPC Regulation
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] or [Directive 2001/82/EC] may, under the terms and conditions provided for in this Regulation, be the subject of a certificate

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

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

As previously mentioned, the purpose of these directives is to ensure the quality, safety and efficacy of medicinal products for the protection of public health across the EU. As well as national authorisations obtained in accordance with the requirements of these directives, Regulation (EC) No. 726/2004 provides a separate mechanism for obtaining centralised marketing authorisations which are granted by the European Commission following a positive opinion of the European Medicines Agency (**EMA**). These centralised authorisations proceed to grant simultaneously across all member states of the European Union. Both national and centralised authorisations may form the basis of an SPC application.

In C-195/09 *Synthon v Merz Pharma* (confirmed in C-427/09 *Generics v Synaptech*), the CJEU decided that the relevant territory for interpreting the meaning of the term "market" in Article 2 is the **European Community** market rather than the market of a member state. Further, the CJEU held that a product which was placed on the market in the European Community as a medicinal product before obtaining a marketing authorisation in accordance with Directive 2001/83/EC (then Directive 65/65/EEC) and, in particular, without undergoing safety and efficacy testing, is not within the scope of the Medicinal SPC Regulation.

The CJEU also ruled that any SPC granted for a product which falls outside the scope of the Medicinal SPC Regulation is **invalid**, notwithstanding the fact that Article 2 is not one of the grounds of invalidity listed in **Article 15**.

Article 15 Medicinal SPC Regulation
1. The certificate shall be invalid if:

(a) it was granted contrary to Art 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

→ Article 3 – Conditions for obtaining a certificate

According to Article 3 Medicinal SPC Regulation, an SPC is to be granted if, in the **member state in which the application is submitted**, and at the date of that application, each of the following conditions are satisfied:

(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 2001/82/EC (concerning veterinary medicinal products) or Directive 2001/83/EC (concerning products for human use);

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

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

→ Article 3(a)

Article 3(a) Medicinal SPC Regulation
The product is protected by a basic patent in force.

To satisfy Article 3(a) it is necessary to fulfil two requirements. First, there must be a basic patent that is still in force at the time the SPC application is filed in the member state in which the SPC application is submitted. Second, the product must be protected by that basic patent. There is no definition of "protected by" in the Medicinal SPC Regulation itself, and it is this limb of the test that has resulted in litigation before the national courts and multiple references to the CJEU for preliminary rulings on questions of interpretation of the SPC Regulation.

In C-392/97 *Farmitalia*, heard in 1999, the CJEU held that whether a product is protected by a basic patent under Article 3(a) is to be determined under national rules governing the basic patent. However, it was unclear what those national rules should be, and two divergent approaches began to emerge across Europe, particularly in the context of cases concerning combination products. These were:

(1) the disclosure test (also referred to in some member states as the "clear pointer" or "subject-matter" test); and

(2) the infringement-type test.

As a consequence of the lack of harmonisation in the interpretation of the SPC Regulation, the CJEU was asked to consider the meaning of Article 3(a) (and 3(b)) in C-322/10 *Medeva v Comptroller General of Patents (**Medeva**)*, which concerned combination products. Consistent with the opinion of the Advocate-General, the CJEU adopted a strict approach to Article 3(a), ruling that it must be interpreted as precluding the grant of an SPC "relating to active ingredients of the authorised product which are **not specified** in the wording of the claims of the basic patent". The *Medeva* case is considered further below.

The UK Court of Appeal, which referred the questions and gave judgment applying the CJEU's ruling, observed that, whilst the judgment of the CJEU makes no reference to the opinion of the Advocate-General, it is consistent with the observations set out in its opinion (see *Medeva v Comptroller General of Patents* [2012] EWCA Civ 523 at section 21).

In other combination cases (C-518/10 *Yeda Research and Development Company v Comptroller General of Patents* (***Yeda***); C-6/11 *Daiichi v Comptroller General of Patents* (***Daiichi***); C-630/10 *Queensland v Comptroller General of Patents* (***Queensland***)), the CJEU reached very similar decisions by reasoned order, referring to the need for active ingredients to be "**identified**" rather than "specified" in the wording of the claims in order to be eligible for the grant of an SPC. Neither the CJEU nor the national courts seem to have drawn a material distinction between these two terms.

Where a question referred to the CJEU is identical to a question on which the CJEU has already been called on to rule, or where the answer to the question admits of no reasonable doubt or may be clearly deduced from existing case law, the CJEU may give its decision by reasoned order rather than a full judgment, as was the case in *Daiichi*, *Queensland* and *Yeda* (see Article 99 Rules of Procedure of the CJEU of 25 September 2012, as amended on 18 June 2013 (OJ L 173, 26.6.2013).

