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**To:** <scit.mail@wipo.int>  
**Date:** Fri, Jun 16, 2000 5:55 PM  
**Subject:** Ref: C. SCIT 2505

Herr Wittig,

Please find attached the response of the United Kingdom Patent Office to the; Survey on the grant and publication of supplementary protection certificates for medicinal and phytopharmaceutical products or equivalent industrial property rights (SPCs). This document has been attached with the file name <scit2505.wpd>.

In reply to questions 6, 8 & 11 reference is made to an excerpt from "The Patents & Designs Journal" of the UK Patent Office. The page concerning SPC's and the front page of a recent edition of this publication are attached under the file name <examples.wpd>.

Both documents have been saved in the WordPerfect version 8 format.

Paper copies of both documents will follow by post. If you encounter any difficulties with this submission or require any further information please do not hesitate to contact me.

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Survey on the grant and publication of supplementary protection certificates for medicinal and phytopharmaceutical products or equivalent property rights (SPC's)

**Ref:** C. SCIT 2505

### Answers of the UK Patent Office

**Question 1: Does your Office grant "supplementary protection certificates" for medicinal products or equivalent industrial property rights (SPCs) that extend the validity of patents covering medicinal, pharmaceutical, agrochemical or cognate products and phytopharmaceutical products?**

(a) In the field of medicinal products

Yes

No **U**

(b) In the field of phytopharmaceutical products

Yes

No **U**

**Question 2: Will your Office start granting SPCs in the future?**

*Not applicable*

**Question 3: Please, specify the legal basis for granting SPCs (national law, regional regulation, etc.).**

(a) In the field of medicinal products

*Regional Regulation EEC No. 1768/92*

(b) In the field of phytopharmaceutical products

*Regional Regulation EC No. 1610/96*

**Question 4: Please specify the name of the SPC granted by your Office.**

(a) In the field of medicinal products

*Supplementary protection certificate*

(b) In the field of phytopharmaceutical products

*as in part a*

10 May 2000 No. 5791



# THE PATENTS AND DESIGNS JOURNAL

**Application Numbers:** GB 0006435.2 - GB 0007067.2  
**Publication Numbers:** GB 2343353 - GB 2343605

**Price £12.25**

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## Proceedings under EC Regulations 1768/92 and 1610/96 (Supplementary Protection Certificates for Medicinal Products and Plant Protection Products, respectively)

These entries include details of all proceedings relating to Supplementary Protection Certificates. Applications for Supplementary Protection Certificates are numbered in a single yearly sequence commencing SPC/GB93/001 covering both medicinal and plant protection products and the same number is retained for the granted certificate. Proceedings are open to public inspection but the granted certificate is not separately published.

The entries are grouped in categories according to the type of proceedings. Within each category the entries are arranged in alphabetical order according to the name of the applicant for, or holder of, the certificate and provide the following information; the name and address of the applicant or holder; the product in respect of which the certificate has been applied for or granted; the product type; ie. "Medicinal" or "Plant Protection"; the number and date of the first authorisation under Directive 65/65/EEC or Directive 81/851/EEC to place the product on the market as a medicinal product in the United Kingdom or the number and date of the first authorisation under Article 4 of Directive 91/414/EEC or an equivalent provision of national law to place the product on the market as a plant protection product in the United Kingdom; where relevant, the country; number and date of the first authorisation to place the product on the market in the European Community; the number and title of the basic UK patent or European patent (UK) which protects the product; and the number of the application or certificate.

The entries will also state as appropriate: the filing date of the application; the date of grant or rejection of the application; the maximum period of the granted certificate; the effective period of the certificate on entry into force; and the date of lapse or invalidity of the certificate.

There follows three examples of entries under these proceedings. The first relates to a new application for a certificate based on a European patent designating the United Kingdom and having first authorisation of the product in the United Kingdom. The second example relates to a certificate granted based, once again, on a European patent designating the United Kingdom but with the first product authorisation in the EEC in Denmark. The third refers to a certificate entering into force based on a United Kingdom patent with first product authorisation in the EEC in Belgium.

