SUPPLEMENTARY PROTECTION CERTIFICATES AND PATENT TERM EXTENSIONS

Response ID:84; wqpu Data

1. Country code page

1. Please enter the two-letter country code corresponding to your Office or Organization.

DE

2. Questions page

2. 1. Does your Office/Organization provide SPCs or PTEs?

Yes

2. If you have answered "NO" to Question 1, will your Office/Organization start providing SPCs or PTEs in the future?

Comments:

3. 3. Please specify for which products an SPC or PTE can be obtained (or are planned to be introduced):

medicinal products
plant protection products

4. 3a. Please describe the requirements for granting SPCs or PTEs.

Examples:
the product has been protected by a patent,
the product has been subject to a regulatory review procedure before its commercial marketing or use,
an SPC or PTE has never been granted on the product.
If available, please provide a link to guidelines on filing applications for SPCs or PTEs.

Substantive requirements for the grant of an SPC in the European Union are laid down in Article 3, procedural requirements in Articles 7-9 of Regulations (EC) No 469/2009 (medicinal products; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R0469&from=DE) and (EC) No 1610/96 (plant protection products; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31996R1610&from=DE) respectively. Examination Guidelines (English version) for the German Patent and Trade Mark Office (DPMA) can be found at https://www.dpma.de/docs/english/formulare/patent_eng/p2799_1.pdf

5. 4. Please specify the legal basis for granting SPCs or PTEs. For example, relevant provisions of the national law (article or rule number), regional regulation, decrees, ordinances etc.

If legal grounds are different for the objects indicated in Question 3, please list all of them, indicating corresponding products.

European Union Regulations (EC) No 469/2009 (medicinal products) and (EC) No 1610/96 (plant protection products) are directly applicable in Germany via Sections 16a and 49a of the German Patent Act (unofficial translation at https://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html).

6. 5. Please give the name(s) of the SPCs or PTEs granted by your Office/Organization in both English and the original language.

Example: **DE – Supplementary Protection Certificate (in German: "Ergänzendes Schutzzertifikat").**

If names are different for the products indicated in Question 3, please list all of the protections, indicating corresponding products.

DE-Supplementary Protection Certificate (German "Ergänzendes Schutzzertifikat")

7. 6. If your Office/Organization assigns (or intends to assign) a specific application and/or grant/registration number to SPCs or PTEs, please give examples and details of:

the numbering system for applications:: Since 1st January 2004 in DE: Two digit identification number (12 for SPCs), followed by four digit year of application (e.g. 2018), followed by six digit annual serial number (e.g. 000011 for the 11th application in the respective year), followed by full stop followed by error checking number (calculated from the numbers before full stop). Example: DE 12 2018 000 011.6

Comments: Since 1st January 2004 in DE: Two digit identification number (12 for SPCs), followed by four digit year of application (e.g. 2018), followed by six digit annual serial number (e.g. 000011 for the 11th application in the respective year), followed by full stop followed by error checking number (calculated from the numbers before full stop). Example: DE 12 2018 000 011.6 Granted SPCs keep same number as indicated above for application.

8. 7. Does your Office/Organization or other relevant national authority publish, or intend to publish, one or more of the following events for an SPC or PTE?

	MEDICINAL PRODUCTS	PLANT PROTECTION PRODUCTS	ALL PRODUCTS SUBJECT TO REGULATORY APPROVAL FOR MARKETING	OTHER
Request (application) for an SPC or PTE filed	X	X		
SPC or PTE granted	X	X		
SPC or PTE not granted	X	X		
SPC or PTE opposed by third parties				
SPC or PTE came into force				
SPC or PTE ceased because of a lapse or expiry	X	X		
Extension of SPC term requested	X	X		
Extension of SPC term granted	X	X		
Extension of SPC term not granted	X	X		

Comments: There are no opposition proceedings for SPCs in Europe (cf. Art.19 (2) of Regulation (EC) No 469/2009). Invalidity actions against granted SPCs and revocation actions against extensions of SPC term are available (cf. Articles 15 and 16 of Regulation (EC) No 469/2009). Filing of a nullity/revocation action and the ultimate decision is published.

9. 8a. In what form is the corresponding event published?

as part of an Official Gazette
through public online databases (please indicate the name and the URL of the database): DPMAregister (https://register.dpma.de/DPMAregister/pat/einsteiger)

10. 8b. What are the minimum elements that this publication must contain?

application number
filing date
name and address of the applicant
number of the relevant patent
title of the invention
name of the product
authorization details
date of the SPC or PTE authorization

11. 8c. What is the planned timetable for publishing this information?

DPMAregister is updated overnight, publication in the Official Gazette ("Patentblatt" in Germany) can take up to 12 weeks.

12. 8d. Please attach an example(s) of published events and/or of corresponding announcements.

DPMAregister__Patente_-_Registerauskunft_12_2007_000_033.pdf
PAT_1220050000418_2019-01-25.pdf
Comments:

13. 9. Does your Office/Organization or other relevant national authority publish (or intend to publish) the announcement of state changes for an SPC or PTE as defined in WIPO Standard ST.27?

	MEDICINAL PRODUCTS	PLANT PROTECTION PRODUCTS	ALL PRODUCTS SUBJECT TO REGULATORY APPROVAL FOR MARKETING	OTHER
Changed to "Active"	X	X		
Changed to "Not active"	X	X		
Changed to "Terminated"	X	X		

14. 10a. In what form is the announcement related to the state change published?

through public online databases (please indicate the name and the URL of the database): DPMAregister (https://register.dpma.de/DPMAregister/pat/einsteiger)

15. 10b. What are the minimum elements that this publication must contain?

registration number allotted to the SPC or PTE, which has come into force
date of SPC or PTE registration, which has come into force
name and address of the SPC or PTE holder
number of the relevant patent
title of the invention
name of the product
authorization details
date of SPC or PTE authorization
duration of the SPC or PTE
other elements, e.g. patent classification (please specify):: As ST.27 will be provided as additional information of the entry in the register, all information present in the register is available, i.e. classification, responsible department at the office, etc.

16. 10c. What is the planned timetable for publishing this information?

Planned to go into production in 2019. Then: DPMAregister is updated overnight.

17. 10d. Please attach a specimen(s) of corresponding announcements.