

SUPPLEMENTARY PROTECTION CERTIFICATES

FOR MEDICINAL AND PLANT PROTECTION PRODUCTS

INTRODUCTION

Note

This section relates to Supplementary Protection Certificates for Medicinal and Plant Protection Products and is divided into three parts, with the paragraphs numbered using the prefixes below:

SP: the general introduction below;

SPM: a discussion of the details of the Medicinal Regulation by Article, including those aspects common to both the Medicinal and Plant Protection Regulations;

SPP: a discussion of the details specific to the Plant Protection Regulation by Article.

In the margins:

"ArtM" refers to the relevant Article of Regulation (EC) No 469/2009 of the European Parliament and of the Council (for Medicinal Products) ("the Medicinal Regulation" or "the EC Medicinal Regulation").

"ArtP" refers to the relevant Article of Regulation (EC) No 1610/96 of the European Parliament and of the Council (for Plant Protection Products) ("the Plant Protection Regulation" or "the EC Plant Protection Regulation").

"ArtPd" refers to the relevant Article of Regulation (EC) No 1901/2006 of the European Parliament and of the Council (on medicinal products for paediatric use) ("the Paediatric Regulation" or "the EC Paediatric Regulation").

"PA 1977" refers to the Patents Act 1977, "s" refers to the relevant section of the Act, "para" and "sch" refer to the relevant paragraphs of the relevant Schedules to the Act.

"reg" refers to the relevant regulation of the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007 (SI 2007/3293) (the "2007 Regulations").

"r" refers to the relevant rule of the Patents Rules 2007 (SI 2007/3291) (the "2007 Rules") and "part" refers to the relevant part of those Rules.

"Fr" refers to the relevant rule of the Patents (Fees) Rules 2007 (SI 2007/3292) (the "2007 Fees Rules") and "FSch" refers to the relevant Schedule of those Rules.

SP0.01 Council Regulation (EEC) No 1768/92 creating a Supplementary Protection Certificate for medicinal products was published in the Official Journal of the European Communities on 2 July 1992, with consequential entry into force on 2 January 1993. This Regulation has subsequently been codified under Regulation (EC) No 469/2009 of the European Parliament and of the Council, which was published in the Official Journal of the European Union L152 on 16 June 2009 and entered into force on 6 July 2009.

ArtM 22

Various amendments that had been made to Regulation (EEC) No 1768/92 were consolidated but no substantive changes were made. Regulation (EC) No 469/2009 repealed Regulation (EEC) No 1768/92 and provides for references to it to be construed as references to Regulation (EC) No 469/2009. Regulation (EC) No 1610/96 of the European Parliament and of the Council creating a Supplementary Protection Certificate for plant protection products was published in the Official Journal of the European Communities on 8 August 1996 and entered into force on 8 February 1997. As set out in the recitals to both Regulations, the certificate is intended to compensate a patentee for the loss of effective protection arising out of the time taken to obtain regulatory approval to place on the market as either a medicinal or plant protection product a product which is protected by a patent ("the basic patent").

SP0.02 The basic patent may protect the product as such, a process to obtain the product or an application of the product (see SPM1.05).

SP0.03 A certificate takes effect at the end of the lawful term of the basic patent but does not extend the term of the patent itself. It extends the protection conferred by the patent in respect of the product covered by the authorization to place the corresponding medicinal or plant protection product on the market, and any use of the product as a medicinal or plant protection product that has been authorized before expiry of the certificate.

SP0.04 In the UK, the marketing authorization for medicinal products takes the form of a Product Licence or Marketing Authorization granted by the appropriate authority (see SPM2.01). Details of granted Licences, including the product, are no longer published in the London, Edinburgh and Belfast Gazettes but are now advertised on the Medicines and Healthcare products Regulatory Agency (MHRA) website (see SPM1.02). Marketing authorization for plant protection products may be an Approval or Authorization granted by the relevant authority (see SPP2.01) and details are published in the Pesticides Register (monthly).

reg 1

SP0.05 A certificate only has effect in the EU State in which it is granted. Certificates granted by the Office have effect in Great Britain and Northern Ireland pursuant to the 2007 Regulations. At present the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 (SI 1992/3091) ("the 1992 Medicinal Regulation") has effect in the Isle of Man pursuant to the Isle of Man Patents (Medicinal Products) Regulations 1993 (Statutory Document 447/93). Similarly the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996 (SI 1996/3120) (the "1996 Plant Protection Regulations") has effect pursuant to the Isle of Man Patents (Plant Protection Products) Regulations 1999 (Statutory Document 746/99). See also paragraph 128B.03.

reg 2

SP0.06 The 2007 Regulations amended the Patents Act 1977 to introduce s.128B and Schedule 4A. These make clear how the Act applies in relation to supplementary protection certificates for medicinal and plant protection products. The operation of these provisions is discussed in paragraphs 128B0.1 to 128B.12. The 2007 Rules and 2007 Fees Rules provide specific procedures for certificates and applications for certificates which differ from patents and applications for patents, including the payment and amount of fees.

ArtM 19,
ArtP 18

SP0.07 Where neither the Medicinal or Plant Protection Regulations nor the 2007 Rules lays down a special procedure for certificates, the provisions of the Patents Act 1977 and respective Rules apply to certificates and applications for certificates as they do to patents and applications for patents.

SP0.08 Regulation (EEC) No 1768/92 entered into force with effect from 1 July 1994 in those EFTA States which were at that date party to the European Economic Area Agreement (Austria, Finland, Iceland, Norway and Sweden). This necessitated amendment of the Regulation for the purposes of the application of the Regulation to those States, but the amendments do not have retrospective effect on applications for

certificates lodged in an existing EU Member State before 1 July 1994. This position was not affected by the accession to the EU of Austria, Finland and Sweden with effect from 1 January 1995. Liechtenstein became a party to the European Economic Area Agreement with effect from 1 May 1995, but did not adopt the Regulation (EEC) No 1768/92 and has not adopted the EC Medicinal Regulation (see SP0.10).

SP0.08.1 The accession to the EU of the ten States (the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic) on 1 May 2004 also necessitated the amendment of Regulation (EEC) No 1768/92 and the Plant Protection Regulation for the purposes of their application to those States (see SPM13.04.2). The accession of Bulgaria and Romania on 1 January 2007 further amended Regulation (EEC) No 1768/92 and the Plant Protection Regulation for the purposes of applying it to these States.

SP0.09 Paragraph 8 of Protocol 1 on Horizontal Adaptations to the European Economic Area Agreement reads:

"Whenever the acts referred to contain references to the territory of the "Community" or of the "common market" the references shall for the purposes of the Agreement be understood to be references to the territories of the Contracting Parties as defined in Article 126 of the Agreement."

This has the effect that for medicinal product applications lodged under Regulation (EEC) No 1768/92 on or after 1 July 1994, or under the EC Medicinal Regulation, references to the Community in Articles 8(1)(a)(iv), 8(1)(c), 9(2)(e), 11(1)(e) and 13(1) of the Regulation are understood to be references to the Contracting Parties to the Agreement (see SP0.08, SPM8.02, SPM9.02, SPM11.01 and SPM13.04). Accordingly, for such applications lodged on or after 1 July 1994 but before 1 May 1995 a first authorization to place the product on the market in the Community included a first authorization in Austria, Finland, Iceland, Norway or Sweden. For applications lodged on or after 1 May 1995, it also included a first authorization in Liechtenstein, even though Liechtenstein has not adopted Regulation (EEC) 1768/92 or the EC Medicinal Regulation. In practice this will be an authorization in Switzerland, since Swiss authorizations are effective in Liechtenstein and Liechtenstein has not always granted marketing authorizations. However, from 1 June 2005 the bilateral agreement between Switzerland and Liechtenstein was amended so that Liechtenstein now maintains a list of medicinal products whose Swiss authorizations are not automatically recognised. Normally this recognition will be 12 months after the Swiss authorization.

SP0.10 Similarly, following Decision No 59/97 of the EEA Joint Committee of 31 July 1997 to adopt the Plant Protection Regulation from 1 August 1997, it entered into force in Liechtenstein on 1 August 1997 and in Iceland and Norway on 2 January 1998, these being the EFTA States which were then party to the European Economic Area Agreement. It follows from paragraph 8 of Protocol 1 on Horizontal Adaptations to the Agreement that, for applications for certificates for plant protection products lodged with the Office under Regulation 1610/96 on or after 1 August 1997, the first authorization within the territories of the existing EU Member States and Iceland, Norway and Liechtenstein constitutes the first authorization in the Community for the purposes of Articles 8(1)(a)(iv), 8(1)(c), 9(2)(e), 11(1)(e) and 13(1) of Regulation 1610/96 (see SP0.08 and SP0.09). As with the Medicinal Regulation, in practice a first authorization in Liechtenstein will be a first authorization in Switzerland (see SP0.09).

SP0.11 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use was published in the Official Journal on 27 December 2006 and entered into force on 26 January 2007. This amended the Regulation (EEC) 1768/92 to provide for a six month extension of a SPC when a requirement was introduced that at the time of marketing authorization application, data on the use of the medicine in children was included. The amendments relating to medicinal products for paediatric use are incorporated in the EC Medicinal

Regulation. Note that Article 7 of Regulation (EC) No 1901/2006 does not apply until 26 July 2008 and Article 8 does not apply until 26 January 2009.

REGULATION (EC) NO 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (MEDICINAL PRODUCTS)

RECITALS TO THE REGULATION

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (OJ C 77, 31.3.2009, p 42),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (Opinion of the European Parliament of 21 October 2008 (not yet published in the Official Journal) and Council Decision of 6 April 2009),

Whereas

(1) Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, p. 1) has been substantially amended several times. In the interests of clarity and rationality the said Regulation should be codified.

(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.

(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(5) This situation leads to a lack of protection which penalizes pharmaceutical research.

(6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.

(7) A uniform solution at Community level should be provided for, 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 and thus directly affect the establishment and the functioning of the internal market.

(8) Therefore, the provision of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which

marketing authorization has been granted is necessary. A Regulation is therefore the most appropriate legal instrument.

(9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market in the Community.

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product.

(11) Provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law,

HAVE ADOPTED THIS REGULATION

SPM0.01 As is stated in Halsbury's Laws of England (4th Edition, vol 51, pages 346-348), reference may be made to the recitals in the preamble of a measure in order to confirm the interpretations to be given to a provision of EU law. This may be necessary in order to arrive at the clear, as opposed to the literal meaning of a provision: literal analysis of a text is not always appropriate when regard is had to the nature and scheme of a measure, or the circumstances in which a provision was adopted. In *Research Corp's SPC* ([1994] RPC 667), the Patents Court, upholding a decision of the hearing officer ([1994] RPC 387), found that Article 5 of the Regulation was clear in the context of Community law as a whole: neither the recitals nor an explanatory memorandum issued by the Commission in 1990 contained anything to suggest that the phrase "same limitations" should exclude endorsement licences of right of a "new existing patent" under the Patents Act 1977. (see also SPM5.01.) The court found the matter *acte claire* and declined to refer the construction of Article 5 to the European Court of Justice. Similarly, in *Draco AB's SPC Application* [1996] RPC 417 the Patents Court declined to refer the decision of the hearing officer (see SPM1.04) to the European Court. However, in *Re Yamanouchi Pharmaceuticals Co. Ltd* (unreported judgment of 31 October 1994) the Patents Court decided to refer the construction of the transitional provisions of Article 19 of Regulation (EEC) No 1768/92 to the European Court (see SPM19.02 and *Yamanouchi Pharmaceuticals Co. Ltd v Comptroller-General* [1997] RPC 844). The Patents Court has also referred *Novartis AG and University College London & Novartis AG and Institute of Microbiology and Epidemiology SPC Applications* (BL O/044/03) and [2005] RPC 33 (see SPM8.02 and SPM13.04) and *Yissum Research and Development Company of the Hebrew University of Jerusalem* (BL O/222/04) (see SPM1.02, SPM1.04 and, SPM3.05) to the European Court.

SPM0.02 In *Draco AB's SPC Application* the Patents Court, also refusing leave to appeal, held that if the court considered the matter to be *acte claire*, then leave to appeal to the Court of Appeal should logically be refused. The court also observed obiter that where a point turned on material leading to the enactment of a European instrument (the travaux preparatoires), it was unlikely to be *acte claire*.

SPM0.03 The Patents Court in *Draco AB's SPC Application*, considering the recitals to Regulation (EEC) No 1768/92, held that the scheme of the Regulation was not for the general protection of the fruits of research. It was to compensate for lost time in the exploitation of inventions which were patented.

SPM0.04 Recital 10 of the EC Medicinal Regulation (i.e. "Whereas all the interests at stake...") is, following the entry into force of the Plant Protection Regulation

on 8 February 1997, to be interpreted as directed in recital (17) of the latter regulation which states:

(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.

In accordance with Article 22 of the EC Medicinal Regulation, reference to recital 9 of Regulation (EEC) No 1768/92 is to be read as reference to recital 10 of the EC Medicinal Regulation. Recitals 12, 13 and 14 of the Plant Protection Regulation are as follows:

(12) Whereas all the interests at stake in a sector as complex and sensitive as plant protection must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years;

(13) Whereas the certificate confers the same rights as those conferred on the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection;

(14) Whereas the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them;

This amplification of recital 10 is consistent with the approach that had already been adopted by the UK Office with regard to the inclusion of salts and esters in the definition of the product (see SPM1.03, SPM2.03, SPM2.04 and SPP1.03-04).

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 medicinal 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;

(c) '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;

(d) 'certificate' means the supplementary protection certificate.

(e) 'application for an extension of the duration' means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and of Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use.

Product and Medicinal Product

SPM1.01 Article 1 distinguishes between the terms "medicinal product" and "product". Although the Medicinal Regulation creates a certificate for medicinal products, it is the product - defined by Article 1(b) as the active ingredient or combination of active ingredients - which is the subject of the certificate pursuant to Article 2.

SPM1.02 These definitions do not always correspond to the terminology used in UK Product Licences and Marketing Authorizations, or the details published in the official Gazettes (see SP0.04). Thus, the product specified in a Product Licence or Marketing Authorization is generally broadly equivalent to the "medicinal product" as defined by Article 1(a), and the "active constituent(s)" or "active ingredient(s)" are generally broadly equivalent to the "product" as defined by Article 1(b). However, as the hearing officer determined in *Yissum Research & Development Company of the Hebrew University of Jerusalem* BL O/222/04 such definitions need not restrict the definition of active ingredient in accordance with Article 1(b) (see SPM1.04.1).

SPM1.03 In view of the imposition of the terms of recital (14) of the Plant Protection Regulation through recital (17) therein in the interpretation of recital 10 of the EC Medicinal Regulation, the term "active ingredient" in Article 1(b) is generally interpreted as including any closely related derivative, in particular a salt or ester, which has obtained an authorization to be placed on the market and is protected by the basic patent, unless the derivative in question can be regarded as a new active ingredient. (See also SPM0.04 and SPM2.03 - 04.)

