STATUTORY INSTRUMENTS

1997 No. 64

PATENTS

The Patents (Supplementary Protection Certificates) Rules 1997

Made - - - -	*16th January 1997*
Laid before Parliament	*17th January 1997*
Coming into force - -	*8th February 1997*

The Secretary of State, in exercise of the powers conferred by section 123 of, and paragraph 14 of Schedule 4 to, the Patents Act 1977(**1**), of the power conferred upon him by the Department of Trade and Industry (Fees) Order 1988(**2**), and of all other powers enabling him in that behalf, after consultation with the Council on Tribunals pursuant to section 8(1) of the Tribunals and Inquiries Act 1992(**3**) and with the consent of the Treasury pursuant to subsection (4) of the said section 123, hereby makes the following Rules:

PART I

GENERAL

Citation, commencement and extent

1.—(1) These Rules may be cited as the Patents (Supplementary Protection Certificates) Rules 1997 and shall come into force on 8th February 1997.

(2) These Rules extend to Great Britain and Northern Ireland.

Interpretation

2.—(1) In these Rules—

"the 1977 Act" means the Patents Act 1977;

(**1**) 1977 c. 37; the power of the Secretary of State to make rules in respect of patents under section 123 of the Patents Act 1977 was extended by the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 (S.I.1992/3091) and the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996 (S.I. 1996/3120) so as to apply to supplementary protection certificates. Section 123 was amended by the Copyright, Designs and Patents Act 1988 (c. 48), section 295 and Schedule 5, paragraph 29.

(**2**) S.I. 1988/93, as amended by S.I. 1990/1473, which was made under section 102 of the Finance (No.2) Act 1987 (c. 51). The relevant provisions of that Order are article 7 and part IV of Schedule 1.

(**3**) 1992 c. 53.

"the EC Regulations" means the medicinal product Regulation and the plant protection product Regulation and any reference in these Rules to an Article followed by a number is a reference to the Article so numbered in the relevant Regulation;

"the medicinal product Regulation" means Council Regulation (EEC) No. 1768/92 of 18th June 1992 concerning the creation of a supplementary protection certificate for medicinal products, a copy of the English language version of which is set out in Part 1 of Schedule 1 to these Rules(**4**);

"the plant protection product Regulation" means Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23rd July 1996 concerning the creation of a supplementary protection certificate for plant protection products, a copy of the English language version of which is set out in Part 2 of Schedule 1 to these Rules(**5**);

"the relevant Regulation" means the EC Regulation under which the application for a supplementary protection certificate is made or such a certificate is granted;

"basic patent" has the meaning assigned to it by—

(i) paragraph (c) of Article 1 of the medicinal product Regulation; or

(ii) paragraph (9) of Article 1 of the plant protection product Regulation,

whichever is the relevant Regulation;

"certificate" has the meaning assigned to it by—

(i) paragraph (d) of Article 1 of the medicinal product Regulation; or

(ii) paragraph (10) of Article 1 of the plant protection product Regulation,

whichever is the relevant Regulation;

"the comptroller" and "the journal" have the same meanings as they have in the 1977 Act;

"the court" has the same meaning as it has in the 1977 Act; and

"register of patents" means the register of patents maintained pursuant to section 32 of the 1977 Act.

(2) Subject to paragraph (3), the forms of which the use is required by these Rules are those set out in Schedule 2 to these Rules.

(3) A requirement under these Rules to use such a form is satisfied by the use either of a replica of that form or of a form which is acceptable to the comptroller and contains the information required by the form set out in Schedule 2 to these Rules.

(4) The fees to be paid in respect of any matter arising under these Rules shall be those (if any) prescribed in relation to such matter in Schedule 4 to these Rules; and any reference to"prescribed fee" and "fees" in these Rules shall be construed accordingly.

PART II

PROVISIONS RELATING TO ARTICLES 4 TO 18 OF THE EC REGULATIONS

Application and fee in respect of application (Articles 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.

(**4**) OJ No. L182, 2.7.92, page 1.
(**5**) OJ No. L198, 8.8.96, page 30.

(2) An application 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 Part 1 or Part 2 of 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 any 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—

(i) subject to payment of the prescribed fee, and

(ii) made on Form SP3, and

(iii) accompanied by a copy thereof and a statement in duplicate setting out fully the grounds and 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.

Transitional provisions

11. Rule 7(3)(i) and (iii) shall apply only to applications under rule 7(1)(a) and (2) made on or after 8th February 1997.

Revocations

12. The Patents (Supplementary Protection Certificate for Medicinal Products) Rules 1992(**6**) and the Patents (Supplementary Protection Certificate for Medicinal Products) (Amendment) Rules 1993(**7**) are hereby revoked.

