Council of the European Union

Brussels, 28 April 2023
(OR. en)

Interinstitutional Files:
2023/0128(COD)
2023/0126(COD)
2023/0127(COD)
2023/0130(COD)

8887/23
ADD 5

PI 55
PHARM 67
COMPET 383
MI 351
IND 204
IA 88
CODEC 746

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2023) 119 final
Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 and Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products

Delegations will find attached document SWD(2023) 119 final.

Encl.: SWD(2023) 119 final

EUROPEAN
COMMISSION

Brussels, 27.4.2023
SWD(2023) 119 final

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the documents

Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast)
and
Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast)
and
Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013
and
Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products

{COM(2023) 221 final} - {SEC(2023) 172 final} - {SWD(2023) 117 final} -
{SWD(2023) 118 final}

Executive Summary Sheet
Impact assessment on a reform of the EU's supplementary protection certificates (SPC) regime, including a proposal for a Regulation creating a procedure for the centralised examination of SPC applications, and a proposal for a Regulation creating a unitary SPC.
A. Need for action
Why? What is the problem being addressed?

Supplementary protection certificates (SPCs) are specific intellectual property (IP) rights that extend by up to 5 years the 20-year term of patents related to medicinal or plant protection products (PPP).

They aim to offset the loss of effective patent protection due to the compulsory and lengthy testing required in the EU to obtain regulatory marketing authorisation for these products.

The relevant EU legislation is:

- Regulation (EC) 469/2009 on SPCs for medicinal
- Regulation (EC) 1610/96 on SPCs for plant protection products.

Between 25 and 81 SPC applications were filed annually per EU country and more than 26,000 national SPCs have been granted since 1993. The average duration of SPC protection is estimated to be 3.5 years.

The Commission's Intellectual Property action plan of November 2020 (COM(2020)760 final), building on the SPC evaluation (SWD(2020) 292 final), highlighted the need to tackle the remaining fragmentation in the EU's IP system, which leads to complex and costly procedures.

The plan noted that, for medicinal products and plant protection products, SPC protection is only available at national level. At the same time, there is a single procedure for granting European patents, as well as a single set of rules for obtaining marketing authorisations.

In the same vein, the Pharmaceutical Strategy for Europe (COM(2020)761 final) emphasised the importance of investment in R&D to provide innovative medicines, while stressing that the differences across EU countries in implementing IP regimes, especially for SPCs, lead to duplications and inefficiencies. These affect the competitiveness of the pharmaceutical industry. Both the EU Council[1] and the European Parliament[2] have called on the Commission to fix these deficiencies.

Of particular importance for this impact assessment is the unitary patent (UP) system expected to enter into force in 2023. It will allow for a single patent covering all participating EU countries in a unitary manner. Alongside it, the new Unified Patent Court will allow for centralised litigation for participating countries. However, without this policy initiative for SPCs, there would not be a corresponding unitary SPC to accompany (extend) unitary patents.

The key problems this initiative aims to tackle are:

1. legal uncertainty about SPC status,
2. cumbersome monitoring of SPCs,

[1] Council conclusions on IP policy of 10 November 2020 https://www.consilium.europa.eu/media/46671/st-12750-2020-init.pdf

[2] European Parliament, Committee on Legal Affairs, Report on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI)), https://www.europarl.europa.eu/doceo/document/A-9-2021-0284_EN.html

3. the high cost and burden of seeking and maintaining SPC protection in the EU.

To obtain SPC protection in the whole EU for the maximum term of 5 years, applicants need to comply with 27 different procedures at national patent offices and pay various national application and maintenance fees totalling €192,000.

Due to these divergent granting practices at national level, the outcome of national procedures is uncertain, including a lack of uniformity both in the length and outcome of the examination. Historically around a quarter of applications relating to the same product have resulted in different decisions.

Generic and biosimilar producers, as well as public buyers in the healthcare sector, face difficulties in ascertaining the status of SPC protection in due time. For producers this may hamper the launch of competing generic or biosimilar products, or their participation in tenders for the purchase of medicines.

