#### STATUTORY INSTRUMENTS

## 1992 No. 3162

## The Patents (Supplementary Protection Certificate for Medicinal Products) Rules 1992

### PART II

#### PROVISIONS RELATING TO ARTICLES 4 TO 18 OF THE EC REGULATION

#### Application and fee in respect of application (Article 8 and 9(1))

- 3.—(1) The application for a certificate shall be—
  - (a) subject to the payment to the Patent Office of a prescribed fee; and
  - (b) lodged with the Patent Office accompanied by the prescribed fee.
- (2) A request for the grant of a certificate shall be made on Form SP1.

#### **Certificate of grant (Article 10)**

4. A certificate shall be in the form set out in Schedule 3 to these Rules.

#### Fees in respect of effective period of certificate (Article 12)

5.—(1) A reference in this rule to—

- (a) "due date" means the date on which a certificate, subject to the requirement to pay fees, would take effect at the end of the lawful term of the basic patent; and
- (b) "maximum period" means the maximum possible period of duration of a certificate as determined in accordance with Article 13.

(2) A certificate shall not take effect, and its actual duration shall not be determined, until payment is made of the fees prescribed in accordance with paragraphs (3) to (10) below.

(3) Subject to paragraph (9), the amount of fees payable in order for a certificate to take effect in respect of any period ("the appropriate fees") shall be the amount calculated by reference to the length of the maximum period, less, if any, such period deducted from the end of the maximum period during which it is desired by the holder of a certificate that the certificate shall not have effect, the resulting period, whether reduced from the maximum period or not, being referred to hereafter as the "effective period".

(4) The appropriate fees payable in respect of any effective period shall be the cumulative amount of fees prescribed—

(a) by reference to the successive twelve month periods of which an effective period is made up (any period of less than twelve months being treated as a twelve month period of which that lesser period forms part); the first such period shall commence on the due date ("the first year"); the second shall commence immediately upon expiry of the first ("the second year"), with corresponding provision in respect of each successive year up to a maximum of five years ("the fifth year") which years shall be referred to herein generally as "effective years", and

(b) in respect of each of the effective years, by the prescribed fees in force-

(i) where payment is made before the due date, on the date on which payment is made;

(ii) in any other case, on the due date.

(5) Subject to paragraphs (7) and (9), the appropriate fees in respect of an effective period shall be paid not later than the due date but may not be paid earlier than three months preceding the due date.

(6) Without prejudice to the provisions of paragraphs (2) and (5), the comptroller shall write to the holder of a certificate not later than two months before the due date—

- (a) notifying him of the due date;
- (b) indicating the prescribed fees applicable in respect of each of the effective years of which the maximum period of the certificate is made up; and
- (c) specifying the period within which fees must be paid to the Patent Office in order for the certificate to take effect;

and the holder of the certificate shall, within the period specified under paragraph (c), notify the Patent Office on Form SP2 of the effective period of the certificate, which notification shall be accompanied by the appropriate fees payable in respect of that period.

(7) Where a certificate is granted later than three months before the end of the lawful term of the basic patent, the provisions of paragraphs (5) and (6) shall be modified as follows—

- (a) the due date for the purposes of payment of the appropriate fees shall be the date three months after the date of grant of the certificate; and
- (b) the comptroller shall write to the applicant for the certificate in the terms prescribed by paragraph (6), subject to subparagraph (a) of this paragraph, on the date on which he notifies him of the grant thereof.

(8) Where the effective period is less than the maximum period of the certificate it shall not subsequently be extended.

(9) Where the period for payment of fees under paragraph (5) or (7), as the case may be, has expired—

- (a) the comptroller shall, not later than six weeks after the applicable due date and if the fees remain unpaid, notify the holder of the certificate—
  - (i) that the fees remain unpaid; and
  - (ii) of the consequences of non-payment; and
  - (iii) of the provisions of subparagraph (b);
- (b) the holder, subject to the payment within a period of six months after the applicable due date of the unpaid fees and an additional late payment fee of an amount equal to one half of the amount of the unpaid fees, shall be treated as having paid the fees on the applicable due date.
- (10) The notices under paragraphs (6) and (9) of this rule shall be sent by the comptroller to—
  - (a) the address for service furnished in writing by the applicant for a certificate or any address replacing it, and,
  - (b) in relation to the basic patent in respect of which the certificate is granted, where it differs from the address referred to in subparagraph (a),
    - (i) the address in the United Kingdom to which any renewal reminder is to be sent as specified by the proprietor on payment of the last renewal fee or any address replacing it, or

(ii) where no such address is specified, the address for service (if any) entered in the register of patents.

6. If the certificate is surrendered or declared invalid on or with effect from a date earlier ("the earlier date") than the date of expiry of the effective period, where the appropriate fees in respect of that period have been paid, the comptroller shall remit the fee paid in respect of any effective year which falls after the end of the effective year (if any) into which the earlier date falls.

#### Declaration of lapse or invalidity of certificate (Articles 14(d) and 15(1)(a) and (c))

7.—(1) On the application of any person, the comptroller may, as the case may be, declare—

- (a) that a certificate has lapsed on the ground set out in Article 14(d); or
- (b) that the ground for lapse under Article 14(d) no longer exists.

(2) The court or the comptroller may declare that a certificate is invalid in accordance with the provisions of Article 15.

(3) An application to the comptroller for a declaration under paragraph (1)(a) or paragraph (2) shall be made on Form SP3 and shall be accompanied by a copy thereof and a statement in duplicate setting out fully the facts upon which the applicant relies and the relief which he seeks.

(4) The comptroller shall send a copy of the application and the statement to the holder of the certificate.

(5) Within the period of two months beginning on the date on which such copies are sent to him, the holder of the certificate shall, if he wishes to contest the application, file a counter-statement in duplicate at the Patent Office setting out fully the grounds on which the application is contested; and the comptroller shall send a copy of the counter-statement to the applicant.

(6) No further statement or counter-statement shall be served by either party without the leave or direction of the comptroller.

(7) The comptroller may give such directions as he may think fit with regard to the subsequent procedure.

**8.** If it appears to the comptroller that a certificate has lapsed in accordance with Article 14(d) he may on his own initiative declare that the certificate has lapsed but shall not do so without giving the holder of the certificate notice of his intention to make such a declaration and affording him an opportunity to make representations within two months of the date of the notice.

#### Forms for use in connection with certificates and applications for certificates (Article 18(1))

**9.** Those forms of which use is required by any provision of the 1977 Act or any rules made thereunder in relation to patents or applications for patents, except where replaced by the forms set out in Schedule 2 to these Rules, shall also be used, with the necessary changes, in the corresponding circumstances in relation to certificates or applications for certificates.

# Publication of: application, grant of certificate, rejection of application, declaration of lapse or of invalidity or of termination of grounds of lapse of certificate (Articles 9(2), 11(1) and (2) and 16)

- 10. Notification of-
  - (a) the application for a certificate;
  - (b) the fact that a certificate has been granted;
  - (c) the fact that the application for a certificate has been rejected;
  - (d) lapse of a certificate;

- (e) invalidity of a certificate;
- (f) termination of grounds for lapse of a certificate under Article 14(d),

shall be published by the comptroller in the journal.