SPM1.04 In the case of *Draco AB's SPC Application* [1996] RPC 417, the applicants applied for a certificate based on a product licence for an unpressurised asthma inhaler containing the corticosteroid budesonide in the form of agglomerated micronised particles. However, two earlier product licences had been granted for inhalers containing budesonide in the form of micronised particles together with a propellant and surfactant as "other constituents". The hearing officer found that the "product" as defined in Article 1(b) was "budesonide" in the case of all three inhalers and thus rejected the applicant's submission that it was "additive free budesonide in the form of agglomerated micronised particles" in the case of the later inhaler and a combination of "budesonide, a propellant and a surfactant" in the two earlier inhalers. The applicant's alternative submission that the agglomerated form of budesonide was a different "product" from the non-agglomerated form used in the earlier inhalers was similarly rejected. The Patents Court upheld the decision, holding that the scope of protection was strictly confined to the active ingredient in view of the definitions in Articles 1(a) and 1(b) (See also SPM4.02). The applicants obtained leave to appeal to the Court of Appeal but withdrew their appeal before being heard.

SPM1.04.1 In *Yissum Research & Development Company of the Hebrew University of Jerusalem* (BL O/222/04) the hearing officer considered that the definition of active ingredients found in a marketing authorization should not necessarily be used to restrict the definition of product in accordance with Article 1(b). The product "calcitriol" had been the subject of previous marketing authorizations and for the purposes of Article 3(d) it was not possible to distinguish these marketing authorizations on the basis of a different medical application. However, the hearing officer found that the active ingredients which define the product are those protected by the basic patent when strictly confined to the corresponding ingredients of the authorized medicinal product. Thus it was possible for a certificate to be granted for calcitriol in combination with the specific ointment base found in the approved medicinal product. On appeal the Patents Court [2004] EWHC 2880 referred this issue to the European Court of Justice (ECJ case C-202/05) which found that Article 1(b) is interpreted as meaning that where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product (see SPM0.01, SPM1.02 and SPM3.05). Questions of a similar nature regarding the interpretation of the term

“combination of active ingredients of a medicinal product” were submitted by the German Federal Court to the ECJ in Massachusetts Institute of Technology (ECJ case C-431/04). The Court ruled that the interpretation of Article 1(b) does not include within the concept of this term a combination of two substances wherein only one substance has a therapeutic effect and the other substance enables a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance.

Basic Patent

SPM1.05 The basic patent may be either a UK patent or a European patent (UK), and may protect the product as such, a process to obtain the product or an application of the product. However, a process for obtaining a known product may not give rise to a new product. The term "basic" does not mean that the patent must be the first patent to protect the product: it is open to a patent holder to designate any patent fulfilling the criteria of Article 1(c) as the basic patent.

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 authorization 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 (OJ L 311, 28.11.2001, p. 67) 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 (OJ L 311, 28.11.2001, p. 1) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

ArtM 1(b)

SPM2.01 A certificate can thus be granted in the UK for a product which has received an authorization to be placed on the market in the UK in accordance with Directive 2001/83/EC (for pharmaceutical products) or Directive 2001/82/EC (for veterinary products). The authorization may be granted for the UK only, whereupon it takes the form of a Product Licence issued under the Medicines Acts, or a Marketing Authorization issued under the Medicines for Human Use (Marketing Authorization etc) Regulations 1994 (SI 1994/3144) or the Marketing Authorizations for Veterinary Medicinal Products Regulations 1994 (SI 1994/3142). UK (only) Product Licences and Marketing Authorizations are granted either by the Medicines and Healthcare Products Regulatory Agency of the Department of Health for a pharmaceutical product, or by the Veterinary Medicines Directorate of the Department for Environment, Food and Rural Affairs for a veterinary product. Alternatively there is a centralised system for granting marketing authorizations for medicinal products for human and veterinary use, established under Council Regulation (EEC) No 2309/93, now repealed and replaced with Regulation (EC) No 726/2004, which provides authorizations which are simultaneously granted in all Member States of the European Union. This type of authorization is issued by the European Agency for the Evaluation of Medicinal Products (EMA) and is accepted by the Office as equivalent to a national authorization.

SPM2.02 A certificate is granted for a product which constitutes the active ingredient or combination of active ingredients of a medicinal product (see SPM1.01).

SPM2.03 A certificate can only cover a single product, i.e. a single active ingredient or combination of active ingredients. Different products will need to be the subject of different certificates, even if they are protected by the same basic patent. Whether a new certificate is required for a derivative (eg a salt or ester) of a product which has already been granted a certificate depends on whether or not the derivative can be regarded as a new active ingredient (see SPM0.04 and SPM1.03). A new certificate may also be granted for a combination of (a) an active ingredient for which a certificate has already been granted with (b) one or more other active ingredients. However, a further certificate will not be granted for the same active ingredient

notwithstanding any changes to the physical form of that ingredient or to other features of the medicinal product (eg use of a different excipient or different pharmaceutical presentation). (See also SPM1.04.)

ArtM 3(a)
(ArtP 3(1)(a))

SPM2.04 A certificate may be granted for a compound optionally in derivative form to the extent that derivatives are protected by the basic patent (see SPM0.04) . Examples of wording which have been accepted are:

X optionally in the form of the hydrochloride;

X optionally in the form of a pharmaceutically acceptable salt such as the hydrochloride;

X optionally in the form of a pharmaceutically acceptable salt.

(see also SPM3.02 and SPM3.02.1).

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

SPM3.01 The conditions of Article 3 must be satisfied at the date of making an application. Thus, at that date:

the basic patent protecting the product must be in force in the UK;

the product must not previously have been the subject of a certificate in the UK;

a valid authorization to place the product on the market in the United Kingdom as a medicinal product must have been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC (see SPM2.01);

this authorization must be the first authorization to place the product on the market as a medicinal product in the United Kingdom (although there may have been an earlier authorization elsewhere in the EU).

SPM3.02 The question of whether the product is protected by the basic patent is determined in accordance with the usual canons of construction of patent claims, as was confirmed by the European Court of Justice in *Farmitalia Carlo Erba S.r.l.'s SPC Application (2)* ([2000] RPC 580 - ECJ Case C-392/97). In *Takeda Chemical Industry's Application* (unreported oral decision on application No SPC/GB93/017), the hearing officer held that a product comprising the acetate salt of a peptide was protected by a basic patent, even though the claims did not on a literal construction include derivatives of the polypeptide, on the grounds that the description made it clear that the polypeptide could be obtained in the form of the acetate. In *Centocor Inc's SPC Application* [1996] RPC 118, the hearing officer held that a product consisting of a monoclonal antibody

was not protected by claims to a combined preparation of a monoclonal antibody and an anti-microbial agent. In *Takeda Chemical Industries Ltd's Applications* [2004] RPC 1 (upheld on appeal to the Patents Court [2004] RPC 3) the hearing officer held that products comprising a combination of ingredients were not protected by patents which related to only one of the ingredients. The basic patents contained no reference to the combinations specified in the SPC applications. The Court of Appeal in *Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd* [2009] EWCA Civ 646, [2009] RPC 23 upheld the earlier decision of the Patents Court ([2008] EWHC 2413 (Pat), [2009] RPC 4) confirming this interpretation. The Court found the SPC for levofloxacin, the (-) enantiomer of the racemic mixture, ofloxacin, to have been properly granted despite the existence of earlier marketing authorisations to this racemic mixture. In *Gilead Sciences, Inc.* (BL O/006/08) the hearing officer held that a basic patent which protected a specific active compound and which claimed a combination of the active substance optionally in combination with other (unspecified) therapeutic ingredients did not protect the combination of the active compound with another specific active compound which was the subject of the SPC application. The claim and a corresponding reference in the description were the only indication of a combination of active ingredients in the basic patent. On appeal the Patents Court held (in *Re Council Regulation (EEC) No 1768/92* [2008] EWHC 1902 (Pat)) that although the specific combination was not disclosed in the specification of the basic patent such a claim did protect the combination within the meaning of Articles 1(c) and 3(a) and therefore that the applicant was entitled to a certificate to the combination of specific active ingredients. In *Astellas Pharma Inc.* (BL O/052/09) the hearing officer similarly found that a patent which disclosed one active ingredient but did not disclose, either specifically or generically, a combination of active ingredients was not a basic patent which protected a combination of active ingredients for the purposes of Article 3(a). On appeal to the Patents Court (*Astellas Pharma Inc v Comptroller-General of Patents* [2009] EWHC 1916 (Pat)), Arnold J upheld the decision of the hearing officer after applying the test articulated in *Gilead*. Arnold J distinguished the facts of *Astellas* from *Gilead* because, unlike in *Gilead*, the basic patent did not specifically disclose and claim a combination of active ingredients. In *Sankyo Company Limited* (BL O/271/10) the hearing officer similarly rejected an SPC application for a combination of active ingredients on the basis that it did not meet the requirements of Article 3(a) of the regulation. On appeal to the Patents Court (*Daiichi Sankyo Company Limited v Comptroller General of Patents*, [2010] EWHC 2897 (Pat)), Floyd J referred questions to the Court of Justice of the European Union (CJEU) for a preliminary ruling concerning the correct test to apply when deciding whether a product is protected by a basic patent under Article 3(a) of the SPC regulation (C-6/11, *Daiichi Sankyo Company v Comptroller-General of Patents*; also see referrals to the CJEU in *Medeva, Georgetown et al., University of Queensland, CSL Ltd* (all SPM3.02.3), and *Yeda Research and Development Company Ltd* (SPM3.02.1)). Following *Takeda* where a combination is not claimed but is disclosed in the description, it may be possible to amend the granted patent under s.27 of the Patents Act 1977 to provide the protection required under Article 3(a).

SPM3.02.1 In *Imclone Systems Inc. Ltd & Aventis Holdings Inc.* (BL O/066/10), the hearing officer found that a marketing authorization for a single active ingredient which additionally specified the clinical use of that active in conjunction with another active ingredient was not, for the purposes of Article 3(b) of the Regulation, a valid authorisation to place a combination product on the market as a medicinal product. The MA referred to how the active ingredient, an antibody known as cetuximab (medicinal product name Erbitux®), which had cytostatic properties, could be used clinically in conjunction with another active ingredient, an anti-cancer drug irinotecan, with cytotoxic properties, to treat certain types of cancer and that the presence of the cetuximab reduced the amount of irinotecan required to achieve a clinical effect. However, the hearing officer found that the MA has to be considered in its entirety and not just in respect of the clinical particulars when deciding what is the authorised medicinal product, and hence what is the product that can be protected by an SPC. Furthermore, in following the approaches taken in *Takeda, Gilead, Astellas* and *Centocor Inc.*, the hearing officer found that a patent protecting a combination of active ingredients did not

protect a single active ingredient for the purposes of Article 3(a). On appeal to the Patents Court (*Yeda Research and Development Company Ltd v Comptroller General of Patents* [2010] EWHC 1733 (Pat), [2010] RPC 29), Lewison J upheld the decision of the hearing officer to refuse the applications and dismissed the appeal, confirming the approaches taken in previous decisions. On appeal to the Court of Appeal (*Yeda Research and Development Company Ltd v Comptroller General of Patents*) the Court referred a question for a preliminary ruling to the Court of Justice of the European Union (CJEU) concerning whether or not secondary infringement should be part of any proposed infringement test for determining what is protected by the basic patent under Article 3(a) (C-518/10, *Yeda Research and Development Company Ltd, Aventis Holdings Inc v Comptroller-General of Patents*; see also the referrals to the CJEU in relation to *Daiichi Sankyo Company Limited* (SPM3.02), *Medeva, Georgetown et al.*, and *University of Queensland, CSL Ltd* (all SPM3.02.3)).

SPM3.02.2 In *Farmitalia Carlo Erba S.r.l.'s SPC Application* (2) the Court also ruled that where an active ingredient in the form of an individual salt is referred to in the notice of authorization, under Article 3(b) the certificate is capable of covering the active ingredient both as referred to and in its derived forms such as salts and esters as medicinal products, provided that the derived forms also enjoy the protection of the basic patent.

SPM3.02.3 The requirements of Articles 3(a) and 3(b) of the Regulation have also been considered in a number of cases relating to medicinal products in the vaccine field. In *Medeva BV's SPC Applications* (BL O/357/09) the hearing officer, in following the *Astellas* and *Gilead* decisions, found that a basic patent protecting only two particular active ingredients did not protect, for the purposes of Article 3(a), a product containing these two active ingredients in combination with other active ingredients. He also found that a marketing authorisation for a medicinal product comprising a combination of active ingredients which included, among others, the two active ingredients was not, for the purposes of Article 3(b), a valid authorisation to place a product consisting of these two active ingredients on the market as a medicinal product. On appeal to the Patents Court (*Medeva BV v The Comptroller General of Patents*, [2010] EWHC 68 (Pat), [2010] RPC 20), Kitchin J upheld the decision of the hearing officer and dismissed the appeal, noting that "...It is plain that "product" must have the same meaning in Article 1(b) and Article 3(a). If the product of Article 1(b) is the whole combination of active ingredients then so it remains for the purposes of Article 3(a)...". On appeal to the Court of Appeal (*Medeva's SPC Applications*, [2010] EWCA Civ 700), the Court referred questions concerning the interpretation of Articles 3(a) and 3(b) to the Court of Justice of the European Union for a preliminary ruling (C-322/10, *Medeva v Comptroller-General of Patents*). In *Georgetown University, Loyola University of Chicago, and University of Rochester's SPC applications* (BL O/401/09) the hearing officer rejected SPC applications for single active ingredients in the vaccine field on the grounds that they did not satisfy the requirements of Article 3(b) of the Regulation as the marketing authorisations provided in support of these applications related to products with multiple active ingredients. On appeal to the Patents Court, Kitchin J referred a question concerning the interpretation of Article 3(b) to the Court of Justice of the European Union (*Georgetown University, University of Rochester, Loyola University of Chicago v Comptroller-General of Patents*, C-422/10; the question was the same as that referred in *Medeva* in respect of Article 3(b)). The hearing officer followed similar approaches in relation to Articles 3(a) and 3(b) in rejecting multiple SPC applications in the vaccine field for either combinations of active ingredients or single active ingredients in *University of Queensland & CSL Limited* (BL O/335/10). On appeal to the Patents Court, Arnold J referred further questions to the Court of Justice of the European Union concerning the interpretation of Article 3(a) and 3(b) (C-630/10, *University of Queensland, CSL Ltd v Comptroller-General of Patents, Designs and Trade Marks*).

SPM3.03 Although Article 3(b) requires a valid authorization to have been granted, there appears to be no requirement that the authorization should still be in force at the date of making the application for a certificate (e.g. it may be withdrawn or

have lapsed before the date of the application for the certificate).