(**6**) S.I. 1992/3162.
(**7**) S.I. 1993/947.

Ian Taylor,
Parliamentary Under-Secretary of State for Science and Technology,
14th January 1997 Department of Trade and Industry

We consent to the making of these Rules

Roger M. Knapman,
Bowen Wells
Two of the Lords Commissioners of Her
16th January 1997 Majesty's Treasury

SCHEDULE 1 Rule 2(1)

PART 1

COUNCIL REGULATION (EEC) NO. 1768/92 OF 18TH JUNE 1992 CONCERNING THE CREATION OF A SUPPLEMENTARY PROTECTION CERTIFICATE FOR MED ICINAL PRODUCTS

THE COUNCIL OF THE EUROPEAN COMMUNITIES

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

Having regard to the proposal from the Commission(**8**).

In cooperation with the European Parliament(**9**).

Having regard to the opinion of the Economic and Social Committee(**10**).

Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;

Whereas 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;

Whereas 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;

Whereas this situation leads to a lack of protection which penalises pharmaceutical research;

Whereas the current situation is creating the risk of research centres situated in the Member States relocating to countries that already offer greater protection;

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 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;

Whereas, therefore, the creation 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; whereas a Regulation is therefore the most appropriate legal instrument;

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 medicinal product in question first obtains authorization to be placed on the market in the Community;

Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account, whereas, for this purpose, the certificate cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product;

(**8**) OJ No. C114, 8.5.1990, p. 10.
(**9**) OJ No. C19, 28.1.1991, p. 94 and OJ No. C150, 15.6.1992.
(**10**) OJ No. C69, 18.3.1991, p. 22.

Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community pharmaceu tical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and Community level;

Whereas the transitional arrangements applicable to applications for certificates filed and to certificates granted under national legislation prior to the entry into force of this Regulation should be defined;

Whereas special arrangements should be allowed in Member States whose laws introduced the patentability of pharmaceutical products only very recently;

Whereas 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;

HAS ADOPTED THIS REGULATION:

ARTICLE 1

Definitions

For the purpose of this Regulation:

(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 medical 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 defined in (b) 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.

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 Council Directive 65/65/EEC(**11**) or Directive 81/851/EEC(**12**) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

(**11**) OJ No. L22, 9.12.1965, page 369. Last amended by Directive 89/341/EEC (OJ No. L142, 25.5.1989, p. 11).
(**12**) OJ No. L317, 6.11.1981, p. 1. Amended by Directive 90/676/EEC (OJ No. L373, 31.12.1990, p. 15).

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 65/65/EEC or Directive 81/851/EEC, as appropriate;

(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 medicinal product.

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.

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.

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(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.

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 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;

(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 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.

2. Member States may provide that a fee is to be payable upon application for a certificate.

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.

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 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 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.

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.

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 that the certificate 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.

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 65/65/EEC or Directive 81/851/EEC. 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.

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

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.

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 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.

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 medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.

In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

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

ARTICLE 20

This Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before the date on which this Regulation enters into force or to applications for a certificate filed in accordance with that legislation before the date of publication of this Regulation in the *Official Journal of the European Communities*.

ARTICLE 21

In those Member States whose national law did not on 1 January 1990 provide for the patentability of pharmaceutical products, this Regulation shall apply five years after the entry into force of this Regulation.

Article 19 shall not apply in those Member States.

ARTICLE 22

Where a certificate is granted for a product protected by a patent which, before the date on which this Regulation enters into force, has had its term extended or for which such extension was applied for, under national patent law, the term of protection to be afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years.

FINAL PROVISION

ARTICLE 23

Entry into force

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

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

Done at Luxembourg, 18 June 1992.

For the Council

The President

Vitor MARTINS

PART 2

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

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(**13**),

Having regard to the opinion of the Economic and Social Committee(**14**),

Acting in accordance with the procedure referred to in Article 189b of the Treaty(**15**),

(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(**16**);

(**13**) OJ C 390, 31.12.1994, p. 21 and OJ C 335, 13.12.1995, p. 15.
(**14**) OJ No C 155, 21.6.1995, p. 14.
(**15**) Opinion of the European Parliament of 15 June 1995 (OJ C 166, 3.7.1995, p. 89), common position of the Council of 27 November 1995 (OJ C 353, 30.12.1995, p. 36) and decision of the European Parliament of 12 March 1996 (OJ C 96, 1.4.1996, p. 30).
(**16**) 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(**17**) 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**) OJ No C 138, 17.5.1993, p. 1.

(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:

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 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.

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(**18**), 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.

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;

(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.

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.

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.

(**18**) 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).

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.

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 refered 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.

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 refered 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.

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.

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.

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.

