EUROPEAN COMMUNITIES (SUPPLEMENTARY PROTECTION CERTIFICATE) REGULATIONS, 1993.

STATUTORY INSTRUMENTS.

(Pl. 9807)

S.I. No. 125 of 1993.

I, RUAIRI QUINN, Minister for Enterprise 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] hereby make the following Regulations:

1.—

(1) These Regulations may be cited as the European Communities (Supplementary Protection Certificate) Regulations, 1993.

(2) These Regulations shall be deemed to have come into operation on the 2nd day of January, 1993.

2.—

(1) In these Regulations—

"the Act of 1992" means the Patents Act, 1992 (No. 1 of 1992);

"certificate" has the meaning assigned to it in Article 1 (d) of the EC Regulations;

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

"the Court" means the High Court;

"the EC Regulation" means Council Regulation (EEC) No. 1768/92;

"the Journal" means the Patents Office Journal;

"the Register" means the Register of Patents;

"the Rules of 1992" means the Patents Rules, 1992 (S.I. No. 179 of 1992), and any rules amending or in substitution for those Rules;

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 25th June, 1993.

(2) A word or expression used in these Regulations and which is also used in the EC Regulation has the same meaning as in the EC Regulation.

3.—

(1) A request for the grant of a certificate in accordance with the EC Regulation shall be made in the form set out in the First Schedule to these Regulations and it shall be accompanied by the fee prescribed in the Second Schedule to these Regulations.

(2) A request shall be accompanied by the documents and information as appropriate, specified in Article 8, paragraph 1 (b) and (c) of the EC Regulations.

4.—

(1) Subject to paragraph (2) of this Regulation, in relation to a request—

(*a*) if the Controller notifies the applicant that it does not comply with a provision of these Regulations or the EC Regulation and the applicant, within 4 months from the date of the

[1] O.J. No. L182/1.

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.

(2) A request may be reinstated in accordance with the provisions of Rule 99 of the Rules of 1992 as if, in that Rule, there were substituted references to a request for reference to an application for a patent.

5.—

(1) The office referred to in Article 9, paragraph 1, of the EC Regulation shall be the Patents Office.

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

6. A certificate shall be in the form set out in the Third Schedule to these Regulations.

7.—

(1) The grant of a certificate 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 shall operate in relation to certificates as if the term of the basic patent to which Article 8 of the EC Regulation refers ran for a further period not exceeding the duration of the certificate.

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

9. The notifications referred to in the following provisions of the EC Regulation—

(*a*) paragraph 2, Article 9,

(*b*) paragraphs 1 and 2, Article 11,

(*c*) Article 16,

shall be published in the Journal.

10. The Controller shall cause the following matters to be entered in the Register—

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

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

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

(*d*) withdrawal of a request for 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 (*b*) and (*d*) of Article 14 of the EC Regulation,

(*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 under Article 14 (*d*) of the EC Regulation,

(*i*) the invalidity of a certificate (Article 15 of the EC Regulation).

11. An application for a declaration of invalidity of a certificate may be made to the Controller or the Court.

12. Wherever a procedure in relation to a certificate or an application for a certificate is not laid down in these Regulations or the EC 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 to certificates and applications for certificates.

13.—

(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 the Second Schedule to these Regulations) apply in the corresponding circumstances in relation to certificates and applications therefor.

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

FIRST SCHEDULE

Regulation 3

REQUEST for the grant of a SUPPLEMENTARY PROTECTION CERTIFICATE (Medicinal Products)

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

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 No. .....

Authorisation Date .....

(ii) If the information at (i) does not relate to the first authorisation to place the produce, the subject of this request, on the market in the European Community, please state

Country which granted the first such Authorisation.....

Authorisation No. .....

Authorisation Date .....

Identity of product thus authorised:

Legal provision under which such Authorisation took place:

5. *Product Identity*

(i) Name, brand or trade name or other description by which the product for which a certificate is requested is commonly known:

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

6. *Items accompanying this Request — tick as appropriate*

(i) Reques t fee.

(ii) Copy of the authorisation specified in Article 8 1.(b) of the EC 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 or Article 5a of Directive 81/851/EEC.

(iii) Where appropriate, the information and a copy of the no tice specified in Article 8 1.(c) of the EC 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 7)

Signed on behalf of Applicants(s):

(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.)

Date:

SECOND SCHEDULE

Regulation 3

	£
Fee payable upon filing of a request for a certificate	75.00

THIRD SCHEDULE

Regulation 6

SUPPLEMENTARY PROTECTION CERTIFICATE

Council Regulation (EEC) No. 1768/92

In accordance with article 10 (1) of the above Regulation, this Certificate

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 19

Controller of Patents, Designs and Trade Marks

GIVEN under my Official Seal this 5th day of May, 1993.

RUAIRI QUINN,
Minister for Enterprise 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 certificates granted. The regulations are for the purpose of giving full effect to Council Regulation (EEC) No. 1768/92 concerning the creation of a supplementary protection certificate for medicinal products with effect from 2nd January, 1993.