SPM3.03.1 In *British Technology Group Ltd's SPC Application* [1997] RPC 118 the hearing officer found that a letter from the Medicines Control Agency granting permission for a product to be supplied for a proposed clinical trial was not an acceptable market authorization in that it was not issued in accordance with Directive 65/65/EEC or Directive 81/851/EEC nor did it provide a summary of product characteristics as required by Article 8(1)(b) (see SPM2.01, SPM10.17.1 and SPP3.02). Directives 65/65/EEC and 81/851/EEC were the Directives in accordance with which the authorization had to have been granted under Article 3(b) of Regulation (EEC) 1768/92. They were repealed and consolidated with Directive 75/319/EEC into 2001/83/EC and 2001/82/EC respectively.

SPM3.04 Article 3(c) precludes the grant of a second certificate for a product where the first certificate has been granted before the date of application for the second certificate. However, in *Chiron Corporation and Novo Nordisk A/S* [2005] RPC 24 the hearing officer concluded that the grant of a supplementary protection certificate for a product to one holder of a basic patent before an application is lodged in relation to the same product by a different holder of a different basic patent on the basis of a common marketing authorization does not provide a ground for rejecting the later application under Article 3(c) of the Regulation. The European Court of Justice in *AHP Manufacturing BV v Bureau voor de Industriële Eigendom* [2009] C-482/07 held that Article 3(c) of the Regulation does not prevent the grant of a certificate to the holder of a basic patent for a product if, at the time of the submission of the application for a certificate, one or more SPCs have already been granted to one or more holders of one or more other basic patents. Thus it may be possible in specific circumstances for a further certificate to be granted when a certificate already exists. In *Takeda Chemical Industries Ltd's Applications* [2004] RPC 2, the hearing officer held that products comprising a combination of ingredients were not precluded from grant of an SPC because one of the ingredients had already been granted an SPC.

SPM3.04.1 Recital (17) of the Plant Protection Regulation (see SPM0.04) must also be considered in respect of Article 3(c) as, from 8 February 1997 when said regulation came into force, Article 3 of the Medicinal Regulation is to be interpreted in accordance with Article 3(2) of the new regulation which states:

ARTICLE 3(2) [EC Plant Protection Regulation]

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.

SPM3.04.2 Consequently, the grant of one certificate to each patent holder in respect of the same product on two or more applications each specifying a different basic patent protecting the product is now allowed. The hearing officer in *Takeda Chemical Industries Ltd's Applications* [2004] RPC 2 found that only one certificate for a product should be granted to the same applicant, having also considered the European Court of Justice decision in *Biogen Inc. v Smithkline Beecham Biologicals SA* ([1997] RPC 23 ECJ Case C-181-95).

SPM3.05 In *Yissum Research & Development Company of the Hebrew University of Jerusalem* (BL O/222/04) the hearing officer found that the condition specified in Article 3(d) will not be met if an authorization to place the product on the market is not the first for the product, regardless of whether the earlier authorization was for a different medical condition. The product "calcitriol" had been the subject of previous marketing authorizations and for the purpose of Article 3(d) these earlier authorizations could not be distinguished on the basis of their different therapeutic applications. This decision was appealed to the Patents Court [2004] EWHC 2880

which referred the matter to the European Court of Justice for a preliminary ruling (case C-202/05) (see SPM0.01, SPM1.02, SPM1.04.1). The ECJ found that when a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product. Questions of a similar nature regarding the interpretation of the term “combination of active ingredients of a medicinal product” were answered by the ECJ in Massachusetts Institute of Technology (case C-431/04) (see SPM 1.04.1).

SPM3.05.1 In *Neurim Pharmaceuticals (1991) Ltd's SPC Application* (BL O/384/09) the hearing officer rejected an SPC application for the product melatonin on the basis that the conditions of Article 3(d) were not met. An earlier veterinary authorisation for the active ingredient melatonin precluded the grant of an SPC based on the later human authorisation. Although the decision of the hearing officer was upheld by the Patents Court (*Neurim Pharmaceuticals (1991) Limited v Comptroller General of Patents*, [2010] EWHC 976 (Pat), [2010] RPC 22), on appeal to the Court of Appeal (*Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents*, [2011] EWCA Civ 228, [2011] RPC 19) questions concerning the interpretation of Article 3(d) (and Article 13) were referred to the Court of Justice of the European Union (C-130/11, *Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents*).

SPM3.06 It is considered that a process for obtaining a known product already covered by a certificate may not give rise to a new certificate (see SPM1.05).

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 authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.

SPM4.01 A certificate extends the protection conferred by the basic patent beyond the term of that patent but only in respect of the product covered by the authorization to place the corresponding medicinal product on the market and any use of the product as a medicinal product that has been authorised before expiry of the certificate. It does not, however, extend the term of the patent itself.

SPM4.01.1 Article 4 of the Medicinal Regulation is to be interpreted in the same way as Article 4 of the Plant Protection Regulation in view of recital (17) of the latter which states:

ARTICLE 4 [EC Plant Protection Regulation]

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 authorizations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorized before expiry of the certificate.

SPM4.01.2 The plural "authorizations" makes clear that one certificate will suffice for the first and subsequent authorizations.

SPM4.02 In *Draco AB's SPC Application* [1996] RPC 417 the Patents Court held that Article 4 was the operative Article to confer protection on the product, which was the active ingredient as defined in Article 1(b).

SPM4.03 In *Novartis AG and Actavis UK Limited*, questions concerning the interpretation of Article 4 (and Article 5) of the Regulation were referred to the Court of Justice of the European Union (C-442/11).

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.

SPM5.01 Subject to Article 4, a certificate confers the same rights as the basic patent and is subject to the same limitations and obligations. Provisions under national law relating to such matters as infringement therefore apply equally to a certificate.

SPM5.02 In *Research Corp's SPC* ([1994] RPC 667), (see also SPM0.01), the Patents Court, upholding a decision of the hearing officer reported at [1994] RPC 387, held that the endorsement of the basic patent licences of right under the provisions of paragraph 4 of Schedule 1 of the 1977 Act was a limitation within the meaning of Article 5. The comptroller therefore had jurisdiction to entertain an application to settle the terms of licence of right under a certificate, pursuant to s.46(3) of the Patents Act 1977 and reg 5 of the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992.

SPM5.03 In *Novartis AG and Actavis UK Limited*, questions concerning the interpretation of Article 5 (and Article 4) of the Regulation were referred to the Court of Justice of the European Union (C-442/11).

ARTICLE 6: EFFECTS OF THE CERTIFICATE

The certificate shall be granted to the holder of the basic patent or his successor in title.

SPM6.01 Article 6 does not prevent an application from being lodged by a person other than the proprietor of the basic patent. However, irrespective of who lodged the application, the certificate can be granted only to the person registered at the time of grant as the proprietor of the basic patent. Where the applicant for a certificate is different from the proprietor of the basic patent or his successor in title the Office will inform the patent proprietor or his successor in title in writing of the filing of the application and invite observations.

SPM6.02 The question of whether, having regard to the wording of Article 6, the holder of a marketing authorization may refuse to give a copy to the holder of the basic patent or his successor in title where it is required by Article 8(1)(b) in order to complete the application was referred to the European Court of Justice by the Tribunal de Commerce, Nivelles, Belgium in *Biogen Inc v SmithKline Beecham Biologicals SA* [1997] RPC 833. The Court ruled that the Regulation does not require the holder of the marketing authorization to provide a copy to the patent holder. Such an obligation may, however, be deemed to be inherent in the contractual relationship between the parties. (See also SPM8.04.1.)

ARTICLE 7: APPLICATION FOR A CERTIFICATE OR AN EXTENSION OF A CERTIFICATE

1. *The application for a certificate shall be lodged within six months of the date on which the authorization 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 authorization 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.*

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.*

SPM7.01 Except where the transitional provisions of Article 19 of Regulation (EEC) No 1768/92 applied, the application must be lodged within six months of the date of grant of either the first UK authorization or the basic patent, whichever is later. In *Abbott Laboratories' SPC Application* [2004] RPC 20 the Hearing Officer held that the relevant date in Article 7(1) is the actual date of grant of the authorization and not the date of publication of grant in the relevant Official Gazette. It was also held that the six month deadline set out in Article 7 is extendable under r.110(1) of the Patents Rules 1995 (now rule 108(1) of the 2007 Rules), in accordance with the provisions of Article 18 of Regulation (EEC) No 1768/92 (now Art 19 of the EC Medicinal Regulation) (see SPM19.11). In respect of Article 7(2); in accordance with Article 97(4) of the European Patent Convention, the date of grant of a European Patent is the date the European Patent Bulletin mentions grant. For a UK patent, the relevant date of grant is taken to be the date of publication of the notice of grant in the Patents Journal under Section 24(1) of the Patents Act 1977 (rather than the date of grant under Section 18(4)).

SPM7.02 An application for an extension can be lodged when an application for a certificate is filed or whilst the application for a certificate is pending or it may be filed after a certificate has been granted. When a certificate is already granted the application shall be lodged not later than two years before the expiry of the certificate. However, for five years from the entry into force of Regulation 1901/2006 an application for an extension must be lodged not later than six months before the expiry of the certificate.

ARTICLE 8: CONTENT OF THE APPLICATION FOR A CERTIFICATE

1. *The application for a certificate shall contain:*
 - (a) *a request for the grant of a certificate, stating in particular:*
 - (i) *the name and address of the applicant;*
 - (ii) *if he has appointed a representative, the name and address of the representative;*
 - (iii) *the number of the basic patent and the title of the invention;*
 - (iv) *the number and date of the first authorization to place the product on the market, as referred to in Article 3(b) and, if*

this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization;

(b) a copy of the authorization to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC;

(c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.

(d) where the application for a certificate includes a request for an extension of the duration:

(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

(ii) where necessary, in addition to the copy of the authorisations to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

2. Where an application for a certificate is pending, an application for an extended duration in accordance with Article 7(3) shall include the particulars referred to in paragraph 1(d) of this Article and a reference to the application for a certificate already filed.

3. The application for an extension of the duration of a certificate already granted shall contain the particulars referred to in paragraph 1(d) and a copy of the certificate already granted.

4. Member States may provide that a fee is to be payable upon application for a certificate and upon application for the extension of the duration of a certificate.

ArtM.8
ArtP.8
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FSch 1

For a certificate

SPM8.01 An application for a certificate must contain a request for the grant of a certificate on Form SP1 (but see also SPM19.04) accompanied by the prescribed application fee (currently £250).

SPM8.02 This request should specify:

the name and address of the applicant (Section 3 of Form SP1);

the name of the applicant's agent (if any) and the address for service in the European Economic Area or Channel Islands (Section 4);

the EC Regulation (469/2009 or 1610/96) under which the application is made (Section 5);

the product in respect of which the certificate is sought (ie the active ingredient or combination of active ingredients of the medicinal product) (Section 6);

the number, title, expiry date and (if later than the first UK authorization) the date of grant of the basic patent (Section 7);

the number and date of the first UK authorization (Section 8);

(where different from the first UK authorization) the State, number and date of the first authorization in the EU, plus the identity of the authorised product and the legal provision under which the authorization took place (Section 9). The wording of Articles 8(1)(a)(iv) and 8(1)(c) does not appear to require such a first authorization to have been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC (see SPM2.01 and *Novartis AG and University College London & Novartis AG and Institute of Microbiology and Epidemiology SPC Applications* BL O/044/03). For applications lodged on or after 1 July 1994, the relevant authorization for the purposes of Articles 8(1)(a)(iv) and 8(1)(c) includes the first authorization in a State which is a Contracting Party to the European Economic Area Agreement (see SP0.08-09; and also SPM9.02, SPM11.01 and SPM13.04).

SPM8.03 Where more than one authorization for the product was granted on the date of the first UK or EU authorization, details of all of the relevant authorizations should be given at Sections 8 and 9 of Form SP1.

SPM8.04 The request should be accompanied by a copy of the first or each UK authorization. This authorization should identify the product and contain the number and date of the authorization and a summary of the product characteristics listed in Directive 2001/83/EC (for pharmaceutical products), Directive 2001/82/EC (for veterinary products) (see SPM2.01). Thus, in the case of a pharmaceutical product, it is necessary to file a copy of the Product Licence or Marketing Authorization granted by the Medicines and Healthcare Products Regulatory Agency, the Veterinary Medicines Directorate or the European Agency for the Evaluation of Medicinal Products (see SPM2.01). The copy should include any enclosure or Schedule referred to in the document of grant, such as an attached authenticated copy of the licence application setting out the particulars of the product.

r.113

SPM8.04.1 The question of the applicant's obligation to provide a copy of the authorization in the Member State was referred to the European Court of Justice by the Tribunal de Commerce, Nivelles, Belgium in *Biogen Inc v SmithKline Beecham Biologicals SA* [1997] RPC 833. The Court ruled that, where the owner of the basic patent and the holder of the marketing authorization were different persons and the patent owner was unable to provide a copy of the authorization in accordance with Article 8(1)(b) of the Regulation, the application for the Supplementary Protection Certificate could not be refused on that ground alone. It was open to the national authority granting the certificate to obtain a copy of the marketing authorization from the national authority which issued it. In the light of the Biogen ruling, the Office will proceed on the basis that, whilst it cannot reject the application merely because the copy of the authorisation is provided by someone other than the applicant, equally it cannot waive at least the minimum requirements of Art 8(1)(b). Thus it is not sufficient for the applicant merely to ask the Office to obtain a copy of the authorization without first having established his own inability to do so. Also, the Office will not make good the lack of a copy by referring to or copying authorization documents held on other files, such as an SPC application filed by another patent holder. Accordingly, where an applicant is unable to obtain a copy of the authorization from the person holding it, the Office will first require the applicant to provide evidence of this and also to provide such information as is available from the authority issuing the authorization such information (eg a gazette notice, a letter or a database printout) as will enable the Office to verify the identity of the product and the date of the authorization stated on Form SP1. The

Office will then ask the issuing authority to supply a copy of the relevant (usually confidential) summary of product characteristics listed in Directive 2001/83/EC or Directive 2001/82/EC (see SPM2.01). It is important to note that this latter document may be covered by a request for confidentiality under Rule 53(1) of the Patents Rules 2007 from the authorization authority and is then solely for Office use and under no circumstances will be made available to the applicant or the public. (See also SPM 6.02.)

[Copies of confidential authorizations obtained from the authorization authorities invoking the Biogen ruling are filed in a separate envelope marked "Not open to the Applicant or the Public"]

SPM8.05 In addition, in order to meet the requirements of Article 8(1)(c), where the UK authorization above is not the first authorization to place the product on the market in the EU (or, where appropriate, in a State which is a Contracting Party to the European Economic Area Agreement - see SPM 8.02), the application should be accompanied by a copy of the notice publishing the (or each) such first authorization in the appropriate official gazette. However, Article 8(1)(c) of the Medicinal Regulation is to be interpreted in the same manner as Article 8(1)(c) of the Plant Protection Regulation (as from 8 February 1997 when the latter regulation came into force) which reads:

Article 8 [EC Plant Protection Regulation]

Content of the application for a certificate

1. (c) if the authorization referred to in (b) is not the first authorization to place the product on the market as a plant protection product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication or, failing such a notice, any other document proving that the authorization has been issued, the date on which it was issued and the identity of the product authorized.