### SPCs EXPIRED

S.A. Nycomed Christiaens N.V.

Chaussee de Gand, 615, B-1080 Brussels, Belgium

**Product:** 3-Isopropylcarbamsylsulphonamide-4-(3'-methyl)-phenylaminopyridine (Torasemide), optionally in the form of a physiologically compatible salt

**Product Type:** Medicinal

**Authorised:**

UK 0075/0073	26 April 1994
UK 0075/0074	26 April 1994
UK 0075/0075	26 April 1994
UK 0075/0076	26 April 1994
UK 0075/0077	26 April 1994
UK 0075/0079	26 April 1994

### Example 1: Applications for Certificates Filed

- (71) Ohmeda Pharmaceutical Products Division Inc.  
110 Allen Road, Liberty Corner, NJ 07938 USA
- (95) **Product:** 2-(Difluoromethoxy)-1,1,1,2-tetrafluoroethane ("Desflurane")
- Product Type:** Medicinal
- (92) **Authorised:** UK 0022/0120 19 July 1993
- (68) **Patent No:** EP(UK) 0285237 (54) 2-(Difluoromethoxy)-1,1,1,2-tetrafluoroethane as an anaesthetic
- (21) SPC/GB93/175 (22) **Lodged:** 24 December 1993

### Example 2: Certificates Granted

- (73) Aktiebolaget Hassle  
Karagatan 5, S-431 83 Molndal, Sweden
- (95) **Product:** Felodipine
- Product Type:** Medicinal
- (92) **Authorised:** UK 0017/0235-0236 15 November 1993
- (93) DK 6499 21 January 1988
- (68) **Patent No:** EP(UK) 0007293 (54) 2,6-dimethyl-4-(2,3-dichlorophenyl)-1,4-dihydropyridine-3,5-dicarboxylic acid-3-methyl ester-5-ethyl ester having hypotensive properties, process for its preparation and pharmaceutical preparations containing it.
- (11) SPC/GB93/134 **Date Granted:** 14 January 1994
- (94) **Maximum period expires:** 20 January 2003

### Example 3: Certificates entered into force

- (73) American Cyanamid Company  
Burden Avenue, Township of Wayne, State of New Jersey 06904, United States of America
- (95) **Product:** Felbinac (4-biphenyl acetic acid)
- Product Type:** Medicinal
- (92) **Authorised:** UK 0095/0119 28 October 1988
- (93) BE 536 1S 91 F 7 21 June 1988
- (68) **Patent No:** GB 1402691(54) Compositions of 4-Biphenyl Acetic Acid
- (11) SPC/GB93/151 (24) **Date entered into force** 7 September 1993
- (94) **Effective period expires** 6 September 1998

BE 914S359F3 01 October 1985  
BE 914S360F12 01 October 1985

**Patent:** GB 1477664, Pyridine derivatives

**SPC/GB94/017** **Date Expired:** 13 April 2000

**Question 5: Please specify for which fields of technology or which products an SPC can be obtained (for example, medicinal products, phytopharmaceutical products, herbicides, agro-chemicals, all products subject to regulatory approval for marketing, etc.).**

*Products placed on the market as a medicinal product subject to authorisation in accordance with directives 65/65/EEC or 81/851/EEC and;*

*Products placed on the market as plant protection products subject to authorisation in accordance with Article 4 of Directive 91/414/EEC*

**Question 6: Does your Office publish or intend to publish the receipt of an application for an SPC?**

(If "Yes," please attach specimen of a front page of an SPC and/or of announcements regarding SPCs made in an Official Gazette.)

