INTELLECTUAL PROPERTY OFFICE

Supplementary Protection Certificates

Guide For Applicants

This booklet aims to give a short introduction to the procedures for applying for a Supplementary Protection Certificate in the United Kingdom. It is intended to serve as a guide only and is not an authoritative statement of the law on Supplementary Protection Certificates. It is therefore advisable to seek independent professional advice about any matters covered by this booklet and not to rely on the booklet alone.

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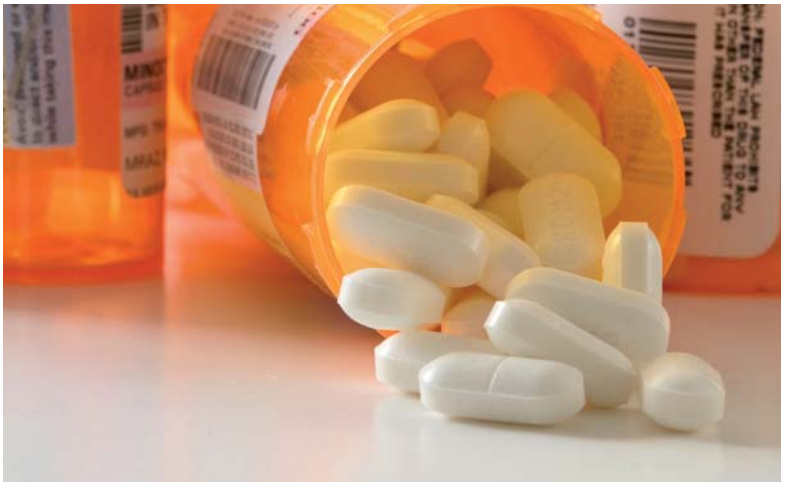

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INTRODUCTION

Legislative framework

1768 Art 23[1]

1.1 Council Regulation (EEC) No 1768/92 created a Supplementary Protection Certificate for medicinal products. It was published in the Official Journal of the European Communities on 2 July 1992, with consequential entry into force on 2 January 1993.

1610 Art 21

1.2 Regulation (EC) No 1610/96 of the European Parliament and of the Council created a Supplementary Protection Certificate for plant protection products. It was published in the Official Journal of the European Communities on 8 August 1996, with consequential entry into force on 8 February 1997.

1.3 The two Regulations (the "EC Regulations") are in broadly similar terms. Except where otherwise indicated, the information in this Guide is applicable to either Regulation.

1901 Art 57

1.4 Council Regulation (EEC) No 1768/92 was amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council to allow for the creation of extensions to the duration of Supplementary Protection Certificates when a medicinal product has been tested for paediatric use. It was published in the Official Journal of the European Communities on 27 December 2006, with consequential entry into force on 27 June 2007.

1.5 The Regulations are directly applicable in all Member States of the EU. However, Supplementary Protection Certificates and their extensions have effect only in the State in which they are granted.

Reg 4

1.6 From the 17 December 2007 the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007 revoked both

[1] In the margin, relevant provisions are identified as follows:
- "Art": An Article in both EC Regulations 1768/92 and 1610/96;
- "1768 Art" or "1610 Art": an Article in Regulation 1768/92 or Regulation 1610/96 only;
- "1901 Art": an Article in Regulation 1901/2006;
- "Reg": a Regulation in the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007
- "Sec" "Para" and "Sch": a Section, a Paragraph or a Schedule in the Patents Act 1977
- "PR rule" "PR Part" and "PR Sch": a Rule, a Part or a Schedule in the Patents Rules 2007; and
- "FR rule" and "FR Sch": a Rule or a Schedule in the Patents (Fees) Rules 2007.

- the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 (SI 1992/3091) (the "1992 Regulations"); and

Reg 2

- the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996 (SI 1996/3120) (the "1996 Regulations").

These 2007 Regulations set out which provisions of the Patents Act 1997 apply to certificates and applications for certificates by inserting Section 128B and Schedule 4A into the Act and provide the legal basis in the Patents Act 1977 for new rules, including those implementing Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use which amended Regulation (EEC) No 1768/92. The Patents Rules 2007 (the "Patents Rules 2007") and the Patents (Fees) Rules 2007 (the "Patents (Fees) Rules 2007") provide the procedures for certificates, as well as for the payment and amount of fees.

