STATUTORY INSTRUMENTS

S.I. No. 307 of 2008

EUROPEAN COMMUNITIES (SUPPLEMENTARY PROTECTION CERTIFICATE) REGULATIONS 2008

(Prn. A8/1180)

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I, MARY COUGHLAN, Minister for Enterprise, Trade and Employment, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), and for the purpose of giving effect to Council Regulation (EEC) No. 1768/92[1], Regulation (EC) No. 1610/96[2] and Regulation (EC) No. 1901/2006[3] hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Supplementary Protection Certificate) Regulations 2008.

2. (1) In these Regulations—

"Act of 1992" means the Patents Act 1992 (No. 1 of 1992), as amended by the Patents (Amendment) Act 2006 (No. 31 of 2006);

"application for an extension of the duration" has the meaning assigned to it in Article 1(*e*) of the Medicinal Regulation as amended by Article 52 of the Medicinal Products for Paediatric Use Regulation;

"certificate" has the meaning assigned to it in Article 1(*d*) of the Medicinal Regulation;

"Controller" means the Controller of Patents, Designs and Trade Marks;

"Medicinal Products for Paediatric Use Regulation" means Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use;

"Medicinal Regulation" means Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, as amended by Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006;

"Plant Protection Regulation" means Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products;

"Regulations of 1993" means the European Communities (Supplementary Protection Certificate) Regulations 1993 (S.I. No. 125 of 1993).

"Rules of 1992" means the Patents Rules 1992 (S.I. No. 179 of 1992).

[1]O.J. No. L182, of 02.07.1992, p. 1
[2]O.J. No. L198, of 08.08.1996, p. 30
[3]O.J. No. L378, of 27.12.2006, p. 1

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 5th August, 2008.

(2) A word or expression used in these Regulations and which is also used in the Medicinal Regulation, the Medicinal Products for Paediatric Use Regulation, or the Plant Protection Regulation has the same meaning in these Regulations as it has in the corresponding Regulation.

3. (1) A request for the grant of a certificate in accordance with the Medicinal Regulation or the Plant Protection Regulation shall be made in the form set out in Schedule 1 and shall be accompanied by the fee prescribed in Schedule 3.

(2) A request for the grant of a certificate in accordance with the Medicinal Regulation or the Plant Protection Regulation shall be accompanied by the documents and information as appropriate, specified in paragraphs 1(*b*) and (*c*) of Article 8, of the corresponding Regulation.

(3) A certificate shall be in the form set out in Schedule 4.

(4) An application for an extension of the duration of a certificate in accordance with the Medicinal Regulation shall be made in the form set out in Schedule 2 and shall be accompanied by the fee prescribed in Schedule 3.

(5) An application for an extension of the duration of a certificate in accordance with the Medicinal Regulation shall be accompanied by the documents and information as appropriate, specified in paragraphs 1(*b*), (*c*) and (*d*) of Article 8 of that Regulation.

(6) An extension of the duration of a supplementary protection certificate shall be in the form set out in Schedule 5.

4. (1) Subject to paragraph (2), in relation to a request for the grant of a certificate or an application for an extension of the duration of a certificate—

(*a*) if the Controller notifies the applicant that it does not comply with a provision of these Regulations, the Medicinal Regulation or the Plant Protection Regulation, and the applicant, within 4 months from the date of the notification, fails to overcome the non-compliance or satisfy the Controller that the provision is complied with, or

(*b*) if the prescribed fee remains unpaid on the expiry of one month from the date of a notification by the Controller that the fee has not been paid,

the Controller shall refuse the request for the grant of a certificate or the application for an extension of the duration of a certificate.

(2) A request for the grant of a certificate or an application for an extension of the duration of a certificate may be reinstated in accordance with the provisions of the Rules of 1992 as if, in the relevant Rule, there were substituted references to a request or an application for reference to an application for a patent.

5. (1) The office referred to in—

(*a*) paragraph 1 of Article 9 of the Medicinal Regulation, and

(*b*) paragraph 1 of Article 9 of the Plant Protection Regulation,

shall be the Patents Office.

(2) A request for the grant of a certificate or an application for an extension of the duration of a certificate shall be submitted to the Controller at the Patents Office.

6. (1) A certificate granted under these Regulations (including a certificate extended under these Regulations) shall be subject to the payment of an annual renewal fee, the amount of which said renewal fee shall be the same as that prescribed under the Rules of 1992 in respect of the 20th year for renewal of a patent.

(2) The provisions of the Act of 1992 and the Rules of 1992 in relation to payment of patent renewal fees shall apply to renewal fees for certificates and extensions and shall operate in relation to certificates and extensions as if the term of the basic patent to which Article 8 of the Medicinal or Plant Protection Regulation refers ran for a further period not exceeding the duration of the certificate or of its extension.

7. The provisions of the Act of 1992 and the Rules of 1992 relating to restoration of lapsed patents shall apply to certificates and extensions to certificates which have lapsed by reason of failure to pay any renewal fee.

