



Brussels, 16 July 2024
(OR. en)

12277/24

LIMITE

PI 126
PHARM 117
PESTICIDE 35
COMPET 801

Interinstitutional Files:

2023/0130(COD)

2023/0128(COD)

2023/0127(COD)

2023/0126(COD)

NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	10126/24
No. Cion doc.:	8869/23 + ADD 1-6, 8851/23 + ADD 1-4
Subject:	Unitary supplementary protection certificates (Unitary SPCs) – Presidency discussion paper on the key institutional questions of the unitary SPC proposals

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (16.10.2024)

I. INTRODUCTION

1. On 27 April 2023, the Commission submitted four proposals concerning supplementary protection certificates (SPCs) for medicinal products and plant protection products. The proposals introduce the possibility of obtaining a unitary SPC¹, as well as a new centralised procedure for the grant of national SPCs².

¹ Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 (**doc. 8869/23 + ADD 1-6**); and proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products (**doc. 8851/23 + ADD 1-4**).

² Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) (**doc. 8894/23 + ADD 1-7**); and proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) (**doc. 8887/23 + ADD 1-5**).

2. According to the procedure suggested in these four Commission proposals, SPC applications – including applications for unitary SPC in Contracting States of the Agreement on a Unified Patent Court (UPCA) – would be examined by the European Intellectual Property Office (EUIPO) as a central authority.
3. First, the EUIPO, involving examiners from national patent offices (NPOs) in the examination procedure, would be given the task of examining applications for unitary SPCs and applications for national SPCs, as well as combined applications, under a new centralised procedure. Following the examination, an examination opinion will be issued which could subsequently be appealed to the EUIPO Boards of Appeal. The decision of the EUIPO Boards of Appeal should, in turn, be amenable to actions before the General Court and, possibly, ultimately before the Court of Justice which has jurisdiction to review appeals limited to points of law in rulings and orders of the General Court.
4. Second, the EUIPO would also be tasked with granting unitary SPCs, while national SPCs, including the ones obtained via the new centralised procedure, would still be granted by national authorities.
5. Third, once a unitary SPC is granted, third parties would be able to initiate actions for a declaration of invalidity of the unitary SPC before the EUIPO, whose decisions may be appealed to the EUIPO Boards of Appeal (which, in turn, are amenable to actions before the General Court and possibly the Court of Justice). Counterclaims for a declaration of invalidity, raised in infringement proceedings, would however have to be filed with the competent court of a Member State, including the Unified Patent Court (UPC) where the applicable conditions are met, subject to a suitable amendment of the UPCA to include unitary SPCs in the definition of SPC.³
6. In respect of national SPCs, the actions for the declaration of the invalidity of SPCs are to be brought before the body responsible under national law for the revocation of the corresponding basic patent, or before a competent court of a Member State, including the UPC.

³ Article 2(h) of the UPCA currently only covers national SPCs granted under the two existing SPC Regulations.

II. STATE OF PLAY OF DISCUSSIONS

7. During the examination of the proposals and discussions held so far, strong concerns have been expressed by delegations regarding the interaction of the different proposed legal remedies, especially in relation to the unitary SPC proposals. One of the major concerns relates to the proposed concept for invalidity actions, according to which (i) the EUIPO (and, subsequently, the EUIPO Boards of Appeal, the General Court and the Court of Justice where applicable, as detailed hereinabove) would be in charge of direct invalidity actions relating to unitary SPCs, while (ii) national bodies in charge of revocation of patents and/or competent national courts, including the UPC, would, where applicable, be handling invalidity actions relating to national SPCs obtained via the new centralised procedure.
8. The majority of Member States, which also represent the quasi-unanimity of Contracting States of the UPCA, have expressed a strong plea, **DELETED** for deleting the invalidity procedure before the EUIPO from the proposals and for specifying that the validity of unitary SPCs should be challenged before the UPC, as the UPC is the specialised European court, common to Member States that have ratified the UPCA, not only for European or unitary patents, but also for national SPCs based on European or unitary patents.
9. In reaction to this call from the Member States, the Belgian Presidency sought political guidance from Coreper on 29 May 2024 on how to define a possible way forward regarding the design of the system of remedies, in particular the invalidity procedure. **DELETED**
- delegations were in favour of a solution, whereby direct invalidity actions regarding unitary SPCs would fall within the jurisdiction of the UPC in order to ensure coherence of jurisprudence regarding unitary and national SPCs and to avoid conflicting judgements concerning the scope of protection of the basic patent and the scope of protection of a unitary SPC. In addition, **DELETED** delegations have expressed their wish to avoid a cascade of procedures in order to guarantee a simple and user-friendly framework for SPCs. **DELETED**
- Member States have **DELETED** expressed support for a role of the EUIPO as the central authority for filing and examining the application for an SPC. In conclusion of the debate, Coreper asked the Commission to explore, in cooperation with the Presidency, solutions to achieve this objective and to ensure coherence with the Unitary Patent system.