In *Yeda*, the claims were all directed to a combination product (A+B), but the authorised medicinal product had been construed by the UK Patents Court as a single active ingredient (A). The CJEU held in that case that Article 3(a) precluded the grant of a SPC where the active ingredient, even though itself identified in the wording of the claims of the basic patent as part of a combination, is not the subject of any claim to that active ingredient alone.

In the context of the product-by-process claim at issue in *Queensland*, the CJEU held that Article 3(a) precluded the grant of an SPC for a product other than that identified in the wording of the claims of the patent as the product deriving from that process. However, whether it is possible to obtain the product *directly* as a result of that process was held to be irrelevant.

Although in *Medeva* the UK Court of Appeal (the referring court subsequently tasked with applying the CJEU's ruling) interpreted the judgment as a rejection of the infringement-type test, there nonetheless remained uncertainty as to what "specified" or "identified" was intended to mean, in particular in non-combination cases.

Following a further referral to the CJEU in C-493/12 *Eli Lilly and Company v Human Genome Sciences*, this time in the context of a single active ingredient rather than a combination product, and a basic patent claiming a class of monoclonal antibodies defined in functional rather than structural terms, the CJEU held that it is not necessary for the active ingredient to be identified in the claims of the basic patent by a structural formula. However, where the active ingredient is covered by a functional formula in the claims, it must be possible to conclude on the basis of those claims, interpreted *inter alia* in the light of the description of the invention, as required by Article 69 EPC and the Protocol on its interpretation, that "... the claims relate, implicitly but necessarily and specifically, to the active ingredient in question ...".

Antibody claims defined in **functional** terms are generally defined by reference to their ability to bind to a particular target antigen.

Antibody claims defined in **structural** terms are generally defined by reference to the amino acid sequence of the antibody itself and/or the sequence of the target antigen to which the antibodies bind.

The CJEU observed that this is a matter for the referring national (UK) court, which subsequently held that the CJEU's decision requires the application of the relevant rules (i.e. Article 69 EPC or Section 125 UK

Patents Act 1977) to ascertain the extent of the invention, and that HGS's claim, to an antibody which binds specifically to a novel antigen, satisfied Article 3(a).

→ Article 3(b)

As reflected under Article 2 above, Article 3(b) states that a valid authorisation must have been granted to place the product on the market in the member state in which the SPC application is submitted, i.e. an authorisation in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

Article 3(b) Medicinal SPC Regulation
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:
[...]

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

In *Medeva*, the Advocate-General recognised that a strict approach to Article 3(a) (see above) should be balanced with a more purposive or teleological approach to Article 3(b).

Therefore, Article 3(b) does not preclude the grant of an SPC for a combination of active ingredients that are specified in the wording of the claims (and so satisfy Article 3(a)) in circumstances where the medicinal product which is the subject of the marketing authorisation contains not only those active ingredients but also additional active ingredients.

The CJEU reached the same conclusion in C-422/10 *Georgetown University v Comptroller General of Patents* (***Georgetown I***).

Georgetown I was joined with *Medeva* for the purposes of the oral procedure, but separate judgments were given. Both judgments were handed down on 24 November 2011.

→ *Practical guidance on satisfying Article 3(a) and (b) in combination product cases*

For multi-component vaccines, such as those at issue in *Medeva* and *Georgetown I*, the medicinal product authorised to be placed on the market (e.g. with active ingredients A+B+C+D+E) often comprises more active ingredients than are claimed in the patent (e.g. A+B only). There is therefore a mismatch between the patented product under Article 3(a) and the authorised product under Article 3(b). However, the effect of the CJEU's combined reasoning on Article 3(a) and (b) means that SPCs can nonetheless be granted on the basis of an application for A+B alone. By contrast, an SPC application filed for A+B+C+D+E would satisfy Article 3(b) but fail under Article 3(a).

This interpretation was confirmed in C-443/12, *Actavis Group PTC EHF and Actavis UK Ltd v Sanofi*
→ see under Article 3(c) below

In this example, A+B are specified/identified in the wording of the claims in accordance with Article 3(a), and Article 3(b) does not prohibit the grant of an SPC based on an MA which authorises a product to be placed on the market comprising more active ingredients than are specified/identified in the claim (e.g. C+D+E).

However, there appears to be no solution where the claims are directed to more active ingredients than the authorised medicinal product. Following *Yeda*, where the claims are directed to A+B but the MA authorises A only, an SPC application based on A alone will fail under Article 3(a).