PR rule 121(2), PR Sch 7

1.7 With effect from 17 December 2007 the Patents Rules 2007 revoked:

- the Patents (Supplementary Protection Certificates) Rules 1997 (SI 1997/64) (the "1997 Rules").

These 1997 Rules themselves revoked:

- the Patents (Supplementary Protection Certificate for Medicinal Products) Rules 1992 (SI 1992/3162) (the "1992 Rules"); and
- the Patents (Supplementary Protection Certificate for Medicinal Products) (Amendment) Rules 1993 (SI 1993/947).

FR rule 2, FR Sch 1

1.8 In particular, the Patents (Fees) Rules 2007 provide for new versions of the three dedicated Forms[2]:

- SP1 Application for grant;
- SP2 Payment of annual fees; and
- SP3 Application for declaration of lapse or invalidity,

[2] Copies of these Forms are available from the Central Enquiry Unit or may be downloaded from the Office web site http://www.ipo.gov.uk/p-pdfword.htm. A requirement to use any of them is satisfied.

which apply to either type of certificate. The fees for these Forms are unchanged (see paragraphs 2.6 and 4.8, below, respectively). The Patents (Fees) Rules 2007 also provide a new dedicated Form which applies to requests for extensions of applications for certificates or to certificates already granted or applications for certificates under Council Regulation (EEC) No 1768/92:

- SP4 Application for grant of an Extension to a Supplementary Protection Certificate and introduced a fee of £200 for Form SP4.

Art 18

PR rule 4

1.9 In general, where the EC Regulations do not lay down a special procedure for certificates, the procedures under the Patents Act 1977 and its Rules apply to certificates as they do to patents. This means that, for actions not covered by Forms SP1, SP2, SP3 and SP4 the relevant Patents Form should be used and the same fee (if any) paid.

For what is the certificate granted?

Art 2

1.10 Certificates are granted for products which constitute:

1768 Art 1(b)

- the “active ingredient”, or combination of active ingredients, of a “medicinal product”; or

1610 Art 1.8

- the “active substance”, or combination of active substances, of a “plant protection product”.

Art 19(1)

These terms are defined in the appropriate EC Regulation. In general, the product must have received its first authorization to place it on the market as a medicinal product, or its first authorization under Article 4 of Directive 91/414/EEC or an equivalent national provision to place it on the market as a plant protection product, in the Community after 1 January 1985. For medicinal products this date is 1 January 1988 in Denmark, Germany and Finland and 1 January 1982 in Belgium, Italy and Austria. Furthermore, there are additional provisions relating to enlargement of the Community concerning the grant of certificates for medicinal or plant protection products in 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, the Slovak Republic, Bulgaria and Romania.

Art 19a

by the use of a replica (e.g. a photocopy) or of a form which is acceptable to the Comptroller and contains the required information.

1.11 Following the adoption of Regulations 1768/92 and 1610/96 by the Council of the European Economic Area Agreement in July 1994 and July 1997 respectively and the accession of Liechtenstein to the EEA in May 1995, it is understood that

- a "first authorization in the Community" includes a first authorization in Norway, Iceland and Liechtenstein, as well as in the present EU Member States, even though Liechtenstein does not grant Supplementary Protection Certificates; and
- a first authorization in Switzerland, which is effective in Liechtenstein, may count as a "first authorization in the Community".

1768 Art 3(a)
1610 Art 3(1)(a)
1768 Art 1(c)
1610 Art 1.9

1.12 In addition, the product must be protected by a UK patent or European patent (UK) in force (the "basic patent"). The basic patent may protect the product as such, a process to obtain the product or an application of the product. For a plant protection product it may specifically protect a "preparation", defined as a mixture or solution composed of two or more substances, of which at least one is an active substance.

1.13 It should be noted that the term "active ingredient" or "active substance" will generally be 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.

1.14 Apart from the case of such derivatives, a certificate can only cover a single product. Different products will need to be the subject of different certificates, even if they are protected by the same basic patent.

What is an extension of a certificate

1901 Art 8,
Art 36(5)

1.15 An extension of a certificate is granted when an authorized medicinal product which is protected by a certificate or by a patent which qualifies for the granting of a certificate has completed all the studies required in compliance with an agreed paediatric investigation plan and provided that the alternative possible reward has not been applied for and obtained.

