

Committee on WIPO Standards (CWS)

Sixth Session
Geneva, October 15 to 19, 2018

REPORT ON TASK NO.50 BY THE PART 7 TASK FORCE

Document prepared by the Part 7 Task Force

INTRODUCTION

1. At its reconvened fourth session held in March 2016, the Committee on WIPO Standards (CWS) agreed on the creation of Task No. 50: “Ensure the necessary maintenance and update of surveys published in Part 7 of the WIPO Handbook on Industrial Property Information and Documentation” and the establishment of a corresponding Task Force (Part 7 Task Force). The International Bureau was designated as the Task Force Leader. (See paragraphs 73 and 122 (e) of document CWS/4BIS/16.)
2. At its reconvened fourth session, the CWS also agreed to extend the scope of Part 7.7 of the WIPO Handbook on Industrial Property Information and Documentation (WIPO Handbook) to cover patent term adjustments (PTAs) and patent term extensions (PTEs) in addition to supplementary protection certificates (SPCs). With the view of extending the scope of Part 7.7, the CWS requested the Part 7 Task Force to review the existing questionnaire on SPCs and to present a proposal for updating it at its fifth session (see paragraph 74 of document CWS/4BIS/16).
3. At the fifth session of the CWS held from May 29 to June 2, 2017, the Part 7 Task Force presented a draft questionnaire on the grant and publication of industrial property protection extensions (IPPEs) for consideration. The CWS discussed the proposed draft questionnaire on IPPEs and identified the several substantive issues, which should be amended. Consequently, the CWS requested the Task Force to revise the draft questionnaire taking into account the issues identified and to present a new proposal for consideration at its sixth session. (See paragraphs 79 to 81 of document CWS/5/22.)

4. At its fifth session, the CWS also requested the Part 7 Task Force to prepare a proposal for the questionnaire on numbering of published documents and registered rights and to present the proposal for consideration at its sixth session. The Committee noted that the questionnaire should cover current and former practices of numbering of published documents and registered rights. (See paragraph 71 of document CWS/5/22.)
5. At its fifth session, the CWS also requested the International Bureau
 - (a) to invite IPOs to update their entries in Part 7.2.4 "Survey on the presentation of priority application numbers", and subsequently to prepare and publish the updated Part 7.2.4 of the WIPO Handbook; and
 - (b) to request the International Bureau to move Part 7.2.1 to the Archive, replace the reference in ST.10/C with Part 7.2.6 (editorial change) and include the link to the archived Part 7.2.1 in Part 7.2.6.

(See paragraph 72 of document CWS/5/22.)

PROGRESS REPORT AND UPDATED DRAFT QUESTIONNAIRE

6. As a follow-up to the requests by the CWS at its fifth session, the International Bureau issued Circular C.CWS 88 inviting IPOs to provide information for Part 7.2.4 of the WIPO Handbook "Survey on the presentation of priority application numbers". The 12 IPOs from the following countries provided their response: AU, CZ, DE, GB, HR, KG, MD, PL, PT, SE, SK and UA. It should be noted that the responses have not been reflected in Part 7.2.4 and the Secretariat plans to publish the updated Part 7.2.4 with the new information in 2018.
7. The Secretariat also conducted the following actions requested by the CWS:
 - (a) moving Part 7.2.1 to the Archive;
 - (b) replacing the reference in ST.10/C with Part 7.2.6 (editorial change); and
 - (c) including the link to the archived Part 7.2.1 in Part 7.2.6.
8. With regard to the request for preparing a proposal for the questionnaire on numbering of published documents and registered rights, the Part 7 Task Force has not started its work and plans to do so after the sixth session and present a proposal for consideration at its seventh session.
9. The Part 7 Task Force carried out four rounds of discussions and prepared five draft versions of the questionnaire, considering the issues identified at the fifth session of the CWS, referring to paragraph 80 of document CWS/5/22. The Task Force presented a final draft questionnaire for consideration by the CWS as Annex to this document.
10. During the discussions about the questionnaire, the Task Force members noted the difference between SPCs/PTEs and PTAs as legal instruments in use in the countries. The SPCs and PTEs are related to delays in marketing due to governmental procedures of accreditation conducted by in general other authorities than the IPO, while the term SPCs is used in the European Economic area, and the term PTEs is, to a certain extent, used in other countries such as Japan, Republic of Korea and United States of America. The term PTAs, however, is related to delays of administrative procedures caused during the examination and grant process in the IPO.