→ Article 3(c)

Broadly speaking, this provision is intended to ensure that only one SPC may be granted for any given product. The underlying rationale is explained in the Explanatory Memorandum, i.e. that a product is understood to mean an "**active substance in the strict sense**", such that minor changes, such as a new dose or a different salt or ester or pharmaceutical form, will not lead to the issue of a new SPC. However, the CJEU has confirmed that there are circumstances in which more than one SPC may be granted per product.

Article 3(c) Medicinal SPC Regulation
The product has not already been the subject of a certificate.

→ See the definition of "product" in Article 1(b) and e.g. section 11 of the Explanatory Memorandum.

First, where a product is protected by a number of basic patents which belong to different patent holders (e.g. a patent which protects the product *per se*, the process for making the product or a therapeutic use of the product), Article 3(c) permits SPCs to be granted to each of those patentees, providing the other conditions for grant are satisfied (see *Biogen* and Case C-482/07 *AHP Manufacturing (**AHP**),* citing Article 3(2) Plant SPC Regulation, which applies equally to the interpretation of Article 3 Medicinal SPC Regulation).

Article 3 Plant SPC Regulation
2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

Recital (17) Plant SPC Regulation indicates that Article 3 Medicinal SPC Regulation is to be interpreted in the light of the above provision.

Secondly, the form of wording used by the CJEU (and later referred to in ***Medeva**)* casts doubt on whether a patentee is entitled to one SPC *per product* per basic patent (as was previously understood by many national patent offices and practitioners) or whether only one SPC per patent was permitted, irrespective of the number of different products protected by a particular basic patent. This issue was recently resolved in C-484/12 *Georgetown University v Octrooicentrum Nederland (**Georgetown II**)* and C-443/12 *Actavis Group v Sanofi (**Actavis**)*, in which the CJEU confirmed that multiple SPCs can be obtained on the basis of the same basic patent, provided that each of the products in respect of which an SPC is sought is protected as such by the basic patent within the meaning of Article 3(a).

The CJEU in *Medeva* stated at section 41 that *"...where a patent protects a product ... only one certificate may be granted for that basic patent (see Biogen, section 28)."*

Georgetown II and *Actavis* were heard together before the CJEU on 12 September 2013 and judgment was handed down on the same day (12 December 2013).

On the facts in *Georgetown II*, the patentee already had an SPC for a combination of active ingredients, but was entitled to obtain a further SPC for one of those active ingredients alone (which, individually, was also protected as such by the patent under Article 3(a)). It was recognised in *Georgetown II* that, even if the protection conferred by the two SPCs were to overlap, they would, in principle, expire on the same date, because the relevant marketing authorisation was the same (see section 35 of *Georgetown II* and the section below on Article 13), so the avoidance of evergreening was not a concern.

Before the CJEU delivered its rulings in *Georgetown II* and *Actavis*, Arnold J of the UK Patents Court held (*obiter dictum*, as the point was not in issue) that two SPCs could be granted based on the same basic patent because they are for different products. See *University of Queensland v Comptroller-General of Patents* [2012] EWHC 223 (Pat) following the reference to the CJEU in *Queensland*.

The CJEU also acknowledged that a different outcome on the Article 3(c) issue could give rise to "circumvention tactics", such as the filing of divisional patents to confer separate protection on each product.

A different conclusion was reached in *Actavis*. Sanofi already had an SPC for a single active ingredient and sought to enforce a second (later) SPC for a combination product which included the same single active as the first SPC. The CJEU referred to the "inventive advance" of the basic patent and held that it would be unacceptable for a patentee to obtain a new

The CJEU declined to rule on the Article 3(a) point referred in *Actavis* in view of the answer given to the Article 3(c) question, which the CJEU regarded as determinative of the issue.

SPC, potentially for a longer period of protection, each time he places on the market a medicinal product containing the core inventive advance of that product and another active ingredient which is not protected as such by that patent.

The CJEU reaffirmed this position in C-577/13 *Actavis v Boehringer,* holding that once an SPC has been obtained on a basic patent claiming a "mono" product, the holder is precluded from obtaining a second certificate on a claim to a combination product containing the same active ingredient.

→ Article 3(d)

Article 3(d) Medicinal SPC Regulation
The valid authorisation in point (b) is the first authorisation to place the product on the market as a medicinal product.

This provision is intended to ensure that the authorisation to place the product on the market in the member state in which the application is lodged is the first such authorisation. Much of the case law that has developed turns on establishing the correct product under Article 1(b).

→ See under Article 1(b) above for more background information on the key CJEU decisions, including *MIT*, *Yissum*, *GSK* and *Forsgren*.

