

Country

Germany

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

No

(b) In the field of phytopharmaceutical products

Yes

No

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

(a) In the field of medicinal products

Yes

No

(b) In the field of phytopharmaceutical products

Yes

No

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

(a) In the field of medicinal products **no change**

(1) Laws

(2) Decrees, ordinances

(3) Other

(b) In the field of phytopharmaceutical products

(1) Laws

Regulation (EEC) No. 1610/96 of the European Parliament and the Council of July 23, 1996 and Amendment to the German Patent Law of March 23, 1993 (Insertion of Sections 16a and 49a)

(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 **no change**

(b) In the field of phytopharmaceutical products

**Supplementary protection certificate
(In German: "Ergänzendes Schutzzertifikat")**

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 products as defined by the EEC Council Regulation No. 1768/92, Art. 1 (a) and phytopharmaceutical products as defined by the Regulation (EC) No. 1610/96 of the European Parliament and the Council, Art. 1 No. 1

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 **no change**

Yes

No

(b) In the field of phytopharmaceutical products

Yes **x**

No

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

no change except (vi) and (viii)

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

***) The Office publishes the date and number of the first authorization to place the product on the market in Germany and, if different, the country, number and date of the first authorization to place the product on the market in the EEC**

(viii) other elements (please specify) **no*)**

***) In addition to the minimum elements prescribed by the Regulation (EEC) the GPTO publishes also the IPC main class symbol of the basic patent and the application number of the SPC.**

(b) In the field of phytopharmaceutical products

(i) number allotted to receipt of the application **no**

(ii) date of said receipt **no**

(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*)**

***) The Office publishes the date and number of the first authorization to place the product on the market in Germany and, if different, the country, number and date of the first authorization to place the product on the market in the EEC**

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

***) see explanation set out in respect of question (vi)**

(viii) other elements (please specify) **no*)**

***) In addition to the minimum elements prescribed by the Regulation (EC) the GPTO publishes also the IPC main class symbol of the basic patent and the application number of the SPC.**

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
 - no change except (vi) and (ix)**
 - (vi) number of any authorization to place the product on the market, including the product identified in that authorization **yes*)**
 - *) The Office publishes the date and number of the first authorization to place the product on the market in Germany and, if different, the country, number and date of the first authorization to place the product on the market in the EEC**
 - (ix) other elements, e.g., patent classification, product name (please specify): **no*)**
 - *) In addition to the minimum elements prescribed by the Regulation (EEC) the GPTO publishes also the IPC main class symbol of the basic patent and the application number of the SPC.**
- (b) In the field of phytopharmaceutical products
 - (i) registration number allotted to the granted SPC **no**
 - (ii) date of registration of the granted SPC **no**
 - (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*)

***) The Office publishes the date and number of the first authorization to place the product on the market in Germany and, if different, the country, number and date of the first authorization to place the product on the market in the EEC**

- (vii) date of the said authorization **yes*)**

***) see explanation set out in respect of question (vi)**

- (viii) duration of the SPC **yes**

- (ix) other elements, e.g., patent classification, product name (please specify): **no*)**

***) In addition to the minimum elements prescribed by the Regulation (EC) the GPTO publishes also the IPC main class symbol of the basic patent and the application number of the SPC.**

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?
no

- (d) through online databases (or the Office's Web site)?
yes*)

***) Bibliographic data and legal status information is available in the patent register and in the database PATDPA**

- (e) by copy delivery of the application on request?
no*)

***) Copies of SPC applications are available in the framework of a file inspection**

(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?
no
- (d) through online databases (or the Office's Web site)?
yes*)

***) Bibliographic data and legal status information is available in the patent register and in the database PATDPA**

- (e) by copy delivery of the SPC on request?
no*)

***) Copies of SPC files are available in the framework of a file inspection**

(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?
no
- (d) through online databases (or the Office's Web site)?
yes*)

***) Bibliographic data and legal status information is available in the patent register and in the database PATDPA**

- (e) by copy delivery of the application on request?
no*)

***) Copies of SPC applications are available in the framework of a file inspection**

(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?
no

(d) through online databases (or the Office's Web site)?
yes*)

***) Bibliographic data and legal status information is available in the patent register and in the database PATDPA**

(e) by copy delivery of the SPC on request?
no*)

***) Copies of SPC files are available in the framework of a file inspection**

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 **no change**
(i) name(s) of database(s)
(ii) bibliographic data elements

(b) In the field of phytopharmaceutical products
(i) name(s) of database(s) **Patent Register, PATDPA**
(ii) bibliographic data elements

Application no. of SPC, application number of basic patent, title of invention, name and address of SPC holder, number/date of authorization and name of product, IPC main class symbol, duration of the SPC

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 **no change**
(i) concerning the numbering system for applications for SPCs

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

- (b) As regards phytopharmaceutical products
 - (i) concerning numbering system for applications for SPCs
The same numbering system as for SPCs for medicinal products is used.

 - (ii) concerning the numbering system for registrations or grants of SPCs (if different from (b)(i))
The number of the granted SPC is identical to the number of the application for a SPC.

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[End of Questionnaire]