(a) In the field of medicinal products

Yes  *See Example 1 in the photocopied pages from the Patents and Designs Journal*

No **U**

(b) In the field of phytopharmaceutical products

Yes  *See Example 1 in the photocopied pages from the Patents and Designs Journal*

No **U**

**Question 7: If your reply to question 6 is "Yes," please indicate the minimum elements a publication must contain:**

(a) In the field of medicinal products

(i) number allotted to receipt of the application

(ii) date of said receipt

(iii) name and address of the applicant

(iv) number of the basic patent

(v) title of the invention

(vi) number of any authorization to place the product on the market, including the product identified in that authorization

*the number(s) and date(s) of the first authorisation in the UK and the first authorisation in the community are quoted. The medicinal product is not identified.*

(vii) date of the said authorization

(viii) other elements (please specify)

*The product name and product type (ie. Medicinal or Plant protection)*

(b) In the field of phytopharmaceutical products

*as in part a*

**Question 8: Does your Office publish or intend to publish the fact that an SPC has been granted?**

*(If "Yes," please attach specimen of a front page of an SPC and/or of announcements regarding the grant of SPCs made in an Official Gazette.)*

(a) In the field of medicinal products

*See Example 2 in the photocopied pages from the Patents and Designs Journal*

(b) In the field of phytopharmaceutical products

*See Example 2 in the photocopied pages from the Patents and Designs Journal*

**Question 9: If your reply to question 8 is "Yes," please indicate the minimum elements a publication must contain:**

(a) In the field of medicinal products

(i) registration number allotted to the granted SPC

(ii) date of registration of the granted SPC

(iii) name and address of the holder of the SPC

(iv) number of the basic patent

(v) title of the invention

(vi) number of any authorization to place the product on the market, including the product identified in that authorization

*the number(s) and date(s) of the first authorisation in the UK and the first authorisation in the community are quoted. The medicinal product is not identified.*

(vii) date of the said authorization

(viii) duration of the SPC

(ix) other elements, e.g., patent classification, product name (please specify):

*Product name and product type (ie. Medicinal or Plant protection)*

(b) In the field of phytopharmaceutical products

*as in part a*

**Question 10: In which form does your Office make or intend to make the publications referred to in questions 6 and 8?**

(a) In the field of medicinal products

(i) As regards applications for SPCs

- (a) as part of an Official Gazette?
- (b) by publishing the application?
- (c) by laying the application open to public inspection?
- (d) through online databases (or the Office's Web site)?
- (e) by copy delivery of the application on request?

(ii) As regards granted SPCs

- (a) as part of an Official Gazette?
- (b) by publishing the SPC?
- (c) by laying the SPC open to public inspection?
- (d) through online databases (or the Office's Web site)?
- (e) by copy delivery of the SPC on request?

(b) In the field of phytopharmaceutical products

(i) As regards applications for SPCs

- (a) as part of an Official Gazette?
- (b) by publishing the application?
- (c) by laying the application open to public inspection?
- (d) through online databases (or the Office's Web site)?
- (e) by copy delivery of the application on request?

(ii) As regards granted SPCs

- (a) as part of an Official Gazette?
- (b) by publishing the SPC?
- (c) by laying the SPC open to public inspection?
- (d) through online databases (or the Office's Web site)?
- (e) by copy delivery of the SPC on request?

**Question 11: If your Office enters or intends to enter data from the documents relating to SPCs in online databases (internal or commercial ones), please indicate the names(s) of the databases(s) and specify the bibliographic data elements:**

(a) In the field of medicinal products

(i) name(s) of database(s)

*RSPC, this is the internal database for SPC's which has been made available on the patent office web site*

*URL: <http://webdb2.patent.gov.uk/rspc/>*

(ii) bibliographic data elements

*as in Examples 1 & 2*

(b) In the field of phytopharmaceutical products

*as in part a*

**Question 12: If your Office allots or intends to allot specific application and/or registration numbers to SPCs, please give details:**

(a) As regards medicinal products

(i) concerning the numbering system for applications for SPCs

*SPC's are identified SPC/GB/, followed by the two digit year and the case number. The case numbers are ordered chronologically by the application date beginning with 001 for the first application of the calendar year, eg SPC/GB/99/001 was the first application received last year.*

(ii) concerning the numbering system for registrations or grants of SPCs  
(if different from (a)(i))

*There is no change to the application number to signify that the application has been granted*

(b) As regards phytopharmaceutical products

*Phytopharmaceutical products and medicinal products are not differentiated in the numbering scheme.*

**Contact details:**

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[End of Questionnaire]