In *Yissum*, the ECJ held that the concept of "product" in Article 1(b) must be interpreted strictly and cannot include the therapeutic use of an active ingredient. Therefore, in a case where a basic patent relied upon protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product. Consequently, the SPC application was denied because the active ingredient had already been granted an authorisation to be placed on the market in respect of the first use, such that the authorisation included in the application was not the first for the purposes of satisfying Article 3(d).

The UK Intellectual Property Office had rejected Neurim's application, relying *inter alia* on the CJEU's earlier preliminary rulings in *Yissum*, *MIT* and *Pharmacia*.

The CJEU has considered Article 3(d) more recently in 2012 in C-130/11 *Neurim Pharmaceuticals v Comptroller-General of Patents (**Neurim**)*. In this case, Neurim had applied for an SPC for melatonin (a natural hormone) based on a basic patent covering the use of appropriate formulations of melatonin for human use in treating insomnia, and a marketing authorisation covering such use. Neurim's SPC application was rejected because of a prior third-party authorisation for the use of melatonin in regulating the seasonal breeding activity of sheep, such that Neurim's marketing authorisation was not considered to be the first to place melatonin on the market as a medicinal product under Article 3(d).

Neurim's position was that the first marketing authorisation for the purposes of Article 3(d) is the first marketing authorisation that falls within the scope of the basic patent. In this case, the earlier marketing authorisation for the use of melatonin in regulating the seasonal breeding activity of sheep was not a use that would fall within the scope of Neurim's patent, so should be ignored.

The CJEU agreed with Neurim, ruling that Articles 3 and 4 are to be interpreted as meaning that the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of an SPC for a *different application* of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent.

It remains unclear how widely the CJEU's judgment in *Neurim* will be interpreted by the national patent offices and courts, particularly on different facts (although the CJEU has already adopted a narrow application of *Neurim* in other contexts – see its subsequent decisions in ***GlaxoSmithKline*** (above) and ***AstraZeneca*** (below)). However, the CJEU's reasoning in sections 25 and 26 of *Neurim* nonetheless suggests that it should be irrelevant whether the earlier use is veterinary or human and whether or not it is protected by an earlier patent (on the facts in *Neurim*, melatonin was not protected as such by an earlier patent).

Importantly, the CJEU confirmed in *Neurim* that the protection conferred by the SPC will not cover the active ingredient as such, but only the new use of that product *(see below on Articles 4 and 5)*.

The section on Article 13 below also discusses what is meant by the "first marketing authorisation" in the context of the "first authorisation to place the product on the market in the Community" for the purposes of calculating SPC duration.

Neurim

"25. Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for **veterinary or human use**, for other therapeutic indications, **whether or not protected by an earlier patent**, the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same active ingredient, as protected by the new patent, may enable its proprietor to obtain an SPC, the scope of which, in any event, could cover, not the active ingredient, but only the new use of that product.

26. In such a situation, only the MA of the first medicinal product, comprising the product and authorised for a therapeutic use corresponding to that protected by the patent relied upon for the purposes of the application for the SPC, may be considered to be the first MA of 'that product' as a medicinal product exploiting that new use within the meaning of Article 3(d) of the SPC Regulation."

In January 2016, in decision 34R104/15, the Higher Regional Court of Vienna followed *Neurim* and confirmed that an SPC application could be filed on the basis of a type II variation of an existing MA (for a new indication of Botox, protected by a second medical use patent) as a "first authorisation" under Article 3(d).

→ Articles 4 and 5 – Scope of protection

According to **Article 5**, an SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and obligations.

However, this is subject to the provisions of **Article 4**, which states that the scope of protection conferred by an SPC extends only to the product authorised to be placed on the market (and for any use of the product as a medicinal product that has been authorised before expiry of the SPC), rather than extending the protection conferred by a basic patent in its entirety.

In C-442/11 *Novartis v Actavis UK (**Novartis**)*, the CJEU confirmed that, once granted, SPCs confer patent-like protection. Where a product comprising a single active ingredient (A) is protected by a basic patent, and if during the lifetime of a basic patent concerning A the patentee was entitled to oppose the marketing of a medicinal product containing A in combination with one or more other active ingredients (e.g. A+B), then the SPC similarly confers the same rights to oppose the marketing of a medicinal product containing A in combination with other active ingredients.

This rationale appeared to be an integral part of the reasoning on Article 3(b) in *Medeva* and *Georgetown I* etc., as this approach allows the grant of an SPC for A based on a patent which protects A and a marketing authorisation for a product comprising A+B+C, etc. to be enforceable under Articles 4 and 5 against the third-party marketing of:

– A or
– A+B or
– A+B+C, and so on

In C-392/97 *Farmitalia,* a case involving a small molecule active ingredient, the CJEU held that an SPC is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent. Accordingly, "the certificate is capable of covering the active ingredient as such and also its various derived forms such as salts and esters".