Duration of the certificate

Art 13

1.16 A certificate takes effect at the end of the lawful term of the basic patent. Subject to the payment of annual fees (see paragraphs 4.6 to 4.8), the term of a certificate is equal to the period which elapsed between the filing date of the patent and the date of the first authorization in the Community reduced by a period of five years. The term of a certificate may not exceed five years, unless an extension of the certificate has been granted (see paragraph 1.18) in which case the term may not exceed five and a half years.

1610 Art 13(3)

1.17 In determining the duration of a certificate for a plant protection product, account is to be taken of a provisional first marketing authorization, but only if it is directly followed by a definitive authorization for the same product.

Duration of the extension of a certificate

1768 Art 13(3)
1901 Art 36(1)

1.18 An extension of a certificate extends the duration of a certificate by a period of six months.

Protection conferred by the certificate

Art 4

1.19 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 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. It does not extend the term of the patent itself.

Art 5

1.20 Subject to this, 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. Similarly, decisions on certificates are open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

MAKING AN APPLICATION FOR A CERTIFICATE OR AN EXTENSION

Who may apply?

Art 6

2.1 The Regulations are silent as to who may apply for a certificate or an extension. However, a certificate may only be granted to the holder of the basic patent or his successor in title. Where the applicant for a certificate is different from the holder of the basic patent or his successor in title, the Office will inform the patent holder or his successor in title in writing of the filing of the application and invite observations. The extension may also only be granted to the holder of the basic patent or the granted certificate.

Where should the application be made?

Art 9(1)

2.2 An application for a UK certificate or extension must be filed with the Intellectual Property Office irrespective of whether the basic patent is a UK patent or a European patent (UK).

What conditions need to be satisfied for an application for a certificate?

2.3 At the date of making an application, the following conditions must be satisfied in accordance with Article 3 of Regulation 1768/92 or Article 3(1) of Regulation 1610/96, as appropriate:

- the basic patent protecting the product is in force;
- the product has not already been the subject of a certificate;[3]

[3] If a certificate has already been granted for the active ingredient or active substance itself, a new certificate may not be granted to the holder of the granted certificate for one and the same active ingredient or active substance, whatever minor changes may have been made regarding other features of the medicinal or plant protection product (e.g. use of a different salt, a different excipient or a different presentation). See also paragraph 1.13 above. However, in some circumstances it may be possible to grant another certificate to a different patent holder for an active ingredient that is already protected by a certificate

- a valid authorization has been granted to place the product on the market in the United Kingdom in accordance with Directive 65/65/EEC or Directive 81/851/EEC (for a medicinal product)[4] or with Article 4 of Directive 91/414/EEC or an equivalent provision of national law (for a plant protection product); and

- this authorization is the first authorization to place the product on the market in the United Kingdom as a product of the appropriate category (although there may have been an earlier authorization elsewhere in the EU).

When can an extension to a certificate be obtained?

1901 Art 36

2.4 An extension to a certificate can be obtained if a medicinal product which is protected by a certificate or a patent that qualifies for the granting of a certificate is authorized and this authorization includes a statement of compliance with an agreed paediatric investigation plan and that the medicinal product is authorized in all Member States as set out in Article 36 of Regulation (EC) No 1901/2006.

When must the application for the certificate or extension be filed?

Art 7(1)
Art 7(2)

2.5 The application for the certificate must normally also be filed within six months of the date on which the first UK authorization was granted. However, if that authorization was granted before the basic patent, the period of six months runs from the date of grant of the patent[5].

2.6 As noted under paragraph 2.3, the basic patent must be in force at the date of application.

Art 7(3)

2.7 An application for an extension can be filed 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 filed 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.

[4] Directive 65/65/EEC (concerning pharmaceutical products) has been repealed and consolidated with Directive 75/319/EEC into Directive 2001/83/EC, Article 128 of which provides that references to 65/65/EEC shall be interpreted as references to 2001/83/EC. Directive 81/851/EEC (concerning veterinary products) has been repealed and consolidated with Directive 75/319/EEC into Directive 2001/82/EC, Article 96 of which provides that references to 81/851/EEC shall be interpreted as references to 2001/82/EC. Therefore a certificate can be granted in the UK for a medicinal product authorized to be placed on the market in the UK in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

[5] In accordance with Article 97(4) of the European Patent Convention, the date of grant of the European patent is the date the European Patent Bulletin mentions grant. For a UK patent the relevant date of grant would appear to be the date of publication of the notice of grant in the Official Journal (Patents) under Section 24(1) of the Patents Act 1977 (rather than the date of grant under Section 18(4)).