SPM8.05.1 If no such publication in a gazette has therefore been made, the copy of the authorization itself or any other document proving that the authorization has been issued, such as a confirmatory letter from the authorization authority, should be furnished in lieu. Any document not in the English language should be accompanied by a translation which need only be verified if there is reason to doubt the accuracy of the translation.

SPM8.06 Except where it is immediately apparent that the product in question is protected by the basic patent, the applicant should also provide whatever information is necessary to enable the Comptroller to confirm that this is so, eg by specifying a claim of the basic patent which refers to the product or indicating how the product is derived from a general formula in a claim.

For an extension of a certificate

SPM8.07 The application for an extension must be made on Form SP4 and accompanied by the prescribed application fee (currently £200).

SPM8.08 This request should specify:

a granted certificate number or certificate application number if these exist (Section 2 of Form SP4);

the name and address of the applicant (Section 3 of Form SP4);

the name of the applicant applicant's agent (if any) and the address for service in the EEA or Channel Islands (Section 4);

the product in respect of which the certificate is sought (i.e. the active ingredient or active substance, or combination thereof, of the medicinal product) (Section 5);

the number, title and expiry date of the basic patent (Section 6);

ArtsPd 36(1),
(2)

the number and date of the authorization containing the statement of compliance with an agreed paediatric investigation plan, including the state if necessary (Section 7);

ArtPd 28(3)

ArtPd 36(3)

whether the product has been authorized in all Member States by an authorization issued by the EMEA or by national authorizations granted by each Member state (Section 8).

SPM8.09 The request should be accompanied by a copy of the statement indicating compliance with an agreed paediatric investigation plan as referred to in Art 36(1) of Regulation (EC) No 1901/2006. In *Merck & Co., Inc.* (BL O/035/09) the hearing officer considered whether an opinion of the Paediatric Committee of the EMEA indicating compliance with a PIP was sufficient to meet this requirement. He found that it was not and that the statement of compliance included in the marketing authorization of the medicinal product was the necessary copy of this statement. The hearing officer considered that the applicant could rectify this deficiency by filing this document (see SPM19.11). In his decision concerning *E I Du Pont de Nemours & Co.'s SPC Application* (BL O/096/09, [2010] RPC 4) the hearing officer similarly found that an application which did not contain a copy of the statement of compliance did not meet the requirements of Article 8(1)(d)(i). This decision was appealed to the Patents Court in *E I Du Pont Nemours & Co.'s SPC Application* [2009] EWHC 1112 (Ch), [2010] RPC 5 and the appeal on these grounds was dismissed. The Court found that while the requirement for the statement to be in the marketing authorization is merely informative, the only substitute for it would be equivalent information on compliance from a properly reliable source. However, the Court of Appeal has since reversed the earlier decisions of the Patents Court and the Office (*E I Du Pont Nemours & Co. v UK Intellectual Property Office* [2009] EWCA Civ 966, [2010] RPC 6). Jacob LJ directed that failure to comply with the provisions of Article 8(d) at the time of submitting an application for an extension of the duration of an SPC is an irregularity which may be cured after the date of application under Article 10(3).

SPM8.10 The request should also be accompanied by proof that it has authorizations to place the product on the market in all other Member States as referred to in Art 36(3) of Regulation (EC) No 1901/2006. The hearing officer in *E I Du Pont de Nemours & Co.'s SPC Application* (BL O/096/09) found that the application did not fulfil the conditions of Article 8(1)(d)(ii) as the documents supplied did not prove that the product was approved for use in all member states and so satisfy all the requirements of Art 36 of Regulation (EC) No. 1901/2006. The appeal to the Patents Court in *E I Du Pont Nemours & Co.'s SPC Application* [2009] EWHC 1112 (Ch) on this matter was dismissed, the Court finding that an application for an extension that does not meet all the requirements of Art 36 is defective. The Court held that Art 36 must be considered as a whole and that the marketing authorization application must be completed before the reward of an extension is available. However, the Court did find that there may be circumstances where if the medicinal product is being approved through the mutual recognition procedure and the reference member state has granted the authorization

then the extension could be granted lawfully, if the only issue outstanding was the administrative completion of the authorization procedure in every member state. The Court held that the deficiencies in the application in this respect were not ones which could be described as irregularities that could be rectified under Art 10(3). However, as noted above, the Court of Appeal has since reversed the earlier decisions of the Patents Court and the Intellectual Property Office on this point (*E I Du Pont Nemours & Co.* [2009] EWCA Civ 966, [2010] RPC 6) and directed that such deficiencies can be rectified by the applicant under Article 10(3) after the date of application for the extension.

SPM8.11 When the certificate has been granted the request should not only should state its number on Form SP4 but must be accompanied by a copy of the granted certificate.

SPM8.12 Except where it is immediately apparent, the applicant should also provide whatever information is necessary to enable the Comptroller to confirm that the product in question satisfactorily completed the agreed paediatric investigation plan and was consequently authorized in all Member States, e.g. where the medicinal product has not been authorized through the centralised EMEA mechanism by providing a list of relevant national market authorizations for the medicinal product in all Member States that can be confirmed.

ARTICLE 9: LODGING OF AN APPLICATION FOR A CERTIFICATE

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 authorization 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.*

The application for an extension of the duration of a certificate shall be lodged with the competent authority of the Member State concerned.

2. *Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:*

- (a) the name and address of the applicant;*
- (b) the number of the basic patent;*
- (c) the title of the invention;*
- (d) the number and date of the authorization to place the product on the market, referred to in Article 3(b), and the product identified in that authorization;*
- (e) where relevant, the number and date of the first authorization to place the product on the market in the Community.*
- (f) where applicable, an indication that the application includes an application for an extension of the duration.*

3. *Paragraph 2 shall apply to the notification of the application for an extension of the duration of a certificate already granted or where an application for a certificate is pending. The notification shall additionally contain an indication of the application for an extended duration of the certificate.*

r.44(7) SPM9.01 The competent industrial property office for the purposes of lodging an

application for a certificate or an extension of a certificate in the UK is the Intellectual Property Office, irrespective of whether the basic patent is a UK patent or a European Patent (UK).

[All new applications for certificates are referred to PD/EX06. Upon receipt of an application PD/EX06 issue a filing receipt.]

SPM9.02 The information prescribed by Article 9(2) concerning an application for a certificate is taken from Form SP1, together with the generic name of the product when this appears in the market authorization document but not on Form SP1, and is published in the Patents Journal, together with the date of lodging the application. For applications lodged on or after 1 July 1994, the first authorization for the purposes of Article 9(2)(e) is the first authorization in a State which is a Contracting Party to the European Economic Area Agreement (see SP0.08-09 and also SPM8.02, SPM11.01 and SPM13.04). The application number (see SPM9.03), product in respect of which protection is sought (from Form SP1) and date of lodging the application are also entered in the register under the entry for the basic patent. However, no separate publication of the application corresponding to the 'A' publication of a patent application under the Patents Act 1977 is made.

SPM9.02.1 Article 9(3) requires that the information prescribed by Article 9(2) is also published in the Patents Journal for an application for an extension. Any additional information necessary will be taken from Form SP4.

[PD/EX06 arrange the publication in the Journal and the entry in the register.]

SPM9.03 Applications are numbered in a yearly sequence, eg SPC/GB93/001. The granted certificate retains this number, (see SPM10.19).

SPM9.03.1 Applications for extensions will also be given the number of the application for a certificate or the granted certificate it will extend as appropriate (see SPM10.19.1).

ARTICLE 10: GRANT OF THE CERTIFICATE OR REJECTION OF THE APPLICATION FOR A CERTIFICATE

1. *Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.*

2. *The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.*

3. *Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.*

4. *If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.*

5. *Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(c) and (d) are met.*

6. *Paragraphs 1 to 4 shall apply mutatis mutandis to the application for an extension of the duration.*

ArtsM 8, 10(3)
(ArtsP8, 10(3))

Formalities examination of an application for a certificate

SPM10.01 An initial examination for formal matters is carried out to determine whether the application

is in the required form, (including the requirements of rule 14 of and Schedule 2 to the Patents Rules 2007 as to size and presentation of documents), and accompanied by the prescribed fee (see SPM8.01);

was lodged within the period prescribed by Article 7 (see SPM7.01);

contains the information prescribed by Article 8(1)(a) (see SPM8.02-03);

is accompanied by a copy of the (or each) first UK product licence (see SPM8.04-04.1);

contains, where appropriate, information regarding the first authorization in the Community and a copy of the relevant notice (see SPM8.05);

and whether the basic patent was in force on the date of application.

[A formalities examiner in PD carries out the examination.]

SPM10.02-03 [Deleted]

ArtM 3(a)
(ArtP3(1)(a))

Substantive examination of an application for a certificate

ArtM 3(b)
(ArtP3(1)(b))

SPM10.04 A substantive examination is also carried out to determine whether the following conditions of Article 3 were complied with at the date of the application:

ArtM 3(c)
(ArtP3(1)(c))

the product is protected by the basic patent;

a valid authorization 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 (see SPM2.01);

the product has not already been the subject of a certificate. (The examiner carries out a search of certificates granted in the UK in order to establish this.)

PA 1977, s.21

Generally, the substantive examination is carried out at the same time as the formalities examination, and all objections arising are reported to the applicant in a single letter (see SPM10.12). If the basic patent has already expired or is about to expire, substantive examination should be carried out as a matter of urgency, in order to avoid delay in the entry into force of the certificate. Substantive examination may however be deferred in cases where the examiner considers it likely that the application may not be able to meet a formal objection.

ArtsM 3(d),
10(5)
(ArtsP3(1)(d),
10(5))

[A substantive examiner in PD/EX06 carries out the examination.]

PA 1977, s.21,
sch 4A, para 4

SPM10.04.1 The applicant may request accelerated examination giving a reasoned statement for the request. If allowed, the applicant is warned that, even when the application is found to be in order for grant at an earlier date, grant will not occur until a period of at least three months has elapsed from the date of publication of the notice of

filing of the application in the Patents Journal to allow for third-party observations.

r.82(1)(a) SPM10.05 Although no search is at present carried out to establish whether the authorization specified was the first authorization to place the product on the market in the UK as a medicinal product, the examiner should also consider whether this requirement is met where there is reason to do so (eg on the basis of information supplied by the applicant, observations by a third party (see SPM10.06) or information in another application for the same product). See also *Draco AB's SPC Application* [1996] RPC 417.

SPM10.06 Any observations by a third party, on the question whether the application meets the conditions of the Regulation should be considered by the examiner as in the case of an application for a patent. However, as in the case of a patent application such observations must be in writing and must be made before a certificate is granted.

ArtsM 8, 10(6) SPM10.07 Where the examiner requires further information in order to make any determination, the applicant should be required to furnish this within a prescribed period.

Formalities examination of an application for an extension

SPM10.08 An initial examination for formal matters is carried out to determine whether the application

is in the required form, (including the requirements of rule 14 of and Schedule 2 to the Patents Rules 2007 as to size and presentation of documents), and accompanied by the prescribed fee (see SPM8.07);

was lodged within the period prescribed by Article 7 (see SPM7.02);

contains the information prescribed by Article 8 (see SPM8.08);

is accompanied by a copy of the statement indicating compliance with an agreed paediatric investigation plan as referred to in Art 36(1) of Regulation (EC) No 1901/2006 as prescribed by Article(1)(d)(i) (see SPM8.09);

contains proof that the product has been authorized in all Member States by an authorization issued by the EMEA or by national authorizations granted by each Member state as prescribed by Article(1)(d)(ii) (see SPM8.10);

where an application for a certificate is pending a reference to the certificate already filed as prescribed by Article 8(2) (see SPM8.08);

where a certificate is granted a copy of the certificate already granted as prescribed by Article 8(3) (see SPM8.11);

[A formalities examiner in PD carries out the examination.]

ArtsPd 36(1),
(2) **Substantive examination of an application for an extension**

ArtPd 36(3) SPM10.09 A substantive examination is also carried out to determine whether, at the date of the application, it entitles the holder of the patent or certificate to the reward set out in Art 36(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council. The examiner may seek to establish that:

ArtPd (5) the marketing authorization identified includes the required statement indicating the compliance with an agreed paediatric investigation plan;

the product is authorized in all Member States;

the product has not already been the subject of the alternative reward set out in Regulation (EC) No 1901/2006 of the European Parliament.

PA 1977, s.21, sch 4A, para 4 Generally, the substantive examination is carried out at the same time as the formalities examination and at the same time as the pending application for a certificate, if appropriate, and all objections arising are reported to the applicant in a single letter (see SPM10.12).

r.82(1)(a) [A substantive examiner in PD/EX06 carries out the examination.]

SPM10.10 Any observations by a third party, on the question whether the application meets the conditions of the Regulation should be considered by the examiner as in the case of an application for a patent. However, as in the case of a patent application such observations must be in writing and must be made before an extension is granted.

ArtsM10(2), 10(3), 10(4) (ArtsP 10(2), 10(3), 10(4)) SPM10.11 Where the examiner requires further information in order to make any determination, the applicant should be required to furnish this within a prescribed period.

r.108

Examination report

SPM10.12 Where it appears to the examiner that formal objections arise, and/or that any of the conditions of Article 3 is not met or that the holder of the patent or certificate is not entitled to the reward set out in Art 36(1) of Regulation (EC) No 1901/2006, the applicant should be informed accordingly and allowed a specified period (generally four months for the first report, two months for the second and two months for the third) for reply. As in the case of formal or substantive examination of an application for a patent, this period may be extended at the request of the applicant. In *Medeva BV v The Comptroller General of Patents* [2010] EWHC 68 (Pat), [2010] RPC 20, Kitchin J (at paragraph 42 of his decision) confirmed that an examination report in respect of an SPC application is not a decision against which an appeal can properly be filed under s.97 of the Patents Act 1977.

SPM10.12.1 Where an application is not in the required form, does not contain all of the required particulars and documents and/or is not accompanied by the prescribed fee, the filing date will not be lost if the applicant rectifies the irregularity or settles the fee within the specified period. If the applicant wishes to extend this period, he should request this in writing before the period expires otherwise the application may be rejected under Article 10(4). For an application for an extension of the duration of a certificate, Jacob LJ directed in *E I Du Pont Nemours & Co.* [2009] EWCA Civ 966, [2010] RPC 6 that failure to comply with the provisions of Article 8(d) at the time of submitting the application for an extension is an irregularity which may be cured after the date of application under Article 10(3).

r.105 **Amendment and correction**

r.31 SPM10.13 The details on Form SP1 or SP4 may be amended or corrected in response to the examination report.

SPM10.14 Where a proposed correction affects the details of application or grant which have already been published (see SPM9.02, SPM11.01), the details of the correction will also need to be published. In such cases a request to correct should be

made in writing identifying the proposed correction. If the Office considers that the correction is allowable, details will be advertised in the Patents Journal.

SPM10.15 Where, before a certificate or extension has been granted, an applicant desires to amend Form SP1 or SP4 other than in response to an official objection (eg to add details of further relevant authorizations of which he has become aware) the amendment should be formally requested in writing.