8. The notifications referred to in the following provisions:

(*a*) paragraphs 2 and 3 of Article 9 of the Medicinal Regulation;

(*b*) Article 11 of the Medicinal Regulation;

(*c*) Article 16 of the Medicinal Regulation;

(*d*) paragraphs 1 and 2 of Article 11 of the Plant Protection Regulation;

(*e*) paragraph 2 of Article 9 of the Plant Protection Regulation; and

(*f*) Article 16 of the Plant Protection Regulation,

shall be published in the Patents Office Journal.

9. (1) The Controller shall cause the following matters to be entered in the Register of Patents—

(*a*) the fact that a request for the grant of a certificate has been filed,

(*b*) the fact that a request for the grant of a certificate has been granted and the duration thereof,

(*c*) rejection of a request for the grant of a certificate,

(*d*) withdrawal of a request for the grant of a certificate,

(*e*) payment of the annual renewal fee for a certificate,

(*f*) lapse of a certificate through non-payment of a renewal fee or the reasons specified in paragraphs (*b*) and (*d*) of Article 14 of the Medicinal Regulation or the Plant Protection Regulation as appropriate,

(*g*) the fact that a certificate which lapsed due to the non-payment of a renewal fee has been restored,

(*h*) any termination of the grounds for lapse of a certificate as provided for under Article 14(*d*) of the Medicinal Regulation or the Plant Protection Regulation as appropriate,

(*i*) the invalidity of a certificate as provided for under Article 15(*a*) of the Medicinal Regulation or Article 15 of the Plant Protection Regulation as appropriate.

(2) In this Regulation—

"a request for the grant of a certificate" includes an application for an extension of the duration of a certificate,

"certificate" includes a certificate extended under these Regulations.

10. An application for a declaration of invalidity of a certificate or a certificate as extended under these Regulations may be made to the Controller or the High Court.

11. Wherever a procedure in relation to a certificate, a request for the grant of a certificate, a certificate as extended under these Regulations or an application for an extension of the duration of a certificate is not laid down in these Regulations, the Medicinal Regulation or the Plant Protection Regulation, the procedures of the Act of 1992 and the Rules of 1992 in relation to patents and patent applications shall, in the corresponding circumstances, apply.

12. (1) The fees prescribed under the Act of 1992 in respect of any proceeding in relation to patents and patent applications shall (with the exception of the fee specified in Schedule 3) apply in the corresponding circumstances in relation to certificates, requests for the grant of certificates, certificates as extended under these Regulations and applications for extensions.

(2) The payment of fees under these Regulations shall be made in accordance with Rule 89 of the Rules of 1992.

13. (1) The Regulations of 1993 are revoked.

(2) Notwithstanding paragraph (1), a certificate issued under the Regulations of 1993 that was in force immediately prior to the commencement of these Regulations shall, after the commencement of these Regulations, continue to operate as if it were a certificate under these Regulations.

Regulation 3.

SCHEDULE 1

REQUEST
for the grant of a
SUPPLEMENTARY PROTECTION CERTIFICATE

The Applicant(*s*) named herein hereby request(*s*) the grant of a Supplementary Protection Certificate on the basis of the information furnished hereunder:

❒ Medicinal Product

❒ Plant Protection Product

1. APPLICANT(S)

Name:

Address:

Nationality/Description:

2. NUMBER OF THE BASIC PATENT

3. TITLE OF THE INVENTION

4. MARKET AUTHORISATION

(i) The following information relates to the first authorisation to place the product, the subject of this request, on the market in Ireland:—

Authorisation Number:

Authorisation Date:

Identity of product thus authorised:

Legal provision under which such Authorisation took place:

(ii) If the information at (i) does not relate to the first authorisation to place the product, the subject of this request, on the market in the EU, please state:—

Country which granted the first such Authorisation:

Authorisation Number(*s*):

Authorisation Date:

Identity of product thus authorised:

Legal provision under which such Authorisation took place:

5. PRODUCT IDENTITY (as defined in Article 1 of Council Regulation (EEC) No. 1768/92 or Regulation (EC) No. 1610/96)

(i) Product (i.e. active ingredient or combination of active ingredients) for which a certificate is requested:

(ii) Information to satisfy the Controller that the product at 5(i) above is protected by the basic patent identified at 2 above:

6. ITEMS ACCOMPANYING THIS REQUEST — tick as appropriate.

(i) ❒ Request fee:— € _____

(ii) ❒ Copy of the authorisation specified in Article 8 1(b) of the corresponding Regulation in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC, Article 5a of Directive 81/851/EEC or Article 4 of Directive 91/414/EEC

(iii) ❒ Where appropriate, the information and a copy of the notice specified in Article 8 l(c) of the corresponding Regulation.