What should the application for a certificate contain?

Art 8
PR rule 116(1)
FR Sch 1
Art 7(4)

2.8 The application for a Supplementary Protection Certificate must be made on Form SP1 and accompanied by the prescribed application fee (currently £250).

Art 7(5)

2.9 Form SP1 should state in particular:

- the name, address and postcode of the applicant (Section 3);
- the name of the applicant's agent, if any (Section 4);
- the address for service in the EEA (Section 4);
- which Regulation the application is made under (Section 5);
- the product in respect of which the certificate is sought (i.e. the active ingredient or active substance, or combination thereof, of the medicinal or plant protection product) (Section 6);
- the number, title, expiry date[6] 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); and
- (where different from the first UK authorization) the State, number and date of the first authorization in the Community, plus the identity of the authorized product and the legal provision under which the authorization took place (Section 9).

2.10 Where more than one "first authorization" is granted in the UK or in the Community on the same day, all these authorizations should be identified at Sections 8 and 9 of Form SP1. The documents identified below at paragraphs 2.9 to 2.13 should be supplied for each such authorization.

Art 9(1)(b)

2.11 Form SP1 should be accompanied by a copy of the first UK authorization. This must identify the product (i.e. the active ingredient(s) or substances(s)). It should also contain the number and date of the authorization and a summary of the product characteristics listed:

[6] As announced in the Official Journal (Patents) of 22 July 1992, it is considered that the full term of a patent expires on the day before the twentieth anniversary of the filing date of the application for the patent.

- for a medicinal product, in Article 4a of Directive 65/65/EEC (pharmaceutical products) or Article 5a of Directive 81/851/EEC (veterinary products); or

- for a plant protection product, in part A.1 (points 1-7) or B.1 (points 1-7) of Annex II to Directive 91/414/EEC or in an equivalent national law.

2.12 It will accordingly normally be necessary to file a complete copy, including any schedules and annexes, of one of the following:

- a Product Licence issued under the Medicines Acts by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health, or by the Veterinary Medicines Directorate (VMD), an executive agency of Defra (see paragraph 2.12 below);

- a Marketing Authorization issued under the Medicines for Human Use (Marketing Authorization &c) Regulations 1994 by the MHRA;

- a Marketing Authorization issued under the Veterinary Medicinal Products Regulations 1994 by the VMD;

- a Marketing Authorization issued by the European Agency for the Evaluation of Medicinal Products (EMEA) under the centralised procedure of Council Regulation (EEC) No 2309/93 providing authorizations which are simultaneously granted in all EU Member States (see paragraph 2.13 below); or

- an authorization issued under the Plant Protection Regulations 1995 (as amended) by the Pesticides Safety Directorate, which is an executive agency of the Department for Environment, Food and Rural Affairs (Defra). (NB: Approvals issued by the Biocides & Pesticides Assessment Unit (BPU), formerly the Pesticides Registration Section (PRS), of the Health and Safety Executive do not generally relate to plant protection products as defined in Regulation 1610/196.)

2.13 Product licences and marketing authorizations in respect of medicinal products usually include a grant document and a separate summary of product characteristics. Other schedules and annexes may also be present.

2.14 Marketing authorizations issued by the EMEA take the form of a Commission Decision incorporating a grant document and various annexes including a summary of product characteristics. The European authorization number to be quoted at Section 8 of Form SP1 is to be found under Article 1 of the grant document and takes the form “EU/1/97/001/001”.

2.15 Authorizations for plant protection products usually consist of a Notice of Approval and a covering letter. Both of these should be filed.

Art 8(1)(c)

2.16 Where the UK authorization above is not the first authorization to place the product on the market in the Community, the application should also be accompanied by a copy of the notice publishing the authorization in the appropriate official gazette, together with a translation if this is not in the English language. If no such notice exists, the applicant should provide the authorization grant document or some other document which proves the fact and date of the issue of the authorization and the identity of the product, e.g. a letter from the foreign licensing authority.

