

Country

IRELAND (IE)

QUESTIONNAIRE

ON THE GRANT AND PUBLICATION OF "SUPPLEMENTARY PROTECTION CERTIFICATES" FOR MEDICINAL AND PHYTOPHARMACEUTICAL PRODUCTS OR EQUIVALENT INDUSTRIAL PROPERTY RIGHTS (SPCs)

Important Remarks

1. The survey published in 1997 concerned only "Supplementary Protection Certificates" for medicinal products or equivalent industrial property titles of protection, but not the "Supplementary Protection Certificates" for phytopharmaceutical products.
2. This questionnaire aims at updating the 1997 survey and at including the industrial property titles of protection for phytopharmaceutical products.
3. In order to facilitate the updating of the said survey and the inclusion of information on phytopharmaceutical products, appropriate entries have been added. For the purposes of the survey, medicinal products and phytopharmaceutical products are both covered by the abbreviation "SPCs."
4. The survey will be made available through the WIPO Web site and will be kept up to date. For this purpose, you are kindly requested to inform the International Bureau of any change in the applicable legislation in your country.
5. Offices not covered by the previous survey are kindly requested to provide information as available.
6. If your Office participated in the previous survey and there are no changes, please indicate "no change."
7. Please, refer to Part 7.2.1 of the WIPO "Handbook on Industrial Property Information and Documentation" when responding to the following questions:

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
- (b) In the field of phytopharmaceutical products
- Yes

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

- (a) In the field of medicinal products
- N/A
- (b) In the field of phytopharmaceutical products
- N/A

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

- (a) In the field of medicinal products
- (1) Laws
- Council Regulation (EEC) No. 1768/92 of 18 June 1992
 - European Communities (Supplementary Protection Certificate) Regulations 1993 (S.I. 125 of 1993)
- (2) Decrees, ordinances
- (3) Other

- (b) In the field of phytopharmaceutical products
 - (1) Laws
 - Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996
 - (2) Decrees, ordinances
 - (3) Other

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
 - Supplementary Protection Certificate

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.).

- **Medicinal Product**
 - as defined in Council Regulation (EEC) No. 1768/92 of 18 June 1992
- **Plant Protection Product**
 - as defined in Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996

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
- (b) In the field of phytopharmaceutical products
 - Yes

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 **(YES)**
 - (ii) date of said receipt **(YES)**
 - (iii) name and address of the applicant **(YES)**
 - (iv) number of the basic patent **(YES)**
 - (v) title of the invention **(YES)**
 - (vi) number of any authorization to place the product on the market, including the product identified in that authorization **(YES – Irish market authorization, and, where relevant, the number and date of the first authorization to place the product on the market in the Community)**
 - (vii) date of the said authorization **(YES)**
 - (viii) other elements (please specify)

- (b) In the field of phytopharmaceutical products
 - (i) number allotted to receipt of the application **(YES)**
 - (ii) date of said receipt **(YES)**
 - (iii) name and address of the applicant **(YES)**
 - (iv) number of the basic patent **(YES)**
 - (v) title of the invention **(YES)**
 - (vi) number of any authorization to place the product on the market, including the product identified in that authorization **(YES – Irish market authorization, and, where relevant, the number and date of the first authorization to place the product on the market in the Community)**

(vii) date of the said authorization **(YES)**

(viii) other elements (please specify)

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 **(YES)**
- (b) In the field of phytopharmaceutical products **(YES)**

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 **(YES – No special registration number is allotted. The number of the application for an SPC is used.)**
 - (ii) date of registration of the granted SPC **(YES)**
 - (iii) name and address of the holder of the SPC **(YES)**
 - (iv) number of the basic patent **(YES)**
 - (v) title of the invention **(YES)**
 - (vi) number of any authorization to place the product on the market, including the product identified in that authorization **(YES – Irish market authorization, and, where relevant, the number and date of the first authorization to place the product on the market in the Community)**
 - (vii) date of the said authorization **(YES)**
 - (viii) duration of the SPC **(YES – duration identified by the date of expiry of the maximum period)**
 - (ix) other elements, e.g., patent classification, product name (please specify): **(where necessary, notification of the fact that the application has been rejected is also published)**

-)
- (b) In the field of phytopharmaceutical products
 - (i) registration number allotted to the granted SPC **(YES – No special registration number is allotted. The number of the application for an SPC is used.)**
 - (ii) date of registration of the granted SPC **(YES)**
 - (iii) name and address of the holder of the SPC **(YES)**
 - (iv) number of the basic patent **(YES)**
 - (v) title of the invention **(YES)**
 - (vi) number of any authorization to place the product on the market, including the product identified in that authorization **(YES – Irish market authorization, and, where relevant, the number and date of the first authorization to place the product on the market in the Community)**
 - (vii) date of the said authorization **(YES)**
 - (viii) duration of the SPC **(YES – duration identified by the date of expiry of the maximum period)**
 - (ix) other elements, e.g., patent classification, product name (please specify): **(where necessary, notification of the fact that the application has been rejected is also published)**

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? **(YES)**

- (b) by publishing the application? **(NO)**
- (c) by laying the application open to public inspection? **(YES)**
- (d) through online databases (or the Office's Web site)?
 - **Certain details are entered on the *PTOLEMY* database under the register entry for the corresponding basic patent – register entry is viewable on our public search system**
- (e) by copy delivery of the application on request? **(YES)**