Re-examination

ArtM 18
(ArtP 17)

SPM10.16 Where the applicant has amended or corrected the application, and/or made submissions in response to any objection to formal or substantive matters raised by the examiner, the application should be re-examined as soon as possible. If formal objections have been met, any deferred substantive examination should now be carried out. Where the examiner is still not satisfied that the conditions of the Regulation are met, either the outstanding objection(s) should be pursued in further correspondence, by telephone or at an interview, or the rejection procedure (see SPM10.17) should be initiated. Unlike the case of patent applications, there is no overall period within which an application for a certificate or certificate must be in order for grant. However, where the basic patent has already expired or is about to expire, re-examination should be carried out as a matter of urgency (see SPM10.04).

Rejection of application

SPM10.17 Where the applicant has not replied to objections raised by the examiner in respect of formal or substantive matters, or the examiner having considered any amendments, corrections and/or submissions made by the applicant in response is still not satisfied that the applicant fully meets the conditions of the Regulation, the applicant should be informed in an official letter of the examiner's opinion and the reasons therefor, and that accordingly, unless the applicant requests to be heard in the matter, the Comptroller proposes to reject the application under Article 10.2 and/or 10.4 as appropriate. As in the case of an application for a patent, any hearing will be taken by a senior officer of the Office acting for the Comptroller and any adverse decision will be subject to appeal to the Patents Court.

PA 1977,
s.14(9)

SPM10.17.1 In *British Technology Group Ltd's SPC Application* [1997] RPC 118, where it had been found that a valid product licence had not been granted, the Hearing Officer went on to refuse permission to keep the application open until the time that the applicants provided a valid authorization in accordance with Article 3(b). To do otherwise would put third parties at a considerable disadvantage. The correct procedure was to file a fresh application when all the requirements of the Regulation could be met, particularly the provision of a valid market authorization. Article 3(c) is then not contravened because the first filed application has not been granted (see SPM3.03.1).

Withdrawal of application

SPM10.18 An applicant may request in writing that his application is to be withdrawn at any time before a certificate or an extension is granted (see 14.199-208). Any such withdrawal may not be revoked. Whilst there appears to be no bar on an application being withdrawn before grant and subsequently being refiled at a later date, grant of such an application would depend upon the time limits of Article 7 being met.

Grant of certificate

ArtM 3(a)

SPM10.19 When all requirements are met, a certificate or an extension is granted. In *Merck and Co., Inc.* (BL O/108/08) the hearing officer found that where an application met the requirements of Article 10 an SPC could be granted even if by applying the calculation of Article 13(1) it would never take effect at the end of the lawful term of the basic patent. The certificate retains the application number (see SPM9.03). It states

the date of expiry of the maximum possible period of its duration and indicates that entry into force is dependent upon the payment of fees.

SPM10.19.1 When an extension is granted on an application for a certificate or pending application then the certificate granted will indicate that the extension has been included in the maximum possible period of its duration. However, if the extension is granted for an existing certificate then an amended certificate stating the extended maximum possible period of duration will be granted.

ArtM 19(2)
(ArtP 18(2))

SPM10.19.2 The Medicinal Regulation does not require that grant of the certificate must occur before the basic patent expires, merely that the latter is in force on the date of filing. Consequently, grant is retrospective to the day after the basic patent expired (see SPM13.01). Therefore, when details of filing of an application are published in the Patents Journal, the public is put on notice that grant of the certificate may occur at any time subsequently.

[PD/EX06 issue the certificate.]

SPM10.20 Opposition to the grant of a certificate or an extension is not allowed (see SPM19.06; see also SPM10.06, SPM10.10 for procedure where a third party makes observations in writing).

SPM10.21 The Medicinal Regulation does not appear to invest the competent industrial property office of the Member State with the power to refuse to grant a certificate on the grounds that the marketing authorization has lapsed or been withdrawn, provided that the requirement of Article 3(b) has been met. Action may, however, be considered after grant for declaration of lapse under Article 14(d) when the certificate has come into force (see SPM14.02 to 14.05).

ARTICLE 11: PUBLICATION

1. *Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9(1). The notification shall contain at least the following information:*

- (a) *the name and address of the holder of the certificate;*
- (b) *the number of the basic patent;*
- (c) *the title of the invention;*
- (d) *the number and date of the authorization to place the product on the market referred to in Article 3(b) and the product identified in that authorization;*
- (e) *where relevant, the number and date of the first authorization to place the product on the market in the Community;*
- (f) *the duration of the certificate.*

r. 44(7)

2. *Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9(1). The notification shall contain at least the information listed in Article 9(2).*

3. *Paragraphs 1 and 2 shall apply to the notification of the fact that an extension of the duration of a certificate has been granted or of the fact that the application for an extension has been rejected.*

SPM11.01 The information prescribed by Article 11, including the generic name of

the product when this appears in the market authorization but not on original Form SP1 or Form SP4, is published in the Patents Journal, together with the date of grant or rejection. For applications lodged on or after 1 July 1994, the first authorization for the purposes of Article 11(1)(e) is the first authorization in a State which is a Contracting Party to the European Economic Area Agreement (see SP0.08-09 and also SPM8.02, SPM9.02 and SPM13.04). The certificate number (see SPM9.03), product, date of grant or rejection and duration of a granted certificate and extension are also entered in the register under the entry for the basic patent.

[PD/EX06 arrange the publication in the Journal and the entry in the register.]

SPM11.02 In both the Journal and the register:

the product is identified as that for which the certificate has been granted, and may differ from that published upon application (see SPM9.02);

the duration of a granted certificate is identified by the date of expiry of the maximum period of duration as determined by Article 13 and if an extension has been granted.

SPM11.03 A copy of the certificate of grant is retained on the file of the application which is open to public inspection. However, no separate publication of the certificate or an extension of a certificate corresponding to the 'B' publication of a patent under the Patents Act 1977 is made.

ARTICLE 12: ANNUAL FEES

Member States may require that the certificate be subject to the payment of annual fees.

SPM12.01 Entry into effect of the certificate is subject to the payment of annual fees in accordance with paragraph 5 of Schedule 4A to the Patents Act 1977 and rule 6 of the 2007 Fees Rules. (See paragraph 128B.10).

SPM12.01.1 The Regulation does not appear to invest the competent industrial property office of the Member State with the power to refuse to allow a certificate to come into force on the grounds that the marketing authorization has lapsed or been withdrawn, provided that the requirement of Article 3(b) had been met. Action may, however, be considered later for declaration of lapse under Article 14(d), after the certificate has come into force (see SPM14.02 to 14.05).

r.116(5) [PD/EX06 deal with all matters relating to the payment of annual fees.]

ArtM 13(1),
13(3),
(ArtP13(1)),
r.116(5)

Effective period of the certificate

SPM12.02 The certificate holder is required to pay annual fees for the effective period of the certificate. This is the maximum period of duration of the certificate, less any period for which the certificate holder does not desire it to have effect.

r.116(2)(a) SPM12.03 The effective period must consist of a single period starting the day after the expiry of the basic patent. Where the certificate holder opts for an effective period less than the maximum period of the certificate, this period cannot subsequently be extended, unless an extension of a certificate under Regulation (EC) No 1901/2006 of the European Parliament is granted.

- r.116(2)(b) **Date for payment**
- SPM12.04 The date by which the annual fees are payable is normally the date on which the certificate is due to take effect at the end of the lawful term of the basic patent. The annual fees may not be paid earlier than three months before that date.
- Fr.6(2) SPM12.05 However, where the certificate is granted later than three months before the expiry of the basic patent, the date for the payment of annual fees is three months after the grant date of the certificate.
- Fr.6(2) **Calculation of annual fees**
- SPM12.06 An annual fee is payable for each year of the effective period of the certificate. Any final period of less than 12 months is treated as a whole year, eg an effective period of 3 years 6 months will therefore require the payment of 4 years' annual fees.
- r.116(3) SPM12.07 The annual fees are payable as a single cumulative amount as a condition of the certificate taking effect. The level of the fees is that applying on the date the certificate is due to take effect or, paid if earlier, the actual date of payment. Currently the fees for the five successive years are £600, £700, £800, £900 and £1,000.
- r.116(8) **Notification that payment is due**
- SPM12.08 The certificate holder is notified not later than two months beforehand of the date on which the fees are payable and of the level of the fee payable in respect of each year. Where the certificate is granted later than three months before the expiry of the basic patent, this notification is sent with the granted certificate.
- SPM12.09 The notification is sent to the address for service provided on Form SP1, or any address replacing it. It is also sent to the following address, where different:
- (i) the United Kingdom address specified for the sending of renewal reminders on payment of the last renewal fee relating to the basic patent, or any address replacing it; or
- r.116(5) (ii) where there is no address under (i), any address for service entered in the register in respect of the basic patent.
- Procedure for payment of fees**
- SPM12.10 The payment of the total sum of the annual fees for the whole effective period should be accompanied by Form SP2 (but see SP18.04). The holder of the certificate should state on this Form the date on which fees are payable (the "due date"), the desired effective period of the certificate, and the amount of fees paid in consequence.
- r.116(6) SPM12.11 The Office confirms the payment of fees and the date of the expiry of the effective period by sending a certificate of payment to the address given in Section 6 of Form SP2. If the holder wishes this certificate to be sent to a different address, he should indicate this at Section 7 of Form SP2 and give the address on a separate sheet.
- Fr.6(4) **Late payment of fees**
- SPM12.12 Where the annual fees are outstanding, the holder of the certificate is notified within 6 weeks of the due date.
- ArtM 14(c) SPM12.13 Subject to an additional late payment fee of one-half of the amount of

(ArtP 14(c))

the unpaid fees, annual fees may be paid up to six months after the due date; this period cannot be extended. The annual fees are then treated as having been filed on the due date.

Non payment of fees

SPM12.14 If the fees are not paid by the due date or in accordance with SPM12.13, the certificate is treated as having lapsed on the date of expiry of the basic patent and so does not take effect. The holder is notified accordingly.

ARTICLE 13: DURATION OF THE CERTIFICATE

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 authorization 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.*

ArtM 12, (ArtP 12)

PA 1977, Sch 4A, para 5

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.*

4. *Where a certificate is granted for a product protected by a patent which, before 2 January 1993, had its term extended or for which such extension was applied for, under national law, the term of protection afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years.*

SPM13.01 A certificate takes effect at the end of the lawful term of the basic patent, provided that:

the basic patent has not previously lapsed or been revoked;

r.44(7)

the annual fees are paid in time (see SPM12.04-05).

SPM13.02 Article 13 defines the maximum period of duration of the certificate. The effective period may however be less than this maximum period if the certificate holder opts to pay fees for a lesser period (see SPM12.02-03).

SPM13.03 The date of entry into force of the certificate and the date of expiry of the effective period (see SPM12.02) are published in the Patents Journal and entered in the register under the entry for the basic patent.

[PD/EX06 arrange the publication in the Journal and the entry in the register.]

Calculation of the duration of the certificate

SPM13.04 Since the term of the basic patent is 20 years, the maximum period defined by Article 13 is either:

a period of 15 years from the date of the first authorization to place the product on the market in the Community; or

a period of 5 years from the date on which it takes effect,

whichever is the lesser (see SPM18.02 for appeal where duration is incorrectly calculated.) For applications lodged on or after 1 July 1994, the period of 15 years runs from the date of the first authorization to place the product on the market in a State which is a Contracting Party to the European Economic Area Agreement. The European Court of Justice in *Novartis AG & University College London & Novartis AG and Institute of Microbiology v Comptroller General of Patents, Designs and Trade Marks for the UK and Ministre de l'Économie v Millennium Pharmaceuticals Inc.* (ECJ Joined Cases C-207/03 and C-252/03) [2005] RPC 33 held that when a Swiss authorization automatically recognized in Liechtenstein was the first in the EEA it constituted the first authorization in the Community for the purposes of Article 13 (see also SP0.08-09, SPM8.02, SPM9.02 and SPM11.01). The period of 15 years also runs from the first pharmaceutical or veterinary authorization for such a State irrespective of whether the first authorization under Article 3(b) to place the product on the market in the UK is pharmaceutical or veterinary. Thus, in *Farmitalia Carlo Erba S.r.l.'s SPC Application* (1) [1996] RPC 111 the hearing officer held that on the plain meaning of Article 13(1), an Italian veterinary authorization of 1987 and not a Netherlands pharmaceutical authorization of 1992 constituted the first authorization in the Community, in a case where the Article 3(b) authorization was pharmaceutical. Similarly, in *Pharmacia Italia SpA v Deutsches Patentamt* [2005] RPC 27 (ECJ Case C-31/03), the authorization as a veterinary product was held by the ECJ to be the first market authorization in the Community for an SPC application made on the basis of a medicinal product for human use. The ECJ therefore ruled that the grant of the certificate was precluded by the veterinary authorization as this took place before the date specified under Article 19(1) of Regulation (EEC) No 1768/92. In *Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents* [2011] EWCA Civ 228, [2011] RPC 19, the Court of Appeal referred questions to the Court of Justice of the European Union (C-130/11, *Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents*) concerning the interpretation of the phrase “the first authorisation to place the product on the market in the Community” in Article 13 (along with questions relating to Article 3(d)).

SPM13.04.1 The question of whether the marketing authorisation which must be identified under Article 13(1) must be compliant with Council Directive 65/65/EEC or whether any marketing authorisation that enables the product to be placed on the market in the Community or EEA should count for the calculation of the duration of the SPC has been considered by the Court of Justice of the European Union in two separate cases (*Generics (UK) Ltd v Synaptech Inc* [2009] EWHC 659 (Ch), referred to the CJEU in *Generics (UK) Ltd v Synaptech Inc*, C-427/09; and *Synthon v Merz Pharma* [2009] EWHC 656 (Pat), referred to the CJEU in *Synthon BV v Merz Pharma GmbH & Co KG*, C-195/09). In both cases the court held that a product which was placed on the market in the European Community as a medicinal product for human use before obtaining a marketing authorisation in accordance with Council Directive 65/65/EEC and, in particular, without undergoing safety and efficacy testing, is not within the scope of the Regulation, and may not be the subject of a supplementary protection certificate. It went on to confirm that any SPC granted for a product which was outside the scope of the Regulation was invalid.

SPM13.04.2 Following the accession of the ten new member states to the Community on 1 May 2004, a national authorization granted in one of these states from the accession date is considered to be valid in the Community. However, such authorizations would be used to determine the length of a certificate only if no other marketing authorization had already been granted in the European Economic Area (see SP0.08.1).

SPM13.05 It follows from Article 13 that a certificate would have no effective duration in the case in which the date of the first authorization to place the product on the market is not more than five years from the filing date of the basic patent.

