

SUPPLEMENTARY PROTECTION CERTIFICATES AND PATENT TERM EXTENSIONS

Response ID:99; vujm Data

1. Country code page

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

US

2. Questions page

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).

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

Yes

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

medicinal products

other: We only grant PTEs for products regulated under specific statutes that either FDA or USDA implements.

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.

<https://www.uspto.gov/web/offices/pac/mpep/mpep-2700.html>

Neutral sentiment (score: 0)

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.

35 U.S.C. 156 Legal Authority for Extension of Patent Term <https://www.govinfo.gov/content/pkg/USCODE-2017-title35/html/USCODE-2017-title35-partII-chap14-sec156.htm>

Neutral sentiment (score: 0.1)

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.

Certificate Extending Patent Term under 35 USC 156

Neutral sentiment (score: 0)

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:

Comments: There is no unique number assigned for the Certificate, it is associated with the patent no.

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			
SPC or PTE granted	X			
SPC or PTE not granted	X			
SPC or PTE opposed by third parties				
SPC or PTE came into force	X			
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:

8. If you have marked at least one cell in the table in Question 7, please respond to the following questions 8a to 8d. If the answers vary for different products or events, please use the "Comments" section below to explain the differences.

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

through public online databases (please indicate the name and the URL of the database): Public PAIR and <https://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156>
by opening the document for public inspection
other (please specify):: Also published in the patents image public database in the Corrections section of the document

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

number of the relevant patent
name of the product
authorization details
date of the SPC or PTE authorization

other elements (please specify):: Original expiry date of the patent as of the grant of the PTE. Duration of Extension

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

Once granted, the PTE certificate is appended to the patent grant image.

Positive sentiment (score: 0.5)

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

[US_question_8d.pdf](#)

Comments: see attachment

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"				
Changed to "Not active"				
Changed to "Terminated"				

10. If you have marked at least one cell in the above table, please respond to the following questions 10a to 10d.

If the answers vary for different products or states, please use the "Comments" section below to explain the differences.

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):

<https://portal.uspto.gov/pair/PublicPair>

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

number of the relevant patent

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):: Original expiry date of the patent as of the grant of the PTE

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

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

3. Review Page

You have reached the end of the survey questions. Your answers have been saved.

If you or your colleagues wish to revise your answers later, you can use the link that was originally emailed to you to return to this page. Then use the Review (or Back) button below to return to your answers.

You can also use the [Save and Continue](#) option at the top of the page to save your answers at any point.

When you are ready to submit your final answers, click the [Submit](#) button below. You will no longer be able to edit your responses after clicking [Submit](#).

You may download a copy of your answers:

4. Thank You!

Thank you for taking our survey. Your response is very important to us.

Response ID: 99

Survey Submitted:	Mar 22, 2019 7:27 am
IP Address:	193.5.93.24
Language:	English (en-US,en;q=0.9,es;q=0.8)
User Agent:	Mozilla/5.0 (Windows NT 10.0; Win64; x64) AppleWebKit/537.36 (KHTML, like Gecko) Chrome/72.0.3626.96 Safari/537.36
Http Referrer:	
URL Variable: sguid	vujm
Page Path:	1 : Country code page (SKU: 1) 2 : Questions page (SKU: 3) 3 : Review Page (SKU: 4) 2 : Questions page (SKU: 3) 2 : Questions page (SKU: 3) 2 : Questions page (SKU: 3) 3 : Review Page (SKU: 4) 4 : Thank You! (SKU: 2)
SessionID:	a28801535f3198fa3b2ecc5e6b33befd

Response Location

Country:	Switzerland
Region:	07
City:	Geneva
Postal Code:	1202
Long & Lat:	Lat: 46.202201843262, Long:6.1456999778748