2.17 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 is protected by the basic patent, e.g. by providing an extract from a suitable publication showing the product name used in the application together with its chemical name or structure and indicating how this is protected by a claim in the basic patent.

What should the application for an extension contain?

Art 8 PR rule 116(1) FR Sch 1

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

Art 8

2.19 Form SP4 should state in particular:

- A granted certificate number or certificate application number if these exist (Section 2);
- the name, address and postcode of the applicant (Section 3);
- the name of the applicant’s agent, if any (Section 4);
- the address for service in the EEA (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 or plant protection product) (Section 5);

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

1768 Art 8(1)(d)(i)
1901 Art 36(1)

2.20 Form SP4 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. This should be the statement included in the marketing authorization of the medicinal product.

1768 Art 8(1)(d)(ii)

1901 Art 36(3)

2.21 The application must also contain 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.

1768 Art 8(1b)

2.22 Where the certificate has been granted Form SP4 should state its number and be accompanied by a copy of the granted certificate.

1768 Art 8(1)(d)(ii)

2.23 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.

EXAMINATION OF AN APPLICATION

How will the application be identified?

3.1 Applications for a certificate will be numbered in a single yearly sequence continuing the existing sequence from SPC/GB93/001 and covering both medicinal and plant protection products. This number should be quoted in all subsequent correspondence with the Office. The granted certificate will retain this number. Applications for extensions will also be given the number of the application for a certificate or the granted certificate it will extend as appropriate.

How will an application for a certificate be dealt with?

3.2 The application will be given an initial examination to ensure that the following formal requirements are complied with:

Art 8(2)
- the application is accompanied by the prescribed fee;

Art 7, Art 9
- the application has been filed within the prescribed period;

Art 8(1)
- the application contains the required particulars and documents;

Art 3
- the basic patent is in force.

3.3 The application will also be referred to a substantive examiner to determine whether the following substantive requirements of paragraphs (a) to (c) of Article 3 of Regulation 1768/92 or of Article 3(1) of Regulation 1610/96, as appropriate, were complied with at the date of the application:

- the product was protected by the basic patent;
- a valid authorization to place the product on the market as a medicinal product or a plant protection product had been granted in accordance with the appropriate legal provision;
- the product had not already been the subject of a certificate.

Art 10(5)
1768 Art 3(d)
1610 Art 3(1)(d)

3.4 Unless there appears reason to do so, at present the examiner will not normally investigate whether the authorization specified was in fact the first authorization to place the product on the market in the UK as a medicinal or plant protection product.

3.5 Wherever possible, substantive examination will be carried out at the same time as the initial formalities examination. The examiner will then report all outstanding objections to the applicant in a single letter and ask for any further information that he considers necessary. A period will be specified for reply. Where an application does not contain the required particulars and documents or is not accompanied by the prescribed fee, the applicant will be given an opportunity to rectify the irregularity within a specified period without loss of filing date.

Art10(3)

Sec 21(1), Para 4(1) of Sch4(A)

3.6 Although opposition to the grant of a certificate is not allowed, the examiner will consider any observations made in writing by a third party before grant of a certificate.

How will an application for an extension be dealt with?

3.7 The application will be given an initial examination to ensure that the following formal requirements are complied with:

- the application is accompanied by the prescribed fee;
- the application has been filed within the prescribed period;
- the application contains the required particulars and documents.

3.8 The application will also be referred to a substantive examiner to establish whether, at the date of the application, the application entitles 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:

- the marketing authorization identified includes the required statement indicating that 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.

3.9 Wherever possible, substantive examination will be carried out at the same time as the initial formalities examination and at the same time as the related pending application for a certificate if appropriate. The examiner will then report all outstanding objections to the applicant in a single letter and ask for any further information that he considers necessary. A period will be specified for reply. Where an application does not contain the required particulars and documents or is not accompanied by the prescribed fee, the applicant will be given an opportunity to rectify the irregularity within a specified period without loss of filing date.

3.10 Although opposition to the grant of an extension is not allowed, the examiner will consider any observations made in writing by a third party before grant of an extension.