Article 4 Medicinal SPC Regulation
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.

This provision is to be interpreted in the light of Article 4 Plant SPC Regulation, which is identical other than referring to "authorisations" (plural) to place the corresponding relevant product on the market.

Article 5 Medicinal SPC Regulation
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.

See also recital (10), which states: "... *The protection granted shall furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.*"

The CJEU's decision in *Novartis* was made by reasoned order with reference to the *Medeva* line of cases (see Article 3(a) and (b) above), since its consideration of the correct interpretation of Articles 4 and 5 was an integral part of its reasoning in respect of Article 3(a) and (b).

This rationale is also reflected in the later CJEU judgments in *Actavis* (see section 35) and *Georgetown II* (see section 39).

In *Pharma v Intervet*, a case referred from the Oslo District Court, the EFTA court apparently approved the reasoning of *Farmitalia* in the context of complex biological products such as the vaccine composition at issue in that case, suggesting that medicinal products that are "therapeutically equivalent" would fall within the scope of a certificate under Article 4. However, the EFTA court also concluded that an SPC would be invalid "to the extent it is granted a wider scope than that set out in the relevant marketing authorisation".

→ Articles 6 to 8 and so-called third-party SPCs

Article 6 states that the certificate is to be granted to the holder of the basic patent or his successor in title, but Articles 7 and 8 (concerning the SPC application itself) do not prescribe who the SPC applicant must be. Consequently, questions have arisen concerning entitlement to SPCs in circumstances where the patentee and the marketing authorisation holder are not the same entity.

The CJEU in *Biogen* (as later confirmed in *AHP*) held that, where a medicinal product is covered by several basic patents which belong to a number of different patent holders, the SPC Regulation seeks to confer supplementary protection without instituting any preferential ranking amongst the patentees according to their relative contribution towards bringing the product to market. The SPC Regulation does not therefore preclude the grant of an SPC to each patentee (in circumstances where only one of them will be the marketing authorisation holder).

However, under Article 3(c) only one SPC may be granted per basic patent (see above).

The CJEU in *AHP* also confirmed that it is not a requirement that, notwithstanding the wording of recital (17) and Article 3(2) Plant SPC Regulation, the earlier SPC applications remain *pending* whilst the later application(s) is/are lodged.

In the UK, in *Eli Lilly v Human Genome Sciences, Inc.* [2012] EWHC 2290 (Pat), Warren J held (at first instance) that the holder of a basic patent can make an application for an SPC "in reliance on a marketing authorisation granted to a third party having **no connection of any sort** with that holder".

See section 62 of this judgment of Warren J. However, whilst Warren J subsequently referred to this as his "clear view", he emphasised that he had not found the matter to be *acte clair* (see *Eli Lilly v Human Genome Sciences, Inc.* [2012] EWHC 2857 (Pat) at section 21).

→ Article 13(1) and (2) – Duration of the certificate

When calculating the duration of an SPC, the Regulation establishes a system that reflects the time taken for the patentee to obtain the first authorisation to put the product on the EU/EEA market.

Article 13 Medicinal SPC Regulation
(1) The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the **first authorisation to place the product on the market in the Community**, reduced by a period of five years.

(2) Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

STEP 1: Supplementary protection granted is equal to the period which elapsed between the filing date of the basic patent application and the date of the first authorisation in the EU/EEA, reduced by a period of five years, as follows:

(A – B) – 5 years = SPC duration

A = First marketing authorisation in the EU/EEA
B = Filing date of the basic patent application

In C-471/14 *Seattle Genetics*, the CJEU confirmed that the term of an SPC is to be calculated from **the date of notification** of the first marketing authorisation.

STEP 2: The total period of supplementary protection under an SPC is also subject to a **maximum duration of five years**. Therefore, even if the time taken to obtain the first MA after the patent application was filed was ten years or more, the SPC duration will nonetheless be capped at five years. This ensures that the total period of exclusivity conferred collectively under the patent and the SPC does not exceed fifteen years.

This five-year maximum period of supplementary protection and the fifteen-year exclusivity cap from the time the medicinal product is first authorised to be placed on the market in the Community are reflected in recitals (9) and (10). The respective periods are said to provide *"adequate effective protection"* taking into account all the interests at stake, including those of public health.

If, on the other hand, the time taken to obtain regulatory approval is less than five years, it is not possible (subject to the availability of paediatric extensions – *see below*) for the patentee to obtain an SPC because he has already enjoyed fifteen years or more of exclusivity under the patent.