For national authorities, this creates problems in procuring medicines, especially jointly with other EU countries.

What is this initiative expected to achieve?

The general objective of the proposed policy measures is to improve the availability of (i) novel medicinal products for EU patients and (ii) plant protection products for agriculture, as well as to incentivise firms to develop those products in the EU.

In connection with the general objectives and the problems identified earlier, 3 specific objectives have been defined:

(1) Increase the predictability and legal certainty of SPC protection in the EU. This specific objective can be obtained by: i) facilitating substantive examination procedures; (ii) facilitating involvement of affected third parties; (iii) facilitating granting procedures.

(2) Facilitate the monitoring of SPCs in the single market, preferably by offering a single point of access to information about the status of SPCs in the EU (e.g. whether they have been filed, granted, refused, invalidated, renounced or withdrawn), as well as access to structured data on the subject.

(3) Reduce the cost and burden of seeking and maintaining SPC protection, by investigating possible administrative cost reductions; improve access to procedures for all stakeholders, especially small and medium-sized firms.

What is the value added of action at the EU level?

EU-level action would increase the integrity of the single market by providing for a unitary/centralised, balanced and transparent SPC system in the EU, and mitigating the negative consequences faced by applicants as a result of the diverging procedures.

Hence, action at EU level is also justified to ensure the smooth functioning of the single market for innovative products that are subject to marketing authorisations, and to permit the benefits of an efficient industrial property framework to be reaped in the relevant product markets.

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

- Option 0: **No policy change** (baseline scenario).

- Option 1: **Guidelines for applying the current SPC regimes.** This would give national patent offices common guidelines/recommendations for applying the existing SPC Regulation, building on their experience and case law from the Court of Justice of the EU. Such guidelines would also recommend common rules for publishing SPC information in national registers and ensuring it is accessible.
- Option 2: **Mutual recognition of national decisions**. It would enable SPC applicants to file an SPC application with a designated national patent office – the "reference office" – whose decision would be recognised by all other national patent offices.
- Option 3: **Centralised filing and examination of SPC applications resulting in a non-binding opinion.** This would create a central authority for filing SPC applications in the EU, which would examine applications and issue an opinion on whether to grant an SPC or not. National patent offices would be free to either follow this opinion or conduct their own examination. Therefore, the decision on granting SPC protection would be kept at national level. Only holders of a European patent – and, for medicinal products, a centralised marketing authorisation – could benefit from this system.
- Option 4: **Centralised filing and examination of SPC applications, resulting in a binding opinion.** This is identical to option 3, but national patent offices would have to follow the opinion. Therefore, while decisions on granting SPC protection would still be taken by national offices, the outcome of these decisions would be determined by a central authority.
- Option 5: **A 'unitary SPC' complementing the unitary patent**. The central authority, in addition to examining applications, would grant a so called "unitary SPC" to applicants holding a European patent with unitary effect. The unitary SPC would be valid only in the territory of the (currently 17) EU countries participating in the UP system.

Options 2 to 5 would allow third parties (e.g. generic producers in pharmaceutical or agrochemical sectors, as well as public buyers in the healthcare sector) to influence the SPC examination process through written observations.

Any EU language could be used to (electronically) file applications and observations. Similarly, the outcome of the centralised SPC examination will be published in all languages in a single (options 3 to 5) and searchable database.

When vesting an institution with SPC responsibilities, the following candidates have been considered: the European Patent Office, the EU Intellectual Property Office, the European Medicines Agency and the European Food Safety Authority.

The considered options would not replace national SPCs, but rather provide for an alternative route for obtaining SPC protection across the EU.

The preferred choice is a combination of options 4 and 5.

This would provide for a centralised procedure that would result in the granting of national SPCs in some or all EU countries and/or a unitary SPC (covering those EU countries in which the basic unitary patent has effect).

It is proposed that the EU Intellectual Property Office (EUIPO) should become the central examination authority.

Who supports which option?

The combination of options 4 and 5 was considered to offer the most balanced and proportionate approach, also taking into account of the views and concerns of stakeholders.