TRANSITIONAL PROVISIONS

Article 19

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 20

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.

FINAL PROVISION

Article 21

Entry into force

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

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

Done at Brussels, 23 July 1996.

For the European Parliament

The President

K. HÄNSCH

For the Council

The President

M. LOWRY

SCHEDULE 2 RULE 2(3)

GENERAL FORMS

Form SP1

Patents (Supplementary Protection Certificates) Rules 1997

The Patent Office

SP1

Application for grant of a Supplementary Protection Certificate

(See the notes on the back of this form. You can also get an explanatory booklet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference

2. Certificate application number
(The Patent Office will fill in this part)

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

ADP number *(if you know it)*

4. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

ADP number *(if you know it)*

5. Are you applying for a certificate under
(a) the EC Regulation for medicinal products (No. 1768/92)?
(b) the EC Regulation for plant protection products (No. 1610/96)?
(Answer by writing (a) or (b))

6. What is the product that you want to protect?

(Identify the active ingredient(s) or active substance(s). If possible use chemical or generic names)

7. Number, title and expiry date of the basic patent (GB or EP(UK)). If the patent was granted after the date of authorization at 8 below, give the patent grant date also.

Number

Title

Expiry date *(day/month/year)*

Grant Date *(day/month/year)*

(The expiry date is the day before the 20th anniversary of the filing date)

Form SP1

Form SP1

8. Number and date of the first authorization to place the product on the market in the UK *(Articles 3 and 8(1) (b) of the EC Regulations)*	Number	Date *(day/month/year)*
9. Where the authorization at 8 is not the first authorization to place the product on the market in the Community, give the information requested about the first such authorization *(Article 8 (1)(c) of the EC Regulations; see also note (d) below)*	State and Number Identify of the product authorized Legal provision under which the authorization took place	Date *(day/month/year)*
10. If you are filing any of the following documents, state which *(Answer by writing (a)-(e) as appropriate)* (a) Copy of a UK authorization at 8 above *(Article 8(1)(b) of the EC Regulations)* (b) Notice publishing authorization at 9 above *(Article 8(1)(c) of the EC Regulations)* (c) Verified translation of (b) if not in English (d) Information showing that the product is protected by the basic patent (e) Other *(please specify)*		
11. I/We request the grant of a certificate on the basis of this application.	Signature	Date
12. Name and daytime telephone number of person to contact		

Reminder

Documents relating to an application for a certificate will normally be open to public inspection. If you want us to keep copies of any documents such as marketing authorizations (or parts of them) confidential, you must ask for this within 14 days of filing or sending the document. You must give reasons for your request.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.

d) In some cases, an authorization in a state which is not an EU Member State, but is a party to the European Economic Area Agreement, may constitute the first authorization in the Community. Please refer to the Patent Office's explanatory booklet (as updated from time to time by notices in the Official Journal (Patents)) for further information. This explains the effect of a first authorization in Switzerland in relation to Liechtenstein.

e) Once you have filled in the form you must remember to sign and date it.

f) For details of the fee and ways to pay please contact the Patent Office.

Form SP2

Patents (Supplementary Protection Certificates) Rules 1997
(Rule 5)

The Patent Office

SP2

Payment of annual fees (and additional fee for late payment)

(See the notes on the back of this form)

The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference

2. Certificate number

3. Full name of the or of each certificate holder

4. When are or were the annual fees due?

5. What period do you want the certificate to be effective for?

6. Amount of annual fees

   Amount of late payment fee

   Total amount paid

7. Name, address and postcode of the person paying the fee

   ADP number *(if you know it)*

8. Normally, we will send a certificate that the fees have been paid to the address at 7 above. If you want us to send this to a different address, give the name, address and postcode here

9. Name and daytime telephone number of person to contact

Form SP2

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) For details of fees and ways to pay, please contact the Patent Office.

Form SP2

Form SP3

Patents (Supplementary Protection Certificates) Rules 1997
(Rule 7)

The Patent Office

SP3

Application for declaration of lapse or invalidity

(See the notes on the back of this form.)

The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference

2. Certificate number

3. Full name of the or of each certificate holder

4. Your full name, address and postcode

   ADP number *(if you know it)*

5. Is this application for:
   (a) A declaration of lapse under Article 14(d) of the EC Regulation for medicinal products (No. 1768/92)?
   (b) A declaration of invalidity under Article 15 of the EC Regulation for medicinal products (No. 1768/92)?
   (c) A declaration of lapse under Article 14(d) of the EC Regulation for plant protection products (No. 1610/96)?
   (d) A declaration of invalidity under Article 15 of the EC Regulation for plant protection products (No. 1610/96)?
   (answer by writing (a), (b), (c) or (d))

6. Name of your agent *(if you have one)*

   "Address for service" in the United Kingdom to which all correspondence should be sent
   (including the postcode)

   ADP number *(if you know it)*

7. Signature Date

8. Name and daytime telephone number of person to contact

Form SP3

Form SP3

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500504.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s) of the form. Any continuation sheets should be attached to this form.

d) You must file this form in duplicate.

e) You must also file two copies of a statement in which you should set out

- *the grounds for a declaration*
- *the full facts which you rely on*
- *what you want the Office to decide*

f) Once you have filled in the form you must remember to sign and date it.

g) For details of fee and ways to pay, please contact the Patent Office.