Compliance with Directives 2001/82 and 2001/83

In C-127/00 *Hässle v Ratiopharm (**Hässle**)*, the CJEU held that "the first marketing authorisation in the Community" refers only to a marketing authorisation granted in accordance with Directive 65/65 (now superseded by Directive 2001/83), even though there is no express reference to the Directive itself. Further, it was irrelevant whether the product could in fact be marketed, or whether further authorisations were required under national pricing and/or reimbursement legislation.

Strictly speaking, *Hässle* concerned Article 19 (transitional provisions), although the same words appear in Article 13. The CJEU held in this case that they must not be interpreted differently depending on the provision in which they appear (see below).

The CJEU also confirmed that Article 13 is not intended to take the place of the marketing authorisation referred to in Article 3(b) of the Medicinal SPC Regulation. Rather, it constitutes a further condition applying in circumstances where the latter (i.e. Article 3(b)) authorisation is not the first authorisation to place the product on the market as a medicinal product in the *Community* as well as the member state in which the application is submitted.

Section 73 *Hässle*

73. At paragraph 24 of Yamanouchi Pharmaceutical, the Court held that the effect of Articles 8(1)(a)(iv) and (b), 9(2)(d) and 11(1)(d) of Regulation No 1768/92 is that the first marketing authorisation in the Community is not intended to take the place of the marketing authorisation provided for in Article 3(b) of the above-mentioned regulation, that is to say, the authorisation granted by the Member State in which the application is submitted; instead, it constitutes a further condition applying in the event that the latter authorisation is not the first authorisation to place the product on the market as a medicinal product in the Community.

The CJEU also made an important general point of principle, deciding that the words "first marketing authorisation" must not be interpreted differently depending on the provision of the Medicinal SPC Regulation in which they appear. This is particularly true of the words "first authorisation ... to place ... on the market ... in the Community".

Section 21 *Pharmacia*

21. Whilst noting that the term 'first marketing authorisation in the Community' must be interpreted in the same way in each of the provisions of the regulation in which it is used, it should be pointed out that, according to the sixth recital in its preamble,that regulation seeks to provide a uniform solution at Community level to the problem of inadequate patent protection, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community.

However, an interpretation such as that proposed by Pharmacia would prevent the realisation of that objective. Under Pharmacia's interpretation, the duration of the protection conferred by the certificate, calculated in accordance with Article 13 of the regulation, might be different for the same product.

Swiss marketing authorisations

Joined cases C-207/03 *Novartis & Others v Comptroller General of Patents* and C-252/03 *Ministre de l'économie v Millenium Pharmaceuticals (**Novartis**)* concerned the assessment of SPC duration based on a Swiss marketing authorisation. First, the CJEU confirmed that, in cases involving an EEA dimension, Article 13 is to be understood as referring to the first authorisation to place the product on the market in any territory covered by the EEA Agreement (i.e. not just the member states of the Community, as referred to in the Medicinal SPC Regulation).

Second, it established that a Swiss marketing authorisation is also capable of being the first marketing authorisation for the purposes of Article 13(1), even though Switzerland is not a member of either the Community or the EEA. This is because Swiss marketing authorisations were, at the relevant time, automatically recognised in Liechtenstein (which is a member of the EEA) pursuant to the regional union between the Swiss Confederation and the Principality of Liechtenstein.

These principles were recently confirmed in November 2013 in C-617/12 *AstraZeneca v Comptroller General of Patents (**AstraZeneca**)*. In particular, the CJEU emphasised that its judgment in *Neurim* was not intended to reflect a departure from its earlier decision in *Novartis*. In cases such as *AstraZeneca*, which involve an EEA dimension, an administrative authorisation granted by the Swiss regulatory authorities and automatically recognised in Liechtenstein must be regarded under Article 13(1) as the first authorisation to place the product on the market in the EEA.

See section 72 *Hässle*.

72. In that connection, as stated in paragraph 57 of the present judgment, the words "first authorisation to place... on the market" must not be interpreted differently depending on the provision of Regulation No. 1768/92 in which they appear. The same is particularly true of the words 'first authorisation to place... on the market ... in the Community' (see, to that effect, Yamanouchi Pharmaceutical, cited above, paragraphs 23 and 24).