Previously, no certificate has been granted in such cases. Instead the applicant has been informed that, subject to any comments which he wishes to make, the Office proposes to treat the application as withdrawn. However, the hearing officer found in *Merck and Co., Inc.* (BL O/108/08) that where an application did meet the requirements of Article 10 an SPC can be granted even if it would never take effect and its term could not extend beyond the end of the lawful term of the basic patent unless it was extended under Article 13(3). After the German Patent and Trade Mark Office rejected an equivalent application to that considered in BL O/108/08, the German Federal Court has referred a question about whether it is possible to grant an SPC in these circumstances to the Court of Justice of the European Union (C-125/10 - Merck & Co Inc v Deutsche Patent- und Markenamt).

Calculation of maximum duration period

SPM13.06 The Office will generally invite the applicant to confirm agreement with the maximum expiry date calculated by the Examiner on the basis of the facts presented on Form SP1 (see SPP17.01).

Duration of an extension

SPM13.07 An extension of a certificate increases the period of duration of the certificate by six months.

ARTICLE 14: EXPIRY OF THE CERTIFICATE

The certificate shall lapse:

- (a) *at the end of the period provided for in Article 13;*
- (b) *if the certificate-holder surrenders it;*
- (c) *if the annual fee laid down in accordance with Article 12 is not paid in time;*
- (d) *if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place on the market in accordance with Directive 2001/83/EC or Directive 2001/82/EC.*

ArtM 17
(ArtP 16)
r.44(7)

The authority referred to in Article 9(1) may decide on the lapse of the certificate either of its own motion or at the request of a third party.

SPM14.01 Notification of lapse is published in the Patents Journal, and is also entered in the register under the entry for the basic patent. (See also SPM17.01)

PR part 7

[PD/EX06 arrange the publication in the Journal and the entry in the register.]

SPM14.01.1 In BL O/252/11 (*The Administrators of the Tulane Education Fund*) the hearing officer held that an SPC could not be brought into effect where the applicant had failed to pay the prescribed fee within the prescribed time period or within the six months following the end of the prescribed period. This decision has been appealed.

PR part 7

Declaration of lapse under Article 14(d)

SPM14.02 The Comptroller may declare that a certificate has lapsed under Article 14(d), either on the application of any person, or on his own initiative.

PR part 7

SPM14.03 An application by a third party to the Comptroller for a declaration of

lapse under Article 14(d) should be made on Form SP3 (but see SPM19.04) accompanied by a copy thereof and by a statement of grounds in duplicate. This starts proceedings before the comptroller to determine the matter, the procedure for which is discussed at paragraphs 123.05 – 123.05.13.

ArtM18 [Applications on Form SP3 for declaration of lapse are referred to Litigation
(ArtP 17) Section.]

SPM14.04 Where the Office becomes aware, other than by an application on Form SP3, of the withdrawal of the appropriate authorization(s) to place on the market a product covered by a certificate, the certificate holder is informed of the withdrawal in an official letter and that, subject to any observations which the holder may make within a specified period (generally two months), the Comptroller proposes to declare that the certificate has lapsed.

r.44(7) SPM14.05 Any decision by the Comptroller, whether on the application of a third party or on his own initiative, is subject to appeal to the Patents Court.

PR part 7 **Restoration of certificate after lapse under Article 14(d)**

SPM14.06 Where a new authorization to place the product on the market is granted, a certificate which has lapsed under Article 14(d) automatically takes effect again from the date of the new authorization (unless the certificate has also been declared invalid or lapsed on any other ground, eg surrender).

r. 42 SPM14.07 The certificate-holder should advise the Office of the grant of the new authorization. Notice of the termination of lapse under Article 14(d) is then inserted in the Patents Journal (see SPM17.01).

SPM14.08 Any person may apply to the Comptroller for a declaration that the ground for lapse under Article 14(d) no longer exists. This starts proceedings before the comptroller to determine the matter, the procedure for which is discussed at paragraphs 123.05 – 123.05.13.

r.106(5)(6)(8) **Surrender of certificate**

SPM14.09 Any offer by the holder to surrender a certificate should be made in writing. No fee is at present required. The offer is examined in accordance *mutatis mutandis* with the procedure under s.29 of the Patents Act 1977 for the surrender of patents (see 29.02-07).

[Offers on Patents Form 2 to surrender a certificate are referred to Litigation Section.]

SPM14.10 If a certificate is surrendered, a remission of annual fees is made for any complete effective year(s) subsequent to the date of surrender. Thus, if a certificate having a term of 4 years 3 months (for which five years' fees would have been paid) is surrendered after 3 years 9 months, the fifth year's fee is remitted.

SPM14.11 No remission is made if a certificate lapses under Article 14(d) unless the holder first surrenders the certificate. This is because lapse under Article 14(d) may not be permanent whereas once surrendered a certificate cannot be re-instated.

ARTICLE 15: INVALIDITY OF THE CERTIFICATE

1. *The certificate shall be invalid if:*
 - (a) *it was granted contrary to the provisions of Article 3;*

ArtM 17, (ArtP
16) r.44(7)

(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.*

PR part 7

2. *Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent.*

SPM15.01 Notification of invalidity of a certificate is published in the Patents Journal and is also entered in the register under the entry for the basic patent (see SPM17.01).

[PD/EX06 arranges the publication in the Journal and the entry in the register.]

SPM15.02 An application for a declaration of invalidity of a certificate may be made to the Comptroller or the Court as in the case of an application for revocation of a patent.

SPM15.03 In *Hässle AB v Ratiopharm* (ECJ Case C-127/00)[2003] ECR I-14781 the European Court found that where a certificate had been granted contrary to the requirements of Article 19 of Regulation (EEC) No 1768/92 the certificate was invalid under Article 15. The Court held that this was the case even if it was not possible to infer that the list of grounds of invalidity of a certificate found in Article 15(1) was not exhaustive (also see SPM20.02).

Application to the Comptroller

SPM15.04 An application to the Comptroller for a declaration of invalidity of a certificate should be made on Form SP3 (but see SPM19.04). The procedure is the same as in the case of an application for a declaration of lapse (see SPM14.03).

[Applications on Form SP3 for declaration of invalidity are referred to Litigation Section.]

ARTICLE 16: REVOCATION OF AN EXTENSION OF THE DURATION

1. *The extension of the duration may be revoked if it was granted contrary to the provisions of Article 36 of Regulation (EC) No 1901/2006.*

2. *Any person may submit an application for revocation of the extension of the duration to the body responsible under national law for the revocation of the corresponding basic patent.*

SPM16.01 Procedures relating to revocation of an extension are in accordance with those for a certificate (see SPM15.01, SPM15.02 and SPM15.04).

r.44(7)

ArtM 14(a)

ArtP 14(a)

ARTICLE 17: NOTIFICATION OF LAPSE OR INVALIDITY

1. *If the certificate lapses in accordance with point (b), (c) or (d) of Article 14, or is invalid in accordance with Article 15, notification thereof shall be*

published by the authority referred to in Article 9(1).

2. *If the extension of the duration is revoked in accordance with Article 16, notification thereof shall be published by the authority referred to in Article 9(1).*

SPM17.01 The notifications required by Article 17, and also notification of termination of lapse under Article 14(d) (see SPM14.07) and notification of lapse at the end of the effective period of the certificate (see SPM14.01), are published in the Patents Journal. These events are also entered in the register under the entry for the basic patent.

PA 1977, s.97
ArtM 13(1)

[PD/EX06 arranges the publication in the Journal and the entry in the register.]

(ArtP 13(1))

ARTICLE 18: APPEALS

ArtsM 13(1),
8.1(a)(iv)

The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Articles 15(2) and 16(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

SPM18.01 Decisions taken by the Comptroller under the Regulation are open to appeal to the Patents Court in the same manner as decisions taken in respect of patents. In *Medeva BV v The Comptroller General of Patents* [2010] EWHC 68 (Pat), [2010] RPC 20, Kitchin J confirmed the procedural details for filing an appeal against an SPC rejection by the Intellectual Property Office (also see SPM10.12).

[Matters within the Office relating to appeals from decisions taken under the Regulation are dealt with by Litigation Section.]

SPM18.02 Recital (17) of the Plant Protection Regulation (see SPM0.04) has the effect that, from 8 February 1997 when said regulation came into force, Article 17 of Regulation (EEC) No 1768/92 (now Article 18 of the EC Medicinal Regulation) is additionally to be interpreted in accordance with Article 17(2) of the Plant Protection Regulation which states:

(ArtsP 13(1),
8(1)(a)(iv))

Article 17(2) [EC Plant Protection Regulation]

Appeals

The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorization to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.

SPM18.03 Such an appeal may be lodged by the applicant or a third party. If the appeal results in a corrected maximum expiry date for the granted certificate the details will be notified to the public in the Patents Journal.

ARTICLE 19: PROCEDURE

1. *In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless that law lays down special procedural provisions for certificates.*

2. *Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.*

SPM19.01 Procedural provisions applicable under national law to the corresponding basic patent apply to the certificate, unless:

- r.116, FSch 1 there are procedural provisions in the Regulation; or
 national law lays down special procedural provisions for certificates.
- Fr.6(2) SPM19.02 In the UK such special procedural provisions are laid down in the 2007 Rules and the 2007 Fees Rules and govern:
- r.106(5),(6),(8)
part 7 the application and fee in respect of the application (Articles 8 and 9);
- r.4 the certificate of grant (Article 10);
- r.44(7) annual fees (Article 12);
- r.116 declaration of lapse or invalidity of the certificate (Articles 14(d) and 15.1(a) and (c));
- Fsch.1 forms for use in connection with certificates and applications for certificates (Article 19.1); and
- Fr.6(2) publication of certain details (Articles 9.2, 11.1, 11.2 and 17).

SPM19.03 In particular the Rules provide for four special Forms:

- SP1 (Request for grant) (see SPM8.01);
- SP2 (Payment of annual fees) (see SPM12.10);
- r.4(2) SP3 (Application for decision of lapse or declaration of invalidity) (see SPM14.03, SPM15.04 and SPM16.01);
- r.4 SP4 (Application for an extension to the duration of a certificate) (see SP0.11);
 and prescribe the fees payable thereon.

SPM19.04 The requirement to use any of these Forms is satisfied by the use of a form which is acceptable to the Comptroller and contains the required information (such as a replica or photocopy of an official Form).

- r.54 SPM19.05 For actions other than those covered by Form SP1, SP2, SP3 and SP4 the relevant Patent Forms should be used and the same fee (if any) paid.

SPM19.06 It follows from Article 19.2 that opposition to the grant of a certificate is not allowed (see SPM10.20).

r.51(2)(b) **Requests for information (caveats)**

- r.53 SPM19.07 Insofar as rule 54 of the Patents Rules 2007 is applicable, information relating to certificates, applications for certificates, extensions of a certificate and applications extensions of a certificate is available upon request as in the case of patents and applications for patents. Paragraphs 5(a), 5(b), 6(a) and 6(d) of rule 54 appear to have no relevance to certificates and applications for certificates. Paragraph

6(c) appears applicable *mutatis mutandis* to the provision of information concerning the payment of annual fees (see SPM12.10-12.13).

r.46, 48

Documents open to public inspection

SPM19.08 Documents are normally made open to public inspection immediately after they are filed at (or sent to) the Office.

r.108

SPM19.09 The person filing or sending a document (other than a Form SP1, SP2, SP3 or SP4), or any other person, may request within 14 days that the document be kept confidential (giving reasons). The comptroller may then direct that the document in question, or part thereof, should be treated as confidential. The document is not open to public inspection while the matter is being determined. Where a request is made to keep a document confidential but no reasons are given the person filing the document is requested to provide suitable reasons within a period of 14 days.

SPM19.10 Copies of any documents which are not treated as confidential are available upon request as in the case of documents relating to patents.

Extensions of time

SPM19.11 In *Abbott Laboratories' SPC Application* [2004] RPC 20 it was held that the six month time limit set out in Article 7 is extendable under r.110(1) of the Patents Rules 1995 (which is equivalent to r.108(1) of the Patents Rules 2007). There are no provisions in the Regulation relating to extension of the Article 7 time limit, and there are no special provisions for such extensions laid down by national law. Hence the applicable provision governing any such extension of time is the appropriate procedural provision under national law corresponding to the basic patent. In *Merck & Co., Inc.* (BL O/035/09) the hearing officer found that the time limit set by the examiner for rectifying an irregularity in filing the required documents was extendable under r.108 (see SPM8.09). The Court of Appeal in *E I Du Pont Nemours & Co.* [2009] EWCA Civ 966, [2010] RPC 6 directed that the time periods for curing irregularities under Article 10(3) in an application for an extension of the duration of a certificate can be extended (see SPM8.09).

ARTICLE 20: ADDITIONAL PROVISIONS RELATING TO THE ENLARGEMENT OF THE COMMUNITY

Without prejudice to the other provisions of this Regulation, the following provisions shall apply:

(a) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Bulgaria, provided that the application for a certificate was lodged within six months from 1 January 2007;

(b) any medicinal product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a medicinal product was obtained:

(i) in the Czech Republic after 10 November 1999 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained,

(ii) in the Community not earlier than six months prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first

market authorisation was obtained;

(c) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Estonia prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or, in the case of those patents granted prior to 1 January 2000, within the six months provided for in the Patents Act of October 1999;

(d) a medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Cyprus prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained; notwithstanding the above, where the market authorisation was obtained before the grant of the basic patent, the application for a certificate must be lodged within six months of the date on which the patent was granted;

(e) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Latvia prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004;

(f) any medicinal product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a medicinal product was obtained in Lithuania prior to 1 May 2004 may be granted a certificate, provided that the application for a certificate was lodged within six months from 1 May 2004;

(g) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate was lodged within six months from 1 May 2004;

(h) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Malta prior to 1 May 2004 may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 May 2004;

(i) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for a certificate was lodged within six months starting no later than 1 May 2004;

(j) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than 1 January 2007;

(k) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovenia prior to 1 May 2004 may be granted a certificate, provided that the

application for a certificate was lodged within six months from 1 May 2004, including in cases where the period provided for in Article 7(1) has expired;

(l) any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained in Slovakia after 1 January 2000 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or within six months of 1 July 2002 if the market authorisation was obtained before that date.

SPM20.01 In the case of a product which was already authorised before entry into force of Regulation (EEC) No 1768/92 the transitional provisions of Article 19 of that regulation allowed for an application to be filed in the UK within six months of the date on which the Regulation entered into force, (ie filed on or before 2 July 1993) provided that:

ArtM 3(a)
(ArtP 3(1)(a))

on that date the product was protected by a valid basic patent; and

the first authorization to place it on the market in the Community was obtained after 1 January 1985.

However the application must still have been filed before the basic patent expired. Such transitional provisions no longer exist in the EC Medicinal Regulation.