Regarding the options set out in the call for evidence, there was overall support for an EU initiative that would comprise a combination of the unitary SPC and a centralised granting procedure. Though national procedures should still exist alongside them.

Some stakeholders took the view that a single granting mechanism alone may not be sufficient to tackle the problems identified. Respondents further highlighted the need for the system to be transparent.

In particular, some stakeholders emphasised that there was a need for a balanced system and that the initiative should not shift the current balance between generics and originators.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

The preferred option would address the 3 identified problems (i.e. high costs and burden of seeking and maintaining SPC protection, legal uncertainty and cumbersome monitoring of SPCs).

It would:

i) Increase predictability and legal certainty in the single market regarding SPC protection, by eliminating the possibility of divergent national decisions on SPC protection across the EU. That would be achieved through unitary SPC protection for the EU countries participating in the UP system and through a binding opinion by the examination authority about the validity of the SPC in the non-participating EU countries;

ii) Significantly decrease the cost of monitoring SPC protection across the EU and therefore boost transparency, since such information would be publicly available through a single access point (a website with search functions).

iii) Significantly decrease the cost and burden of seeking SPC protection in the EU, as it would simplify the SPC procedure and reduce the current cost generated by launching up to 27 national SPC procedures.

For instance a 5-year long SPC protected across the EU would cost 55% less than in the baseline scenario, producing savings of around €137,000 per applicant.

The bulk of savings would result from the unitary SPC, as firms would avoid having to pay renewal fees annually for unitary patent protection in each of the participating EU countries (17 currently).

In addition, the opportunity to involve a single patent agent/attorney to file and prosecution of a single SPC application would also lead to savings, compared to the current need to potentially involve up to 27 patent agents/attorneys.

Table 1. Costs and savings to applicants for receiving EU27-wide, 5-year long SPC protection (options 4+5)

	€ per applicant	Savings compared to the baseline
Filing fees	38,800	-30,000
Maintenance fees for 5 years	71,900	111,100
Translation costs	0	4,000
Agent/attorney's fees	2,000	52,000
Total	112,700	137,100

Source: In-house estimates, numbers rounded to 100s.

What are the costs of the preferred option (if any, otherwise main ones)?
It could be claimed that a more efficient and coherent SPC system could, indirectly, adversely affect access to less expensive generic or biosimilar equivalents. Based on historical data, the estimated additional expenditure to healthcare systems during the additional period of protection could reach up to 0.48% in Latvia, while being negligible for many other countries (e.g. Luxembourg, Belgium, and Italy). The revenue from application and maintenance fees that could be lost by the national patent offices (as some SPCs will no longer submitted via the national route) is estimated at up to 0.4% of their budgets – but their operating costs might be also reduced. Attorneys representing clients before national patent offices might see their revenues drop by around €2,000 per case, with the overall loss depending on the number of EU countries where the centralised SPC is chosen instead of the national route.
How will businesses, SMEs and micro-enterprises be affected?
Small and medium-sized firms are expected to benefit from lower SPC application and maintenance fees (up to 55% cheaper), which, together with other savings (attorneys, translations, etc.), would equate to around €137,000 per applicant for a given product. Smaller generic and biosimilar firms should also benefit from easier access to SPC information, allowing for better market monitoring and business planning (expected to affect around 300 firms annually, with savings of up to €40,000 per firm).
Will there be significant impacts on national budgets and administrations?
For EU countries participating in the UP system– except Malta (data not available) – the total additional health budget spending would amount to €37 million a year. If the above cost for public healthcare budgets was re-invested in R&D by innovative companies, the option would produce a cost-neutral outcome. The possible revenue losses by national patent offices (maximum €0.5 million per EU country) are the corollary of applicants' savings, depend on the demand for the unitary/centralised SPC and will be mostly compensated by a reduction in the workload.
Will there be other significant impacts?
There are no other significant impacts expected.
D. Follow-up
When will the policy be reviewed?
The first evaluation report should be completed 5 years after the entry into effect of the first SPC granted through the new central procedure.