Form SP3

SCHEDULE 3 Rule 4

CERTIFICATE

PART 1

"EEC REGULATION NO: 1768/92SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCT

In accordance with Article 10(1) of the above Regulation,
Supplementary Protection Certificate No .....
is hereby granted to .....
in respect of the product .....
protected by basic patent no .....
entitled.....

This certificate will take effect (subject to the payment of the prescribed fees) at the end of the lawful term of the basic patent and its maximum period of duration in accordance with Article 13 will expire on ..... subject to the provisions of Articles 14 and 15.

Dated this ..... day of ..... 19....

Comptroller-General of Patents,
Designs and Trade Marks.

PART 2

"EC REGULATION NO: 1610/96SUPPLEMENTARY PROTECTION CERTIFICATE FOR PLANT PROTECTION PRODUCT

In accordance with Article 10(1) of the above Regulation,
Supplementary Protection Certificate No .....
is hereby granted to .....
in respect of the product .....
protected by basic patent no .....
entitled.....

This certificate will take effect (subject to the payment of the prescribed fees) at the end of the lawful term of the basic patent and its maximum period of duration in accordance with Article 13 will expire on ..... subject to the provisions of Articles 14 and 15.

Dated this ..... day of ..... 19....

Comptroller-General of Patents,
Designs and Trade Marks.

SCHEDULE 4 Rule 2(4)

FEES

Number of corresponding Supplementary Protection Certificate Form	Item	Amount £
SP1	Application for grant of certificate under Article 8 and rule 3	250
SP2	Annual fees under Article 12 and rule 5:	
	for first year or part thereof	600
	for second year or part thereof	700
	for third year or part thereof	800
	or fourth year or part thereof	900
	for fifth year or part thereof	1,000
SP3	Application for declaration of lapse or invalidity under Articles 14 or 15	50

EXPLANATORY NOTE

(This note is not part of the Rules)

Council Regulation (EEC) No. 1768/92 (a copy of which is set out in Part 1 of Schedule 1 to these Rules) created, and set out the conditions relating to applications for and the grant of, a supplementary protection certificate for medicinal products. Such a certificate, when granted, extends the protection afforded by a patent ("the basic patent") in respect of a medicinal product covered by it for a period which extends to a period not more than five years from the date when it takes effect.

Regulation (EC) No. 1610/96 of the European Parliament and of the Council (a copy of which is set out in Part 2 of Schedule 1 to these Rules) creates, and sets out the conditions relating to applications for and the grant of, a supplementary protection certificate for plant protection products and takes effect on 8th February 1997. Such a certificate extends to plant protection products, protection of a kind similar to the certificate granted in respect of medicinal products, subject to similar conditions.

Both Regulations are directly applicable in the United Kingdom and have effect so that any certificate granted under them confers the same rights and is subject to the same limitations and obligations as the basic patent; the decisions of the comptroller taken in respect of the certificate are open to the same appelas as those provided against similar decisions taken in respect of patents and, in the absence of specific procedural provisions in the Regulations or national laws, the procedural provisions applicable to the corresponding basic patent are to apply to the certificate.

These Rules revoke and substantially re-enact the Patents (Supplementary Protection Certificate for Medicinal Products) Rules 1992 (for general changes see below) and also make provision for the supplementary protection certificate for plant protection products, to the extent that both EC Regulations enable Member States to make provision for the procedure applicable to certificates (in so far as the procedure is to differ from the procedure applicable to patents and applications for patents) (Article 18) and for the payment, and the amount, of fees (Articles 8(2) and 12).

Provision is additionally made:

(i) for an application to the Comptroller for a declaration of lapse or invalidity of a certificate to be subject to payment of a fee of £50 (rule 7);

(ii) in the case of such an application, requiring the statement accompanying it to also set out fully the grounds upon which the applicant relies (rule 7);

(iii) for new forms (Schedule 2).

A compliance cost assessment is available, copies of which have been placed in the libraries of both Houses of Parliament. Copies are available also from the Legal Division, Patents and Designs Directorate, the Patent Office, Newport, Gwent, NP9 1RH.