

## 世界知识产权组织标准委员会（CWS）

### 第六届会议

2018年10月15日至19日，日内瓦

### 第七部分工作队关于第50号任务的报告

第七部分工作队编拟的文件

### 导 言

1. 在2016年3月举行的第四届会议续会上，产权组织标准委员会（CWS）同意设立第50号任务，即“确保对产权组织《工业产权信息与文献手册》第七部分公布的调查进行必要的维护和更新”，并同意组建一支相关工作队（第七部分工作队）。国际局被指定为工作队牵头人（见文件 CWS/4BIS/16 第73段和第122段（e）项）。
2. 在第四届会议续会上，标准委员会还同意扩大产权组织《工业产权信息与文献手册》（《产权组织手册》）第7.7部分的范围，除补充保护证书（SPC）外，还包括专利期调整（PTA）和专利期延长（PTE）。对于扩大第7.7部分的范围，标准委员会要求第七部分工作队审查关于SPC的现有调查问卷，并提交提案以在其第五届会议上进行更新（见文件 CWS/4BIS/16 第74段）。
3. 在2017年5月29日至6月2日举行的标准委员会第五届会议上，第七部分工作队编拟了关于授予和公布工业产权保护延期（IPEE）的调查问卷草案供审议。标准委员会讨论了拟议的IPEE问卷草案，并查明多个应予修正的实体问题。因此，标准委员会要求工作队考虑已查明的问题，对问卷草案进行修正，并向第六届会议提交新提案供审议（见文件 CWS/5/22 第79段至第81段）。
4. 在第五届会议上，标准委员会还要求第七部分工作队就已公布文件编号和已注册权利编号的问卷编拟提案，并在第六届会议上提交提案供审议。委员会注意到，问卷应当包括已公布文件编号和已注册权利编号的现行做法和以前做法（见文件 CWS/5/22 第71段）。

5. 在第五届会议上，标准委员会还要求国际局：
  - (a) 请各工业产权局对它们在第 7.2.4 部分“优先权申请号表示方法调查”中的条目进行更新，随后编拟并公布更新后的《产权组织手册》第 7.2.4 部分；并且
  - (b) 要求国际局将第 7.2.1 部分归档，将其在 ST.10/C 中的提及替换为对第 7.2.6 部分的提及（编辑修改），并在第 7.2.6 部分中增加对已归档的第 7.2.1 部分的链接。

（见文件 CWS/5/22 第 72 段。）

#### 进展报告和更新后的问卷草案

6. 作为对标准委员会第五届会议上所提要求的跟进，国际局发出通函 C.CWS 88，请各工业产权局提供关于《产权组织手册》“优先权申请号表示方法调查”的信息。来自下列国家的 12 个工业产权局已提供答复：AU、CZ、DE、GB、HR、KG、MD、PL、PT、SE、SK 和 UA。应指出，这些答复尚未在第 7.2.4 部分中体现，秘书处计划于 2018 年公布更新后的第 7.2.4 部分和新信息。

7. 秘书处也已采取标准委员会要求的下列行动：
  - (a) 将第 7.2.1 部分归档；
  - (b) 将其在 ST.10/C 中的提及替换为对第 7.2.6 部分的提及（编辑修改）；以及
  - (c) 在第 7.2.6 部分中增加对已归档的第 7.2.1 部分的链接。

8. 关于就已公布文件编号和已注册权利编号的问卷编拟提案的要求，第七部分工作队尚未开始工作，计划于第六届会议后开始，向第七届会议提交提案供审议。

9. 第七部分工作队考虑标准委员会第五届会议上查明的问题，参考文件 CWS/5/22 第 80 段，进行了四轮讨论，并编拟了五版问卷草案。工作队已编拟问卷草案终稿，作为本文件附件，供标准委员会审议。

10. 在讨论问卷过程中，工作队成员注意到 SPC/PTE 和 PTA 在各国法律文书使用中存在差异。SPC 和 PTE 涉及工业产权局以外其他机构一般进行政府认证程序导致的市场延迟，而术语 SPC 是在欧洲经济区用语，术语 PTE 在某种程度上是在其他国家，例如日本、大韩民国和美利坚合众国使用。而术语 PTA 与工业产权局审查和授权过程中导致的行政程序延迟有关。

11. 工作队最初考虑将问题分为两部分，第一部分是关于 SPC 和 PTE 的问题；第二部分是关于 PTA 的问题。考虑到这两组性质有所差异，以及《产权组织手册》第 7.7 部分的范围，工作队同意仅保留与 SPC 和 PTE 有关的问题。未来如有必要，需要为 PTA 编拟新的问卷。因此，作为本文件附件的问卷草案终稿仅包含与 SPC 和 PTE 有关的问题。

12. 请标准委员会：

(a) 注意本文件中的内容；

(b) 审议并批准转录于附件中的问卷草案；并且

(c) 如上文第 6 段所述，要求秘书处发出通函，请各工业产权局参与关于授予和公布补充保护证书以及专利期延长的调查；

(d) 如上文第 6 段所述，要求国际局编拟并公布更新后的第 7.2.4 部分；

(e) 如上文第 8 段所述，要求第七部分工作队就已公布文件编号和已注册权利编号的问卷编拟提案，并在第六届会议上提交提案供审议。

[后接附件]

**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.

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### 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.

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### 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.

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### 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?

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

Attachments

Comments: \_\_\_\_\_

[附件和文件完]