Grant of a certificate or an extension

Art 10(1)

3.11 When all requirements are met, a certificate will be granted. The certificate will state the date of expiry of the maximum possible period of its duration and will indicate that entry into force is dependent upon the payment of fees.

Art 10(6)

3.12 Similarly, when all the requirements are met, an extension will be granted. If the 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.

Requirements for grant not met

Art 10(2)
Art 10(4)
Art 10(6)Art 17
PR rule 80, 82

3.13 Where any outstanding objections cannot be resolved, the applicant will be entitled to be heard in the matter before the application for a certificate or an extension is rejected. 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.

ENTRY INTO FORCE

Conditions for entry into force

Art 13

4.1 A certificate takes effect at the end of the lawful term of the basic patent provided that:

Art 15

- the basic patent has not previously lapsed or been revoked; and

Art 12
Para 5 of Sch 4A

- the annual fees are paid in time.

Effective period of the certificate

1768 Art 13(3)
1901 Art 36(1)

4.2 The effective period is the maximum period of duration of the certificate, less any period for which the certificate holder does not desire it to have effect. This period will include any extension of duration allowed under Art 13(3) of Regulation (EEC) 1768/92 and Article 36 of Regulation (EC) No 1901/2006.

PR rule 116(5)
1768 Art 13(3)
1901 Art 36(1)

4.3 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 duration under Art 13(3) of Regulation (EEC) 1768/92 and Article 36 of Regulation (EC) No 1901/2006 is allowed.

When are the annual fees payable?

Para 5 of Sch 4A
FR rule 6(5)
PR rule 116(2)(a)

4.4 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.

PR rule 116(2)(b)

4.5 However, where the certificate is granted later than three months before the expiry of the basic patent, the deadline for the payment of annual fees is three months after the grant date of the certificate.

Calculation of annual fees

FR rule 6

4.6 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. For instance, an effective period of 3 years 6 months will require the payment of 4 years' annual fees.

PR rule 116(5)

4.7 It is extremely important to note that the annual fees are payable as a single cumulative amount as a condition of the certificate taking effect. It is not possible for an applicant to opt to pay renewal fees one year at a time on a Supplementary Protection Certificate in the United Kingdom. As noted in paragraph 4.3 above, where the effective period chosen by the applicant for which he requires protection (specified at Section 5 of Form SP2) is less than the maximum allowable period of the certificate, it cannot be subsequently extended. UK Supplementary Protection Certificate practice is therefore different from that of UK patent renewals during the lawful term of the patent and from annual renewal practice for certificates in some other EU states, such as France.

FR rule 6(2)

4.8 The level of the fees is that applying on the date the certificate is due to take effect or, if paid earlier, the actual date of payment. Currently the fees for five successive years are £600, £700, £800, £900 and £1000.

Notification that payment is due

PR rule 116(3)

4.9 The certificate holder will be notified not later than two months before the date on which the fees are payable that payment is due, giving 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 will be sent with the granted certificate.

PR rule 116(8)

4.10 Notification that payment is due will be sent to the address for service provided in respect of the application for the certificate. It will also be sent to the following address, where different:

- (i) the 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
- (ii) where there is no address under (i), the address for service in respect of the basic patent.

Procedure for payment of fees

PR rule 116(5)

4.11 The payment of the total sum of the annual fees for the whole effective period should be accompanied by Form SP2. This Form should state 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 (Sections 4-6).

4.12 The Office will confirm the payment of fees and the date of expiry of the effective period by sending a certificate of payment to the address given in Section 6 of Form SP2. If the holder wished this certificate to be sent to a different address, this should be indicated at Section 8 of Form SP2 and the address given on a separate sheet.

Late payment of fees

PR rule 116(6)(7)

4.13 Where the annual fees are outstanding, the holder of the certificate will be notified within 6 weeks of the due date.

FR rule 6(4)
Para 5(b) of Sch 4A

4.14 Subject to an additional late payment fee of one half of the amount of the unpaid fees, annual fees may be paid up to six months after the due date. The annual fees will then be treated as having been filed on the due date.

What happens if the fees are not paid?

Art 14(c)

4.15 If fees are not paid, the certificate will be treated as having lapsed on the date of expiry of the basic patent and so will not take effect. The Office will notify the holder accordingly and publish a notice to this effect in the Patents Journal (see paragraph 6.1 below).