7. AUTHORISED AGENT

The following is authorised to act as agent in all proceedings connected with the obtaining of a supplementary protection certificate to which this request relates and in relation to any certificate granted:

Name:

Address:

8. ADDRESS FOR SERVICE (if different from that at item 7)

Signed on behalf of Applicant(*s*):

By: _____

Date: _____

(Note: this Request may be signed by the Applicant(*s*) or by the Agent authorised in connection with the basic patent. It may also be signed by another Agent provided an authorisation in favour of that Agent is submitted within 3 months after the filing of this Request).

Regulation 3.

SCHEDULE 2

APPLICATION

for an

EXTENSION of the DURATION

of a

SUPPLEMENTARY PROTECTION CERTIFICATE

The Applicant(*s*) named herein hereby request(*s*) the grant of an extension to the duration of a Supplementary Protection Certificate on the basis of the information furnished hereunder:

1. APPLICANT(S)

Name:

Address:

Nationality/Description:

2. SPC application no. to which the request relates:—

(i) where an SPC application is pending or has been granted, the application no. of the SPC:

(ii) where an SPC application no. has not yet been issued by the Patents Office, any reference no. and the date upon which the relevant SPC application was made:

3. NUMBER OF THE BASIC PATENT

4. TITLE OF THE INVENTION

5. PRODUCT IDENTITY (as defined in Article 1 of Council Regulation (EEC) No. 1768/92)

Product (i.e. active ingredient or combination of active ingredients) for which a certificate is requested:

6. ITEMS ACCOMPANYING THIS REQUEST — tick as appropriate.

(i) ❒ Request fee:- € _____

(ii) ❒ 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.

(iii) ❒ Proof of authorisation(s) to place the product on the market of all Member States, as referred to in Article 36(3) of Regulation (EC) No. 1901/2006.

7. AUTHORISED AGENT

The following is authorised to act as agent in all proceedings connected with the application for the grant of an extension of the duration of a supplementary protection certificate to which this request relates and in relation to any extension of the certificate granted:

Name:

Address:

8. ADDRESS FOR SERVICE (if different from that at item 7)

Signed on behalf of Applicant(*s*):

By: _____

Date: _____

(Note: this Request may be signed by the Applicant(*s*) or by the Agent authorised in connection with the basic patent. It may also be signed by another Agent provided an authorisation in favour of that Agent is submitted within 3 months after the filing of this Request).

Regulation 3.

SCHEDULE 3

Fee payable upon filing of a request for the grant of a certificate	€95.00
Fee payable upon filing of an application for an extension of the duration of a certificate	€95.00

SCHEDULE 4 *Regulation 3.*

SUPPLEMENTARY PROTECTION CERTIFICATE

Council Regulation (EEC) No. 1768/92 or Regulation (EC) No. 1610/96

In accordance with Article 10(1) of the relevant Regulations above,

Certificate no. .....

is granted to.....

in respect of the product.....

which is protected by patent no. .....which was granted

for an invention entitled.....

This certificate will expire on.....

Dated this.....day of.....20...

Controller of Patents, Designs and Trade Marks

Regulation 3.

SCHEDULE 5

EXTENSION OF THE DURATION

OF A

SUPPLEMENTARY PROTECTION CERTIFICATE

Council Regulation (EEC) No. 1768/92 as amended by Article 52 of Regulation (EC) No. 1901/2006

In accordance with Article 10(1) of the above Regulation, this Extension

is granted to.....

in respect of the product.....

which is protected by patent no. ..... which was granted

for an invention entitled .....

.....

and which has been granted a Supplementary Protection Certificate no. ..... in respect of the abovementioned product.

This extension will expire on.....

Dated this.....day of.....20...

Controller of Patents, Designs and Trade Marks.

L.S.

GIVEN under my Official Seal,
25 July 2008

MARY COUGHLAN
Minister for Enterprise, Trade and Employment.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These regulations lay down the fees and procedural requirements which apply to requests for supplementary protection certificates and to requests for extensions of the duration of supplementary protection certificates and to certificates granted and to extensions of the duration of certificates granted. The regulations are for the purpose of giving full effect to Council Regulation (EEC) No. 1768/92, Regulation (EC) No. 1610/96 and Regulation (EC) No. 1901/2006 concerning the creation of a supplementary protection certificate for medicinal products, and for plant protection products and the creation of an extension of the duration of a supplementary protection certificate for medicinal products for paediatric use with effect from 26th July 2008. (These regulations revoke the earlier Statutory Instrument No. 125 of 1993 concerning requests for and the grant of supplementary protection certificates. These regulations provide that a certificate issued under the Regulations of 1993 and in force immediately prior to the entry into force of these regulations shall, after the commencement of these regulations continue to operate as if it were a certificate under these regulations).

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,
CONTAE MHAIGH EO,
(Teil: 01 - 6476834/37 nó 1890 213434; Fax: 01 - 6476843 nó 094 - 9378964)
nó trí aon díoltóir leabhar.

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