11. The Task Force initially considered to split questions into two parts, Part I - questions regarding SPCs and PTEs; and Part II - questions related to PTAs. Taking into account the difference in nature between the two groups and the scope of Part 7.7 of WIPO Handbook, the Task Force agreed to keep only the questions which are related to SPCs and PTEs. If necessary in the future, a new questionnaire needs to be prepared for PTAs. Therefore, the final draft questionnaire annexed to this document contains only the questions which are related to SPCs and PTEs.

12. *The CWS is invited to:*

(a) note the content of the present document;

(b) consider and approve the draft questionnaire, as reproduced in the Annex; and

(c) request the Secretariat to issue a circular inviting IPOs to participate in the survey on the grant and publication of Supplementary Protection Certificates and Extensions of the Patent Term, as referred to in paragraph 6 above.

(d) request the International Bureau to prepare and publish the updated Part 7.2.4, as referred to in paragraph 6, above

(e) request the Part 7 Task Force to prepare a proposal for the questionnaire on numbering of published documents and registered rights and to present the proposal for consideration at its sixth session, as indicated in paragraph 8 above.

[Annex follows]

DRAFT QUESTIONNAIRE ON THE GRANT AND PUBLICATION OF SUPPLEMENTARY PROTECTION CERTIFICATES AND EXTENSIONS OF THE PATENT TERM

CONTACT DETAILS

Name

Please indicate the name of the person who completed the questionnaire in the format "First Name LAST NAME"

Title

Please indicate the title of the person who completed the questionnaire

Country/Organization

Please indicate the country name or name of your Organization and the corresponding ST.3 code

E-mail address

Please indicate the e-mail address of the person who completed the questionnaire

Facsimile

Please indicate the facsimile of the person who completed the questionnaire

Telephone

Please indicate the telephone number of the person who completed the questionnaire

This questionnaire relates to mechanisms that enable owners of patents under certain conditions to obtain, during a limited period, continued protection for certain products that are subject to pre-market regulatory approval, namely supplementary protection certificates (SPCs) and patent term extensions (PTEs).

Question 1

Does your Office/Organization provide SPCs or PTEs?

- Yes
- No

Question 2

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

- Yes. Please use the field below for comments to indicate when.
- No.

Comments: _____

Question 3

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

- medicinal products
- plant protection products
- all products subject to regulatory approval for marketing
- other: _____

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.

Question 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.

Question 5

Please give the name of the SPC or PTE granted by your Office/Organization in 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 them, indicating corresponding products.

Question 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: _____
- the numbering system for registration or grant (if different from the above): _____

Comments: _____

Question 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? Please mark the corresponding cell in the table below with an "X".

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

Comments: _____

Question 8

If you have marked at least one cell in the table in Question 7, please respond to the following questions 8.1 to 8.4. If the answers vary for different products or events, please use the "Comments" section below to explain the difference or copy questions 8.1 to 8.4 and answer them for each of the products or events.

8.1 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)_____
- by opening the document for public inspection
- by delivering a copy of the publication on request
- other (please specify):_____

8.2 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 said authorization
- other elements (please specify):_____

8.3 What is the planned timetable for publishing this information?

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

Attachments

Comments:_____

Question 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?

Please mark the corresponding cell in the table below with an "X".

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

Question 10

If you have marked at least one cell in the above table, please respond to the following questions 10.1 to 10.4.

If the answers vary for different products or states, please use the "Comments" section below to explain the difference or copy questions 10.1 to 10.4 and answer them for each of the products or states.

10.1 In what form is the announcement related to the state change published?

- as part of an Official Gazette
- through public online databases (please indicate the name and the URL of the database)_____
- by opening the document for public inspection
- by delivering a copy of the publication on request
- other (please specify):_____

10.2 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 said authorization
 - duration of the SPC or PTE
 - other elements, e.g. patent classification (please specify): _____
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10.3 What is the planned timetable for publishing this information?

10.4 Please attach a specimen(s) of corresponding announcements.

Attachments

Comments: _____

[End of Annex and of document]