- (ii) As regards granted SPCs
 - (a) as part of an Official Gazette? **(YES)**
 - (b) by publishing the SPC? **(NO)**
 - (c) by laying the SPC open to public inspection? **(YES)**
 - (d) through online databases (or the Office's Web site)?
 - **Certain details are entered on the *PTOLEMY* database under the register entry for the corresponding basic patent – register entry is viewable on our public search system**
 - (e) by copy delivery of the SPC on request? **(YES)**

- (b) In the field of phytopharmaceutical products
 - (i) As regards applications for SPCs
 - (a) as part of an Official Gazette? **(YES)**
 - (b) by publishing the application? **(NO)**
 - (c) by laying the application open to public inspection? **(YES)**
 - (d) through online databases (or the Office's Web site)?
 - **Certain details are entered on the *PTOLEMY* database under the register entry for the corresponding basic patent – register entry is viewable on our public search system**
 - (e) by copy delivery of the application on request? **(YES)**

 - (ii) As regards granted SPCs
 - (a) as part of an Official Gazette? **(YES)**
 - (b) by publishing the SPC? **(NO)**
 - (c) by laying the SPC open to public inspection? **(YES)**
 - (d) through online databases (or the Office's Web site)?

- **Certain details are entered on the *PTOLEMY* database under the register entry for the corresponding basic patent – register entry is viewable on our public search system**
- (e) by copy delivery of the SPC on request? **(YES)**

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)
- Ptolemy (internal database)
 - Ptolemy Public Search System
- (ii) bibliographic data elements
- Application number – identical to the grant publication number
 - Whether application is for medicinal or plant protection product
 - Date of application
 - Date of publication of application
 - Name and address of applicant
 - Basic patent
 - Date of expiry of patent
 - Title of patent
 - Irish market authorization number, date of grant, identity of product authorized, legal provision of the authorization
 - Community market authorization, country, date of grant, identity of product authorized, legal provision of the authorization
 - Product identity
 - Address for service
 - Application status
 - Date of grant
 - Date of publication of grant
 - Renewal fees
- (b) In the field of phytopharmaceutical products
- (i) name(s) of database(s)
- Ptolemy (internal database)
 - Ptolemy Public Search System
- (ii) bibliographic data elements
- Application number – identical to the grant publication number
 - Whether application is for medicinal or plant protection product
 - Date of application
 - Date of publication of application
 - Name and address of applicant
 - Basic patent
 - Date of expiry of patent
 - Title of patent
 - Irish market authorization number, date of authorization, identity of product authorized, legal provision of the authorization
 - Community market authorization, country, date of authorization, identity of product authorized, legal provision of the authorization
 - Product identity
 - Address for service
 - Application status
 - Date of grant

- Date of publication of grant
- Renewal fees

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
- The Office uses the format SPC YYYYNNN, where YYYY represents the year in which the application is filed and NNN identifies the application number, commencing with 001 for the first application filed in a given year.
- (ii) concerning the numbering system for registrations or grants of SPCs (if different from (a)(i))
- The granted SPC retains the application number given.
- (b) As regards phytopharmaceutical products
- (i) concerning numbering system for applications for SPCs
- The Office uses the format SPC YYYYNNN, where YYYY represents the year in which the application is filed and NNN identifies the application number, commencing with 001 for the first application filed in a given year.
- (iii) concerning the numbering system for registrations or grants of SPCs (if different from (b)(i))
- The granted SPC retains the application number given.

**Gazette announcements showing (1) receipt of application for an SPC
and (2) grant of SPC**

(1) Request for Grant of Supplementary Protection Certificate

The name and address of the requester follow the number allocated to the request. The date in brackets following the name and address is the date of receipt of the request. The patent number is that under which the product in respect of which a certificate is sought is, allegedly, protected. Market authorisation references in respect of the product concerned are also shown.

SPC 2000003 PHARMACIA & UPJOHN S.P.A.,
Via Robert Koch, 1.2, 20152 Milano, Italy

(22 February 2000)

Patent No: 58949; SUBSTITUTED ANDROSTA-1,4-DIENE-3,17-DIONES AND
PROCESS FOR THEIR PREPARATION

Product: Exemestane

Market Authorisation: Ireland PA 16/63/1

12 November 1999

United Kingdom PL 00032/0236

16 December 1998

(2) Supplementary Protection Certificates Granted

The name and address of the grantee follow the number allocated to the application for grant of a certificate; this number applies also to the granted certificate. The date in brackets following the name and address is the date of grant of the certificate. The number of the basic patent and the title of the invention are followed by the name of the product for which the certificate is granted. Market authorisation references in respect of the product concerned are also shown, followed by the date of expiry of the certificate.

SPC 1999009 MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.,
18 rue Dicks, L 1417 Luxembourg

(09 August 1999)

Patent No: 48802, Mercapto derivatives of substituted prolines

Product: Zofenopril and its salts, in particular its calcium salt

Market Authorisation: Ireland, PA865/3/1-4 and PA865/4/1-4

04 March 1999

United Kingdom, PL 16239/0002-0005

30 July 1998

Certificate expires on: 09 August 2004

Contact details:

- | | |
|---------------------------------|----------------------------------|
| (a) Name: | Dolores Cassidy |
| (b) Title: | Patent Examiner |
| (c) Office/Organization: | Irish Patents Office |
| (d) E-mail: | dolores_cassidy@entemp.ie |
| (e) Facsimile: | + 353 56 20100 |
| (f) Telephone: | + 353 56 20104 |

[End of Questionnaire]