LAPSE AND INVALIDITY

When will the certificate lapse?

Art 14

5.1 The certificate will lapse:

a) at the end of its effective period;

b) if the holder surrenders it;

c) if the annual fees have not been paid in time; or

d) if and as long as the product covered by the certificate may no longer be placed on the market in the United Kingdom following the withdrawal of the appropriate authorization(s).

Art 14(d)
PR Part 7

5.2 The Comptroller may declare that a certificate has lapsed on the ground set out under (d) above either at the request of any person or on his own initiative. In either case, no declaration will be made without giving the holder of the certificate an opportunity to make observations.

When may the certificate be declared invalid?

Art 15(1)

5.3 A declaration of invalidity may be made if:

a) the certificate was granted contrary to the provisions of Article 3 (see paragraph 2.3 above);

b) the basic patent has lapsed before its full term period; or

c) the basic patent has been revoked or limited (or if, after expiry of its term, grounds exist which would have justified such action) so that the product would no longer be protected by the patent.

Art 15(2)
PR Part 7

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

When may an extension be declared invalid?

1768 Art 15A(1)

5.5 A declaration of invalidity may be made if:

a) the extension was granted contrary to the provisions of Article 36 of Regulation (EC) No 1901/2006.

1768 Art15A(2)

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

Third party applications to the Comptroller for invalidity and lapse

PR rule 4
PR Part 7
FR Sch 1
PR Part 7

5.7 An application to the Comptroller for a decision of lapse under Article 14(d) or a declaration of invalidity under Article 15 should be made on Form SP3. The application should be accompanied by a statement in duplicate setting out fully the grounds and the facts relied on, and the prescribed fee (currently £50). The Comptroller will send a copy of the application and statement to the holder of the certificate or extension.

PR Part 7

5.8 If the holder of the certificate or extension wishes to contest the application, he must file a counter-statement in duplicate setting out his grounds in full. The Comptroller will send a copy of the counter-statement to the applicant and may give directions as he thinks fit with regard to the subsequent procedure.

Art 17

5.9 As in the case of patents, any decision by the Comptroller will be subject to appeal to the Patents Court.

Restoration after lapse under Article 14(d)

Art 14(d)

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

5.11 The certificate-holder should advise the Office of the grant of the new authorization so that notice of the termination of lapse under Article 14(d) can be inserted in the Patents Journal (see paragraph 6.1 below).

PR Part 7

5.12 Any person may apply to the Comptroller for a declaration that the ground for lapse under Article 14(d) no longer exists. There are no formal requirements governing this procedure.

Remission of fees

PR rule 106(5)

5.13 If a certificate is surrendered or is declared invalid, a remission of annual fees may be made for any subsequent effective year(s). Thus, if a certificate having a term of 4 years 3 months (for which five years' fees would have been paid) is surrendered or declared invalid after 3 years 9 months, the fifth year's fee will be refunded on written request by the holder.

5.14 No refund will be 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 (see paragraph 5.8) whereas once surrendered a certificate cannot be reinstated.

PUBLICATION OF PROCEEDINGS

What information will be published?

PR rule 44(7)

6.1 Notification of:

Art 9(2)
Art 9(3)

- application for a certificate or an extension, including information relating to the applicant, basic patent and authorization(s);

Art 11(1)
Art11(3)

- grant, including information relating to the holder of the certificate, basic patent, authorization(s) and duration of a certificate or an extension;

Art 11(2)
Art11(3)

- rejection;
- entry into force;
- expiry under Art 14(a);
- lapse under Article 14(b), (c) or (d) and termination of lapse under Article 14(d); and

Art 16(1)

- declaration of invalidity under Article 15 or Article 15A

Art 16(1)
Art16(2)

will be published in the Patents Journal. These events will also be entered in the Register of Patents. The Register, an electronic version of the Journal and a Supplementary Protection Certificate database which is searchable by SPC or basic patent number may be accessed via http://www.ipo.gov.uk/types/patent/p-os/p-find/p-find-spc.

6.2 No separate publication of either an application for a certificate or an application for an extension, or of a granted certificate or granted extension corresponding to the 'A' and 'B' publications under the Patents Act 1977 will be made.