SPM20.02 In *Yamanouchi Pharmaceuticals Co. Ltd v Comptroller-General* [1997] RPC 844 an application under Regulation (EEC) No 1768/92 had received its first authorization to be placed on the market in the EC after 1 January 1985, but had not yet received an authorization to be placed on the market in the UK. The Hearing Officer had declined to accept that the transitional provisions of Article 19 of Regulation (EEC) No 1768/92 obviated the need to comply with the requirements of Articles 3(b), 8(1)(a)(iv) and 8(1)(b) and accordingly refused the application for non-compliance with these Articles. On appeal the Patents Court (unreported judgment of 31 October 1994) decided to refer the matter to the European Court of Justice. Upholding the Hearing Officer's decision, the European Court ruled that the regulation was intended to prevent the grant of SPCs whose duration varied from one Member State to another. In those circumstances, Article 19(1) of Regulation (EEC) No 1768/92 could not be construed as meaning that the existence of an authorization in the Member State in which the SPC was sought was of no relevance. Under Articles 3(b) and 4 of the regulation, entitlement to an SPC was strictly linked to the existence of a marketing authorization granted in the Member State in which the application was submitted and to the date of that application. Accordingly, the grant of an SPC pursuant to Article 19 of Regulation (EEC) No 1768/92 was conditional on a valid authorization to place the product on the market as a medicinal product having been granted in the Member State in which the application was submitted and at the date of the application. In *Hässle AB v Ratiopharm* (ECJ Case C-127/00) [2003] ECR I-14781 the European Court found that the first authorization referred to in Article 19(1) of Regulation (EEC) No 1768/92 meant the first authorization required under the provisions on medicinal products within the meaning of Council Directive 65/65 (now Directive 2001/83/EC, see SPM3.03.1) and not to authorizations required for legislation on the pricing or reimbursement for medicinal products in a member state (also see SPM15.03).

ARTICLE 21: TRANSITIONAL PROVISIONS

1. This Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before 2 January 1993 or to applications for a certificate filed in accordance with that legislation before 2 July 1992.

With regard to Austria, Finland, and Sweden, this Regulation shall not apply to certificates granted in accordance with their national legislation before 1 January 1995.

2. This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia prior to 1 May 2004 and the national legislation of Romania prior to 1 January 2007.

ARTICLE 22: REPEAL

Regulation (EEC) No 1768/92, as amended by the acts listed in Annex I, is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

ARTICLE 23: ENTRY INTO FORCE

This Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

SPM23.01 The EC Medicinal Regulation was published in the Official Journal of the European Union on 16 June 2009. It therefore entered into force on 6 July 2009.

ANNEX I: REPEALED REGULATION WITH LIST OF ITS SUCCESSIVE AMENDMENTS (referred to in Article 22)

Council Regulation (EEC) No 1768/92 (OJ L 182 2.7.1992, p. 1)

Annex I, point XI.F.I. of the 1994 Act of Accession (OJ C 241 29.8.1994, p. 233)

Annex II, point 4.C.II, of the 2003 Act of Accession (OJ L 236 23.9.2003, p. 342)

Annex III, point 1.II, of the 2005 Act of Accession (OJ L 157, 21.6.2005, p. 56)

Regulation (EC) No 1901/2006 of the European Parliament and of the Council, Only Article 52 (OJ L 378, 27.12.2006, p. 1)

ANNEX II: CORRELATION TABLE

<i>Regulation (EEC) No 1768/92</i>	<i>This Regulation</i>
-	<i>Recital 1</i>
<i>Recital 1</i>	<i>Recital 2</i>
<i>Recital 2</i>	<i>Recital 3</i>
<i>Recital 3</i>	<i>Recital 4</i>
<i>Recital 4</i>	<i>Recital 5</i>

<i>Recital 5</i>	<i>Recital 6</i>
<i>Recital 6</i>	<i>Recital 7</i>
<i>Recital 7</i>	<i>Recital 8</i>
<i>Recital 8</i>	<i>Recital 9</i>
<i>Recital 9</i>	<i>Recital 10</i>
<i>Recital 10</i>	-
<i>Recital 11</i>	-
<i>Recital 12</i>	-
<i>Recital 13</i>	<i>Recital 11</i>
<i>Article 1</i>	<i>Article 1</i>
<i>Article 2</i>	<i>Article 2</i>
<i>Article 3, introductory wording</i>	<i>Article 3, introductory wording</i>
<i>Article 3, point (a)</i>	<i>Article 3, point (a)</i>
<i>Article 3, point (b), first sentence</i>	<i>Article 3, point (b)</i>
<i>Article 3, point (b), second sentence</i>	-
<i>Article 3, points (c) and (d)</i>	<i>Article 3, points (c) and (d)</i>
<i>Article 4 to 7</i>	<i>Article 4 to 7</i>
<i>Article 8(1)</i>	<i>Article 8(1)</i>
<i>Article 8(1a)</i>	<i>Article 8(2)</i>
<i>Article 8(1b)</i>	<i>Article 8(3)</i>
<i>Article 8(2)</i>	<i>Article 8(4)</i>
<i>Article 9 to 12</i>	<i>Article 9 to 12</i>
<i>Article 13(1), (2) and (3)</i>	<i>Article 13(1), (2) and (3)</i>
<i>Article 14 and 15</i>	<i>Article 14 and 15</i>
<i>Article 15a</i>	<i>Article 16</i>
<i>Article 16, 17 and 18</i>	<i>Article 17, 18 and 19</i>
<i>Article 19</i>	-
<i>Article 19a, introductory wording</i>	<i>Article 20, introductory wording</i>
<i>Article 19a, point (a), points (i) and (ii)</i>	<i>Article 20, point (b), introductory wording, points (i) and (ii)</i>

Article 19a, point (b)

Article 19a, point (c)

Article 19a, point (d)

Article 19a, point (e)

Article 19a, point (f)

Article 19a, point (g)

Article 19a, point (h)

Article 19a, point (i)

Article 19a, point (j)

Article 19a, point (k)

Article 19a, point (l)

Article 20

Article 21

Article 22

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Article 23

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Article 20, point (c)

Article 20, point (d)

Article 20, point (e)

Article 20, point (f)

Article 20, point (g)

Article 20, point (h)

Article 20, point (i)

Article 20, point (k)

Article 20, point (l)

Article 20, point (a)

Article 20, point (j)

Article 21

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Article 13(4)

Article 22

Article 23

Annex I

Annex II

REGULATION (EC) NO 1610/96 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (PLANT PROTECTION PRODUCTS)

RECITALS TO THE REGULATION

The European Parliament and The Council of The European Union

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (OJ No C 390, 31.12.1994, p 21 and OJ No C 335, 13.12.1995, p 15)

Having regard to the opinion of the Economic and Social Committee (OJ No C 155, 21.6.1995, p 14),

Acting in accordance with the procedure referred to in Article 189b of the Treaty (Opinion of the European Parliament of 15 June 1995 (OJ No C 166, 3.7.1995, p 89), common position of the Council of 27 November 1995 (OJ No C 353, 30.12.1995, p 36) and decision of the European Parliament of 12 March 1996 (OJ No C 96, 1.4.1996, p 30)),

(1) Whereas research into plant protection products contributes to the continuing improvement in the production and procurement of plentiful food of good quality at affordable prices;

(2) Whereas plant protection research contributes to the continuing improvement in crop production;

(3) Whereas plant protection products, especially those that are the result of long, costly research, will continue to be developed in the Community and in Europe if they are covered by favourable rules that provide for sufficient protection to encourage such research;

(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 (OJ No L 182, 2.7.1992, p. 1.);

(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 authorization 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 penalises 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;

(8) Whereas, in its Resolution of 1 February 1993 (OJ No C 138, 17.5.1993, p. 1.) on a Community programme of policy and action in relation to the environment and sustainable development, the Council adopted the general approach and strategy of the programme presented by the Commission, which stressed the interdependence

of economic growth and environmental quality; whereas improving protection of the environment means maintaining the economic competitiveness of industry; whereas, accordingly, the issue of a supplementary protection certificate can be regarded as a positive measure in favour of environmental protection;

(9) Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to hinder the free movement of plant protection products within the Community and thus directly affect the functioning of the internal market; whereas this is in accordance with the principle of subsidiarity as defined by Article 3b of the Treaty;

(10) Whereas, therefore, there is a need to create a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a plant protection product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;

(11) Whereas the duration of the protection granted by the certificate should be such as to provide adequate, effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the plant protection product in question first obtains authorization to be placed on the market in the Community;

(12) Whereas all the interests at stake in a sector as complex and sensitive as plant protection must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years;

(13) Whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection;

(14) Whereas the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them;

(15) Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community plant protection industry to catch up to some extent with its main competitors, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the agricultural policy and environment protection policy pursued at both national and Community level;

(16) Whereas only action at Community level will enable the objective, which consists in ensuring adequate protection for innovation in the field of plant protection, while guaranteeing the proper functioning of the internal market for plant protection products, to be attained effectively;

(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,

HAVE ADOPTED THIS REGULATION:

SPP0.01 Council Regulation (EEC) No 1768/92 has subsequently been codified under Regulation (EC) No 469/2009 of the European Parliament and of the Council according to Article 22 of which, with reference to an annexed correlation table, all

references to Regulation No 1768/92 are to be construed as references to Regulation (EC) No 469/2009 (see SP0.01, SPM0.04 and Annex II to Regulation (EC) No 469/2009). Articles 3(1)(a) and (c), 5, 6, 8(1)(a)(i) to (iv), 8(2), 9 to 12, 13(1) and (2), 14(a) to (c), 15, 16, 17(1) and 18(2) of Regulation (EC) 1610/96 for plant protection products are identical in wording to Articles 3(a) to (c), 5, 6, 8(1)(a)(i) to (iv), 8(4), 9 to 12, 13(1) and (2), 14(a) to (c), 15, 17, 18 and 19(2) respectively, of Regulation (EC) 469/2009 for medicinal products. For commentary on the said Articles in the Plant Protection Regulation reference should be made to the corresponding paragraphs in SPM3.01 to 19.11 relating to the Medicinal Regulation. For commentary on the Recitals and the remaining Articles of the Plant Protection Regulation the following paragraphs should be consulted as well as the equivalent paragraphs in SPM0.01 to 20.02.

ARTICLE 1: DEFINITIONS

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

1. *"plant protection products": active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:*

(a) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;

(b) influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators);

(c) preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;

(d) destroy undesirable plants; or

(e) destroy parts of plants, check or prevent undesirable growth of plants;

2. *"substances": chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;*

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;

4. *"preparations": mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection products;*

5. *"plants": live plants and live parts of plants, including fresh fruit and seeds;*

6. *"plant products": products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves as defined in point 5;*

7. *"harmful organisms": pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;*

8. *"product": the active substance as defined in point 3 or combination of active*

substances of a plant protection product;

9. *"basic patent": a patent which protects a product as defined in point 8 as such, a preparation as defined in point 4, 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;*

10. *"certificate": the supplementary protection certificate.*

Product and Plant Protection Product

SPP1.01 Article 1 distinguishes between the terms "plant protection product" and "product". Although the EC Plant Protection Regulation creates a certificate for plant protection products, it is the product - defined by Article 1(8) as the active substance or combination of active substances - which is the subject of the certificate pursuant to Article 2. The meaning of "product" was clarified by the European Court of Justice in *BASF AG v Bureau Voor de Industriële Eigendom* [2002] RPC 9. It was held that a "product" as defined by Article 1(8) includes, along with the active substance, any impurity which inevitably results from the manufacturing process of that substance. However, two products which differ only in the proportion of active substance to impurity they contain (one being more pure than the other) are considered to be one and same "product" within the definition of Article 1(8) - the court holding that a product "cannot change solely because of an alteration in the unit quantity of impurities where both the chemical compound it contains and that compound's action on its targets remain unchanged". The fact that, in the case in question, the two products of differing purity required separate marketing authorisations was not relevant in determining whether they amounted to the same "product" within the definition of Article 1. See also SPP3.01.

SPP1.02 The definitions of the terms "plant protection products" to "product" in Article 1(1) to 1(8) are identical to those specified in Article 2 of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. However, these definitions do not always correspond to the terminology used in UK Marketing Authorizations, or the details published in official Gazettes, because Articles 2 and 3(1)(b) of the Plant Protection Regulation allow for the authorization on which the SPC application is based to be either in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national (e.g. United Kingdom) law. Thus, the product specified in the Marketing Authorization is generally broadly equivalent to the "plant protection product" as defined in Article 1(1), and the "active constituent(s)" or "active ingredient(s)" are generally broadly equivalent to the "product" as defined by Article 1(8).

SPP1.03 The term "active substance" in the Plant Protection Regulation is identical in effect to "active ingredient" in the Medicinal Regulation. In accordance with recital (13) the term "active substance" in Article 1(8) is interpreted as including any closely related derivative, in particular a salt or ester, which has obtained authorization to be placed on the market and is protected by the claims of the basic patent.

SPP1.04 If the derivative in question can be regarded as a new and inventive active substance which is protected by a patent which specifically relates to it, e.g. a selection patent, recital (14) allows for the new derivative to be protected by its own certificate in spite of the fact that the non-derivatised form of the active substance and its non-inventive derivatives are the subject of a different certificate.

Basic Patent

SPP1.05 The basic patent may be either a UK patent or a European patent (UK) (see SPM1.05).

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 plant protection product, to an administrative authorization procedure as laid down in Article 4 of Directive 91/414/EEC (OJ L 230, 19.8.1991, p. 1. Directive as last amended by Directive 95/36/EC (OJ L 172, 22.7.1995, p. 8).), or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorization was lodged before Directive 91/414/EEC was implemented by the Member State concerned, may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

SPP2.01 A certificate can be granted in the UK for a product which has received an authorization to be placed on the market in accordance with Directive 91/414/EEC or 95/36/EEC, or with an equivalent provision of national law. The authorization may be granted for the UK only, whereupon it takes the form of an approval issued under the Control of Pesticides Regulations (COPR) 1986 (as amended), or an authorization issued under the UK Plant Protection Product Regulations (UKPPPR) 1995 (as amended), by the Pesticides Safety Directorate of the Ministry of Agriculture, Fisheries and Food. The UKPPPR 1995 implement Directive 91/414/EEC in the UK. COPR is an equivalent provision of national law for the purposes of Article 2. Those plant protection products whose active substance(s) are already on the market in the EC continue to be regulated under UK national legislation under COPR 1986 whose continuation is permitted by virtue of the transitional provisions of EC Directive 91/414/EEC. Those plant protection products that contain active substances new to the Community fall to be regulated under UKPPPR 1995 (which implements EC Directive 91/414/EEC in the UK). Those with a combination of "old" and "new" active substances fall to be regulated under COPR.