10. On the basis of the guidance provided by Coreper on 29 May 2024, the Presidency in exchange with the Commission explored **DELETED** options that would in a legally sound way confer jurisdiction to the UPC to rule on the validity of unitary SPCs. **DELETED** this discussion paper **DELETED** will be submitted for the consideration of delegations **DELETED**.

III. POSSIBLE AVENUES FOR CONSIDERATION

11. This paper puts **DELETED** options for consideration of delegations.

These **DELETED** options, **DELETED**, address the following aspects:

- the granting of the unitary SPC,
- the rejection of the unitary SPC application,
- the appeal against the examination opinion,
- the appeal against the decision of the national patent offices and
- the invalidity proceedings.

Any aspects related to third party observations and oppositions are not addressed here.

*(a) Common aspects of the **DELETED** avenues*

12. **DELETED**

allowing for direct actions for the declaration of invalidity of unitary SPCs to be brought before the UPC.

13. **DELETED** its **validity could be reviewed by the UPC**, as requested by delegations. However, to achieve this result, a minor amendment of the SPC definition set out in Article 2(h) of the UPCA would be needed to encompass also unitary SPCs. This is currently also the case for national SPCs for the UPCA Contracting States, insofar as the underlying European patent has not been opted out of the UPC's jurisdiction.

14. **DELETED**

(i) Unitary character of the unitary SPC

15. **DELETED**

Article 5(2)

of both unitary SPC proposals states that a unitary SPC has “*unitary character*” providing “*uniform protection*” and having “*equal effect*” “*in all Member States in which with the basic patent has unitary effect*”. In the unitary SPC proposals, that “*unitary character*” is conferred upon the unitary SPC by an act of EU law in which the EU legislator is establishing European intellectual property rights **DELETED**

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19. **DELETED**

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its **validity could be reviewed by the UPC**, subject to a minor amendment of the SPC definition set out in Article 2(h) of the UPCA to encompass also unitary SPCs.

22. **DELETED**



23. **DELETED** it would guarantee that the UPC has full competence to rule on the validity of unitary SPCs, both for direct invalidity actions and for counterclaims for declarations of invalidity of unitary SPCs. **DELETED**.

24. **DELETED**

the number of unitary SPCs granted per year is (initially) expected to be low (perhaps around 20 per year), **DELETED**

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it would also allow for **the validity of the unitary SPC be reviewed by the UPC**, subject to the amendment of the SPC definition set out in Article 2(h) of the UPCA, to encompass also unitary SPCs.

35. **DELETED**



36. **DELETED.**

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37. **DELETED**

38. **DELETED**

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Financial issues linked to invalidity actions before the UPC are outside the scope of the proposed Regulations and would be entirely governed by the legislation applicable to the UPC. It must be noted, however, that invalidity procedures before the UPC will likely be substantially more expensive than invalidity procedures before the EUIPO.

39. Regarding the **translations**, it is to be noted that the examination opinion **DELETED**

As regards invalidity actions before the UPC, the existing UPC rules would apply with regard to languages. There would be no need to translate the related UPC judgement into all EU languages since that judgement would not be included in the Register, only the outcome of the proceedings would be reflected.

IV. CONCLUSION

40. Delegations are invited to share their views on the different options described in this discussion paper, as well as to propose amendments thereto, in order to facilitate the identification of the key building blocks of the most acceptable solution for the Council, which would form the basis of future work.