Veterinary or human marketing authorisations

In C-31/03 *Pharmacia Italia, formerly Pharmacia & Upjohn (**Pharmacia**),* the CJEU ruled that the grant of a marketing authorisation for a veterinary medicinal product in a particular member state precluded the grant of an SPC based on a later authorisation for the medicinal product in human use granted elsewhere in the Community. In other words, no distinction was made between authorisations for medicinal or veterinary use, so the first authorisation for veterinary use counted as the first marketing authorisation to place the product on the market in the Community. However, a similar issue was considered more recently in the second question referred in *Neurim*, and the answer given suggests a different outcome, depending on the nature of the patents in question. Consistent with the approach taken in respect of Article 3(b) in *Neurim*, the CJEU held that the relevant marketing authorisation for the purposes of assessing duration under Article 13(1) should be the authorisation of the product which is within the limits of protection conferred by the basic patent relied upon in the SPC application (not the earlier veterinary authorisation for the same product).

On 1 June 2005 the Swiss Confederation and the Principality of Liechtenstein abolished the automatic recognition mechanism. Now authorisations granted by the Swiss regulatory authorities are typically recognised after a 12-month period.

→ Article 13(3) – Six-month paediatric extensions and negative-term SPCs

The SPC Regulation was amended by Regulation (EC) No. 1901/2006 (**Paediatric Use Regulation**), which was intended to incentivise the study of the safety, efficacy and quality of medicinal products in paediatric patients. Consequently, Article 13(3) now allows for a further six-month extension of exclusivity for medicinal products in respect of which clinical trials have been conducted in accordance with an agreed paediatric investigation plan. This extension is available irrespective of whether the paediatric studies lead to the authorisation of a paediatric indication, provided that the results of those studies are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the relevant medicinal product (see Article 36(1) Paediatric Use Regulation).

Importantly, paediatric extensions apply only to products that are protected by an SPC or under a patent which qualifies for the granting of an SPC. Therefore if an SPC application is refused because the duration would result in one of negative or zero duration, the patentee would not be entitled to obtain a paediatric extension either, which could adversely affect the purpose of the Paediatric Use Regulation.

This issue was resolved in C-125/10 *Merck Sharp & Dohme v Deutsches Patent- und Markenamt* (***Merck***), where the CJEU ruled that SPCs can be granted where less than five years have elapsed between the date of the application for the basic patent and the date of the first marketing authorisation, in order to enable patentees to seek paediatric extensions. The CJEU confirmed that the duration of the resulting SPC will be **negative** in those cases and should not be rounded up to zero. Thus, the total paediatric extension period will be less than six months in duration (rather than the entire six-month period).

Applications for paediatric extensions

Like SPCs themselves, applications for a paediatric extension must be lodged with the competent intellectual property office of the member state concerned.

Under **Article 7(3) and (4)**, applications for a paediatric extension *may* be made:

(a) when the application for an SPC is lodged at the relevant national intellectual property office (provided the requirements of Article 8(1)(d) are satisfied); or

(b) when the SPC application is pending (provided the requirements of Article 8(2) are satisfied).

However, applications for a paediatric extension *must* now be made not later than two years before the SPC expires.

Article 13 Medicinal SPC Regulation
3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

Article 36(1) and (4) of Regulation (EC) No 1901/2006 of 12 December 2006 on products for paediatric use
1. Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or SPC shall be entitled to a six-month extension of the period referred to in Article 13(1) and (2) of the SPC Regulation.

The first sub-paragraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

4. Paragraphs 1, 2 and 3 shall apply to products that are protected by an SPC under the SPC Regulation, or under a patent which qualifies for the granting of the SPC.

Article 9 Medicinal SPC Regulation
1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent...

Article 7 Medicinal SPC Regulation
3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled.

4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.

5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.

Plant SPC Regulation

The main principles and objectives of the Plant SPC Regulation are the same as those underlying the Medicinal SPC Regulation, namely to confer a level of protection for innovation which is equivalent to the Medicinal SPC Regulation by ensuring that patentees are adequately compensated for the period that elapses between the filing of a patent application for a new plant protection product and the grant of an authorisation to place that product on the market.

Much of the background information and case law explained above in the context of medicinal products therefore applies equally to the Plant SPC Regulation. However, certain key differences between the two regimes are described below.

Active substances

Article 1 Plant SPC Regulation includes a detailed definition of "plant protection products" and "products" which refers to preparations containing one or more active substances. Unlike the Medicinal SPC Regulation, the term "active substances" is defined to some extent under **Article 1(3)**.

The CJEU recently considered the meaning of active substances as applied to safeners in C-11/13 Bayer CropScience (***Bayer***). According to the referring court, safeners have at the most an *"indirect effect"* on plants or harmful organisms but are *"sometimes essential for the use of an active substance"*. Consistent with its earlier judgments in *MIT* (concerning excipients) and *GSK* (concerning adjuvants), the CJEU held that the term "active substance" may cover a substance intended to be used as a safener, where that substance has a *"toxic, phytotoxic or plant protection action of its own"*. If so (which is a matter for the referring court), it falls within the definition of a product under Article 1(8) and may result in the grant of an SPC, provided the necessary conditions in Article 3 are satisfied.