SPP2.02 Recital 4 of the EC Plant Protection SPC Regulation states that the level of protection for innovation for plant protection products is to be equivalent to that granted to medicinal products under Regulation 1768/92, a purpose which is reflected in the similarity of wording of the two Regulations. A medicinal product which had obtained a market authorization and/or was marketed prior to 1 January 1985 would not have been granted a supplementary protection certificate because Articles 3(d) and 19 of Regulation (EEC) No 1768/92 effectively dictated that the first authorization had to be after 1 January 1985. It is therefore the view of the Office that a parallel situation must apply to plant protection products so that any marketing authorization or marketing prior to 1 January 1985 will prevent the grant of a certificate. Whereas the marketing of medicinal products has been regulated by statutory authorization schemes throughout the lifetime of all patents likely to give rise to certificates, this is not the case for plant protection products. Prior to 6 October 1986, when the statutory authorization scheme under the COPR entered into force in the UK, it was theoretically possible for applicant to have marketed a plant protection product without authorization under any provision of national law (even though he may voluntarily have delayed marketing to await authorization under the COPR). In practice, the marketing of plant protection products before this date was regulated under voluntary schemes, particularly the Pesticides Safety Precautions Scheme (PSPS). This consisted of a formal agreement between trade associations (eg the British Agrochemicals Association and the British Pest Control Association) and the UK government departments and agencies responsible for agriculture, health and safety. An agrochemical company who was a member of a trade association party to the agreement was required to apply for clearance of any new pesticide that it intended to market; in practice this was automatic, since it appears there was little likelihood of commercial acceptance of a pesticide without PSPS approval. Approval was subject to an administrative procedure involving inspection by government authorities and marketing of the new product was inevitably delayed. It therefore appears that such products fall within the spirit, if not the strict scope, of Article 2 (see SPP19.01 as to their acceptability under Art 19(1)). In consequence, before deciding whether a certificate may be granted for a plant protection product where the basic patent has a filing date between 9 February 1977 (the earliest date allowable under Art 3(1)(a)) and 6 October 1986, the Office may request the following information in addition to the details given on the

application Form SP1:

- whether any authorization under PSPS for the product was obtained, details of the authorization number and date of issue and a copy of the grant document being required;

-whether the product was marketed in the UK prior to 1986 with or without authorization, details of the date of marketing being required;

-whether the applicant was a member of a trade association bound by the PSPS agreement throughout the period from the filing date of the basic patent until 6 October 1986.

(See also SPP19.01.)

ARTICLE 3: CONDITIONS FOR OBTAINING A CERTIFICATE

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

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

(b) a valid authorization 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;

for the purposes of this subparagraph and the Articles which refer to it, an authorization to place the product on the market granted in accordance with the national legislation of the EFTA State shall be treated as an authorization granted in accordance with Directive 91/414/EEC or an equivalent provision of national law of an EC Member State.

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

(d) the authorization referred to in (b) is the first authorization to place the product on the market as a plant protection product.

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.

SPP3.01 The conditions of Article 3 must be satisfied at the date of making an application. Thus, at that date:

- the basic patent protecting the product must be in force;
- the product must not previously have been the subject of a certificate in the UK;
- a valid authorization or approval to place the product on the market in the United Kingdom as a plant protection product must have been granted in accordance with Directive 91/414/EEC or a provision of UK law i.e. the Control of Pesticides Regulations (COPR) 1986 or the UK Plant Protection Product Regulations 1995 (see SPP2.01):
- this authorization must be the first authorization to place the product on the market as a plant protection product in the United Kingdom (although there may

have been an earlier first authorization elsewhere in the EC).

For example, in *BASF AG v Bureau Voor de Industriële Eigendom* [2002] RPC 9 (see SPP1.01), the product in question was a plant protection product manufactured according to a patented process, which resulted in a product of higher purity than previously achieved. A marketing authorisation for this higher purity product was granted in 1987, but marketing authorisation for a lower purity product was granted in 1967. The ECJ held that the higher purity product amounted to the same “product” within the meaning of Article 3 as the lower purity product and so held that in such circumstances the conditions of Article 3(1)(d) were not satisfied.

SPP3.02 Under the Control of Pesticides Regulations 1986 marketing approvals are issued at three progressive levels of approval:

- Experimental permit for supply, storage and use only, for a limited period;
- Provisional approval for sale, supply, storage, use and advertisement for a limited period whilst outstanding data are obtained;
- Full (unlimited) approval for sale, supply, storage, use and advertisement, where there are no outstanding data requirements.

Experimental permits only allow experimental work on new substances or new uses to be carried out over a limited area to produce data in support of a future application for approval for commercial use. Such permits are not acceptable as a basis for making an SPC application under Article 2 or 3(1)(b) as they do not allow marketing to take place. (see also SPM3.03.1). Provisional and full authorizations under COPR both allow marketing of the product from the date of grant thereof and are granted under a relevant provision of national (UK) law equivalent to the administrative authorization procedure as laid down in Article 4 of Directive 91/414/EEC. Consequently both provisional and full UK authorizations are acceptable under Article 3(1)(b). In *Hogan Lovells International (C-229/09)*, the Court of Justice of the European Union confirmed that Article 3(1)(b) of Regulation No 1610/96 is interpreted as meaning that a supplementary protection certificate can be issued for a product in respect of which a provisional MA has been granted under Article 8(1) of Directive 91/414.

SPP3.03 Article 3(2) precludes the granting of more than one certificate for a single product to the holder of a portfolio of related patents all covering the said product, even when the SPC applications are all pending together and meet the requirements of Article 3(1)(c). When the product is protected by several patents held by an applicant e.g. by a patent for the product per se, a patent for a process for making the product and a patent for a plant protection formulation comprising the product, it is for the holder of the patents concerned to choose one of them as the basic patent, bearing in mind that the subject-matter protected by the certificate is constrained by the protection conferred by the patent.

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 authorizations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorized before the expiry of the certificate.

SPP4.01 A certificate extends the protection conferred by the basic patent beyond the term of that patent but only in respect of the product covered by the authorization or approval to place the corresponding plant protection product on the market and any use of the product as a plant protection product that has been authorized or approved before expiry of the certificate. It does not, however, extend the term of the patent itself.

ARTICLE 5: EFFECTS OF THE CERTIFICATE

Subject to 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.

ARTICLE 6: ENTITLEMENT TO THE CERTIFICATE

The certificate shall be granted to the holder of the basic patent or his successor in title.

ARTICLE 7: APPLICATION FOR A CERTIFICATE

1. The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3(1)(b) to place the product on the market as a plant protection product was granted.

2. Notwithstanding paragraph 1, where the authorization 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.

SPP7.01 The requirements to be met with respect to the period for filing an application under the Plant Protection Regulation are identical to those under the Medicinal Regulation (see SPM7.01).

ARTICLE 8: CONTENT OF THE APPLICATION FOR A CERTIFICATE

1. The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

(i) the name and address of the applicant;

(ii) the name and address of the representative, if any;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3(1)(b) and, if this authorization is not the first authorization to place the product on the market in the Community, the number and date of that authorization;

(b) a copy of the authorization to place the product on the market, as referred to in Article 3(1)(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Part A.I (points 1 - 7) or B.I (points 1 - 7) of Annex II to Directive 91/414/EEC or in equivalent national laws of the Member State in which the application was lodged;

(c) if the authorization referred to in (b) is not the first authorization to place the product on the market as a plant protection product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication or, failing such a notice, any other document proving that the authorization has been issued, the date on which it was issued and the

identity of the product authorized.

2. Member States may require a fee to be payable upon application for a certificate.

SPP8.01 The request for grant of a certificate should specify:

- the name and address of the applicant (Section 3 of Form SP1);
- the name of the applicant's agent (if any) and address for service in the European Economic Area or Channel Islands (Section 4);
- the EC Regulation (1768/92 or 1610/96) under which the application is made (Section 5);
- the product in respect of which the certificate is sought (i.e. the active substance or combination of active substances of the plant protection product) (Section 6);
- the number, title, expiry date and (if later than the first UK authorization or approval) the date of grant of the basic patent (Section 7);
- the number and date of the first UK authorization or approval (Section 8);
- (where different from the first UK authorization or approval) the State, number and date of the first authorization in the EC, plus the identity of the authorized product and the legal provision under which the authorization took place (Section 9). The wording of Articles 8(1)(a)(iv) and 8(1)(c) does not appear to require such a first authorization to have been granted in accordance with Directive 91/414/EEC. For applications lodged on or after 1 August 1997, the relevant authorization for the purposes of Articles 8(1)(a)(iv) and 8(1)(c) includes the first authorization in a State which is a Contracting Party to the European Economic Area Agreement (see SP0.09-10).

ARTICLE 9: LODGING OF AN APPLICATION FOR A CERTIFICATE

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 authorization referred to in Article 3(1)(b) to place the product on the market was obtained, unless the member State designates another authority for the purpose.

2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:

- (a) the name and address of the applicant;*
- (b) the number of the basic patent;*
- (c) the title of the invention;*
- (d) the number and date of the authorization to place the product on the market, referred to in Article 3(1)(b), and the product identified in that authorization;*
- (e) where relevant, the number and date of the first authorization to place the product on the market in the Community.*

ARTICLE 10: GRANT OF THE CERTIFICATE OR REJECTION OF THE APPLICATION

- 1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.*
- 2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.*
- 3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.*
- 4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the application shall be rejected.*
- 5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(1)(c) and (d) are met.*

ARTICLE 11: PUBLICATION

- 1. Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9(1). The notification shall contain at least the following information:*
 - (a) the name and address of the holder of the certificate;*
 - (b) the number of the basic patent;*
 - (c) the title of the invention;*
 - (d) the number and date of the authorization to place the product on the market referred to in Article 3(1)(b) and the product identified in that authorization;*
 - (e) where relevant, the number and date of the first authorization to place the product on the market in the Community;*
 - (f) the duration of the certificate.*
- 2. Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9(1). The notification shall contain at least the information listed in Article 9(2).*

ARTICLE 12: ANNUAL FEES

Member States may require the certificate to be subject to the payment of annual fees.

ARTICLE 13: DURATION OF THE CERTIFICATE

- 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 authorization 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.

3. For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorization only if it is directly followed by a definitive authorization concerning the same product.

Provisional first authorization

SPP13.01 During the substantive examination of the application the applicant will generally be requested to provide details of any full authorizations which have followed an acknowledged first provisional authorization so that the provisions of Article 13(3) can be given effect. However, it is considered that Article 13(3) does not prevent the grant of a certificate on the basis of provisional authorizations which allow marketing of the product (see SPP3.02).

ARTICLE 14: EXPIRY OF THE CERTIFICATE

The certificate shall lapse:

(a) at the end of the period provided for in Article 13;

(b) if the certificate-holder surrenders it;

(c) if the annual fee laid down in accordance with Article 12 is not paid in time;

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place it on the market in accordance with Article 4 of Directive 91/414/EEC or equivalent provisions of national law. The authority referred to in Article 9(1) may decide on the lapse of the certificate either on its own initiative or at the request of a third party.

Declaration of lapse under Article 14(d)

SPP14.01 Article 14(d) of the Plant Protection Regulation is equivalent to Article 14(d) of the Medicinal Regulation but refers, naturally, to the relevant Directive 91/414/EEC or equivalent provisions of national (UK) law (see SPM14.02 -08).

ARTICLE 15: INVALIDITY OF THE CERTIFICATE

1. The certificate shall be invalid if:

(a) it was granted contrary to the provisions of Article 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.

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the

revocation of the corresponding basic patent.

ARTICLE 16: NOTIFICATION OF LAPSE OR INVALIDITY

If the certificate lapses in accordance with Article 14(b), (c) or (d) or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9(1).

ARTICLE 17: APPEALS

1. The decisions of the authority referred to in Article 9(1) or of the body referred to in Article 15(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorization to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.

SPP17.01 A decision to grant a certificate is open to appeals seeking to correct the duration of a certificate where the date of the first authorization to place the product on the market in the Community contained in an application is wrong. (See also SPM13.06).

ARTICLE 18: PROCEDURE

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent and, where appropriate, the procedural provisions applicable to the certificates referred to in Regulation (EEC) No 1768/92, shall apply to the certificate, unless national law lays down special procedural provisions for certificates as referred to in this Regulation.

2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

SPP18.01 In the UK procedural and fees provisions are laid down in the 2007 Rules and 2007 Fees Rules. (see SPM19.01-19.03).

ARTICLE 19: TRANSITIONAL PROVISIONS

1. 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 authorization to place it on the market as a plant protection product in the Community was obtained after 1 January 1985 under Article 4 of Directive 91/414/EEC or an equivalent national provision may be granted a certificate.

2. An application made under paragraph 1 for a certificate shall be submitted within six months of the date on which this Regulation enters into force.

ARTICLE 19A: PROVISIONS RELATING TO THE ENLARGEMENT OF THE COMMUNITY

Without prejudice to the other provisions of this Regulation, the following shall apply:

(a) (i) any plant protection product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a plant protection product was obtained in the Czech Republic after 10 November 1999 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained,

(ii) any plant protection product protected by a valid basic patent in the Czech Republic and for which the first authorisation to place it on the market as a plant protection product was obtained in the Community not earlier than six months prior to the date of accession may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained;

(b) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Estonia prior to the date of accession may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or, in the case of those patents granted prior to 1 January 2000, within the six month period provided for in the Patents Act of October 1999;

(c) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Cyprus prior to the date of accession may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained; notwithstanding the above, where the market authorisation was obtained before the grant of the basic patent, the application for a certificate must be lodged within six months of the date on which the patent was granted;

(d) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Latvia prior to the date of accession may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession;

(e) any plant protection product protected by a valid basic patent applied for after 1 February 1994 and for which the first authorisation to place it on the market as a plant protection product was obtained in Lithuania prior to the date of accession may be granted a certificate, provided that the application for a certificate is lodged within six months of the date of accession;

(f) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Hungary, provided that the application for a certificate is lodged within six months of the date of accession;

(g) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Malta prior to the date of accession may be granted a certificate. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession;

(h) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that

the application for a certificate is lodged within six months starting no later than the date of accession;

(i) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Slovenia prior to the date of accession may be granted a certificate, provided that the application for a certificate is lodged within six months of the date of accession, including in cases where the period provided for in Article 7(1) has expired;

(j) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained in Slovakia after 1 January 2000 may be granted a certificate, provided that the application for a certificate was lodged within six months of the date on which the first market authorisation was obtained or within six months of 1 July 2002 if the market authorisation was obtained before that date;

(k) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Bulgaria, provided that the application for a certificate is lodged within six months of the date of accession;

(l) any plant protection product protected by a valid basic patent and for which the first authorisation to place it on the market as a plant protection product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession.

SPP19.01 In contrast to Article 2, Article 19(1) refers to "an equivalent national provision" rather than "an equivalent provision of national law". Consequently it appears that marketing authorizations obtained under voluntary as well as statutory procedures in the UK are acceptable as first authorizations under the transitional provisions of Article 19. The Office therefore takes the view that voluntary authorizations granted under the Pesticides Safety Precautions Scheme from 1 January 1985 until 5 October 1986 satisfy the requirements of Article 19(1). (see also SPP2.02).

ARTICLE 20:

1. In those Member States whose national law did not, on 1 January 1990, provide for the patentability of plant protection products, this Regulation shall apply from 2 January 1998.

Article 19 shall not apply in those Member States.

2. This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia prior to the date of accession.

ARTICLE 21: ENTRY INTO FORCE

This Regulation shall enter into force six months after its publication in the Official Journal of the European Communities.

SPP21.01 The Plant Protection Regulation was published in the Official Journal of the European Communities on 8 August 1996. It therefore entered into force on 8 February

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