What documents will be open to public inspection?

PR rule 51

6.3 Documents provided in support of an application for a certificate or an extension, including marketing authorizations, will normally be made open to public inspection after they are filed or sent to the Office.

PR rule 53

6.4 However, within 14 days of filing or sending a document (other than Form SP1, SP2, SP3 or SP4 or a Patents Form), the person filing or any party to the proceedings to which the document relates may request that the document in question should be treated as confidential. A reminder about this is included in Form SP1. The document will not be open to public inspection while the matter is being determined. Adequate reasons for the request, which outweigh the generally overriding public interest for disclosure, are required. Documents which are already in the public domain, e.g. Marketing Authorizations which have been published on the website of the body responsible for their grant, will not be kept confidential.

PR rule 46, 48

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

ANNEX

Frequently asked questions

What is meant at Section 9 on form SP1 by the term “Legal provision under which the authorization took place”?

The legislation under which the foreign authorization was granted should be identified and entered here. For example there may be a Swedish authorization granted under the Medicinal Products Act 1992: 859, in which case “Medicinal Product Act 1992: 859” should be entered in Section 9. This is a requirement of Article 8(1)(c) of the Regulation.

If a UK Marketing Authorization has lapsed or has been withdrawn, does that mean that the Supplementary Protection Certificate will also lapse or have to be withdrawn?

No. The Supplementary Protection Certificate application can still carry on. 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. For example, it may be withdrawn or have lapsed before the date of application for the certificate. Once a certificate has been granted, Article 14(d) provides for the lapse and restoration of a certificate following the withdrawal of the authorization (see paragraphs 5.1-5.2, 5.10-5.12 above).

Can a Supplementary Protection Certificate cover a combination of active ingredients?

Yes, as long as the basic patent and the marketing authorization are for the combination of active ingredients. For a combination of active ingredients A + B, both the basic patent and marketing authorization must be for A + B.

Does a Supplementary Protection Certificate cover a manufacturing process?

No. Although the basic patent may cover a manufacturing process, the SPC will only cover the active ingredient or substance or combination of active ingredients or substances contained in the medicinal or plant protection product (see paragraphs 1.10 and 1.19 above).

Where can I obtain a UK Marketing Authorization?

Marketing Authorizations can be obtained from the Medicines and Healthcare Products Regulatory Agency (MHRA), the Veterinary Medicines Directorate (VMD) or the European Agency for the Evaluation of Medicinal Products (EMEA).

How do I search for Supplementary Protection Certificates on the UK Intellectual Property Office website?

Go to http://www.ipo.gov.uk.
Click on “Online Services” then, under “Online Patents Services”, click on “Find supplementary protection certificates by number”.
Select “SPC Number” or “Patent number” and type in either the SPC number (SPC/GB**/***) or the Patent number (EP******* or GB*******) and click on “Search”.

The Patents Journal can also be searched online for information on Supplementary Protection Certificates. Click on “Online Services” then, under “Online Patents Services”, click on “Searchable Patents Journal” and click on “SPCs” tab.

Can you have more than one certificate, if the product has more than one use? For example if Product X is used to treat cancer and Product X is later discovered to treat diabetes.

No. Even though a separate marketing authorization will be required for Product X (cancer) and Product X (diabetes), the certificate will cover the product for ANY authorized use within the limits of the basic patent.

If the basic patent has more than one holder, could just one of the patent holders apply for a certificate on that basic patent?

Yes. One of the patent holders can apply for a certificate on their own. However, the Office will inform the other patent holders in writing of the filing of the application and invite observations.

Can you apply for a certificate to cover a medical device?

Possibly. Regulation 1768/92 concerning certificates for medicinal products states that a marketing authorization in accordance with Directive 65/65/EEC or 81/851/EEC (now to be interpreted as 2001/83/EC or 2001/82/EC) needs to have been granted in order to obtain a certificate. However, this does not guarantee the certificate will be granted. An important point to consider is whether the medical device essentially incorporates an active substance which can be defined as the product in a suitable way for the certificate and which is authorized in accordance with these directives.

When does a UK patent expire?

It was announced in the Official Journal (Patents) on 22 July 1992 that the full term of a patent is considered to expire on the day before the 20th anniversary of the filing date of the application for the patent.

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