See e.g. recitals (4) to (7) Plant SPC Regulation

(4) Whereas the competitiveness of the plant protection sector, by the very nature of the industry, requires a level of protection for innovation which is equivalent to that granted to medicinal products by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (4);

(5) Whereas, at the moment, the period that elapses between the filing of an application for a patent for a new plant protection product and authorisation to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research;

(6) Whereas this situation leads to a lack of protection which penalizes plant protection research and the competitiveness of the sector,

(7) Whereas one of the main objectives of the supplementary protection certificate is to place European industry on the same competitive footing as its North American and Japanese counterparts;

Article 3(2) Plant SPC Regulation
2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

Articles 2 and 3 – Scope and conditions for obtaining a certificate

These provisions are very similar to those for the Medicinal SPC Regulation, except that both **Articles 2 and 3(1)(b)** refer not only to the corresponding regulatory Directive for plant protection products, but specifically to **Article 4** of Directive 91/414/EEC or an **equivalent provision of national law**.

In C-229/09 *Hogan Lovells International v Bayer CropScience* (***Hogan Lovells***), the CJEU was asked to consider whether a provisional marketing authorisation granted for a plant protection product under national

Article 1(3) Plant SPC Regulation
For the purposes of this Regulation, the following definitions shall apply:
...
3. 'active substances': substances or micro-organisms including viruses, having general or specific action:
(a) against harmful organisms; or
(b) on plants, parts of plants or plant products;

legislation intended to transpose Article 8(1) Directive 91/414/EEC (rather than Article 4 Directive 91/414/EEC) was capable of satisfying Article 3(1)(b). The CJEU recognised that applications for provisional MAs submitted under Article 8(1) Directive 91/414/EEC must be examined in accordance with the scientific criteria applicable to definitive MAs under Article 4 Directive 91/414/EEC. The CJEU decided that this "link of functional equivalence" between the criteria meant that Article 3(1)(b) did not preclude the grant of an SPC based on a provisional MA. The CJEU also found support for its conclusion in the overall objectives of the Regulation and the specific wording of Article 13, which expressly refers to the assessment of duration of an SPC taking account of a provisional first MA in appropriate circumstances (see below).

However, the CJEU subsequently ruled in C-210/12 *Sumitomo Chemical v Deutsches Patent- und Markenamt* (***Sumitomo***) that Article 3(1)(b) is not satisfied by the grant of an "emergency" marketing authorisation under Article 8(4) Directive 91/414/EEC. In particular, it distinguished *Hogan Lovells* on the basis that emergency authorisations under Article 8(4) Directive 91/414/EEC lack the same *"link of functional equivalence"* with the scientific requirements as to reliability that are found in Article 4 Directive 91/414/EEC. Further, such emergency marketing authorisations are expressly described in Directive 91/414/EEC as not complying with Article 4.

Article 2 Plant SPC Regulation
Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure as laid down in Article 4 of Directive 91/414/EEC (6), *or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorisation was lodged before Directive 91/414/EEC was implemented by the Member State concerned*, may ... be the subject of a certificate.

Article 3(1)(b) Plant SPC Regulation
A valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC *or an equivalent provision of national law.*

Articles 2 and 3(b) Plant SPC Regulation are not referred to in the list of provisions said to apply equally when interpreting the Medicinal SPC Regulation (see Recital (17) Plant SPC Regulation).

Article 4 Directive 91/414/EEC sets out the requirements for a definitive marketing authorisation.

Article 8(1) Directive 91/414/EEC sets out the requirements for a provisional marketing authorisation, as considered by the CJEU in *Hogan Lovells*.

Article 8(4) Directive 91/414/EEC sets out the requirements for an emergency marketing authorisation, as considered by the CJEU in *Sumitomo*.

Article 13 – Duration of the certificate

The general principles set out above concerning the assessment of duration of an SPC apply equally to plant protection products. However, an additional sub-paragraph is included in Article 13 Plant SPC Regulation which states:

> *"13(3). For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorisation only if it is directly followed by a definitive authorisation concerning the same product."*

This sub-paragraph 13(3) was cited by the CJEU in *Hogan Lovells* when assessing the grant of SPCs based on provisional marketing authorisations (see above), although the significance of the words *"only if it is **directly followed** by a definitive authorisation"* is yet to be considered in detail by the CJEU.