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NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	10591/26
Subject:	Supplementary Protection Certificates (SPCs) – Stocktaking paper

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (25.08.2026)

As the Cyprus Presidency is coming to an end, this stocktaking paper has been prepared to summarise the progress achieved in the examination of the proposals on unitary supplementary protection certificates (SPCs), with the aim of ensuring a smooth handover and facilitating a productive continuation of discussions on the SPC package.

This paper is to be read in conjunction with the partial revised text on the recitals for the unitary SPC proposal for medicinal products set out in the Annex.

I. BACKGROUND

1. On 27 April 2023, the European Commission submitted four proposals concerning Supplementary Protection Certificates (SPCs) for medicinal products and plant protection products. This legislative reform aims to reduce the fragmentation of the SPC landscape within the Union, to simplify the granting of SPCs, increase the predictability and enhance the legal certainty of the SPC system, and to lower the costs and reduce the administrative burden for applicants.

2. To that end, the proposals aim to introduce a new centralised procedure for the grant of national SPCs, and the possibility of obtaining a unitary SPC complementing the Unitary Patent.
3. On 28 February 2024, the European Parliament adopted its first reading position on the four SPC proposals.
4. Under Hungarian Presidency, legal questions, most notably on the legal basis of the unitary SPC proposals, were raised by the Council Legal Service (CLS) in autumn 2024. On 28 January 2025, the CLS issued a written opinion on the legal basis of the unitary SPC proposals **DELETED**.
5. Following the delivery of the CLS written opinion, the question of the legal basis was discussed, among other substantive aspects relating to the unitary SPC proposals, during the Polish and Danish Presidencies, more specifically at Council Working Party meetings on 31 January 2025, 11 and 28 March 2025, 3 and 28 April 2025 and 5 December 2025.
6. Based on the valuable feedback received from delegations, both orally and in writing, the Cyprus Presidency submits below a progress report (together with an updated version of the partial revised recitals) of the discussions held so far on the proposals for unitary SPC Regulations, in particular as regards the legal basis. The report is intended to provide a basis for further reflection and future work on the proposals.

II. PROGRESS ACHIEVED

7. The Cyprus Presidency focused the work of the Council Working Party on Intellectual Property on the exploration of possible and viable solutions to address the question of the appropriate legal basis for the unitary SPC proposals and elaborated several options¹ aimed to address the concerns raised by the CLS. Those solutions, as summarised in the three concepts set out below, were examined by the Working Party on Intellectual Property at its meetings on 21 January 2026, 18 February 2026, 18 and 31 March 2026, 27 April 2026, 22 May 2026, 4 and 22 June 2026.

a) 'Newly envisaged model (Bundle Concept)'

8. Following an exchange of views on possible alternative approaches held between the CLS and the Commission at the meeting of the Working Party on Intellectual Property on 5 December 2025, the Working Party, at its meetings in January and February 2026, explored the feasibility of relying on Article 114 TFEU as a means to achieve effects similar to those sought in the unitary SPC proposals.
9. More specifically, a concept, which was referred to as '*newly envisaged model*', considered the idea of a '*European SPC*' granted through a centralised procedure as a '*bundle of national rights*'.
10. However, this bundle concept did not gain much support, as many delegations considered it would introduce additional complexity and fragmentation rather than the envisaged simplification and legal certainty, and therefore risked undermining the very objectives of the SPC reform. Most importantly, as most of the effects of SPCs established under this model would remain national, this concept would not provide for a genuinely unitary right complementing the unitary patent system. Delegations also emphasised that it would hardly provide any added value in comparison to the SPC recast proposals², which are based on Article 114 TFEU and provide for the possibility to obtain national SPCs in a centralised procedure.

¹ Doc. 5438/26, doc. 6196/26, doc. 7319/26, doc. 7727/26, **DELETED**, doc. 9218/26.

² Commission proposals doc. 8887/23 and doc. 8894/23.

b) Derogation solution (so-called ‘Solution A’)

11. In response to delegations stressing the importance of maintaining a genuinely unitary SPC, the Cyprus Presidency worked on a derogation-based solution, bearing in mind that any derogations from the uniform application of Union law in all Member States may only be justified if they are temporary and based on objective reasons.
12. The tabled derogation concept preserved the idea of establishing a unitary SPC based on Article 118 TFEU by ensuring that the unitary SPC Regulations apply in general terms to all Member States, **DELETED**.
13. The proposed solution built on the concept initially presented by the Polish Presidency **DELETED**³.
14. The derogation concept was presented to the Working Party on Intellectual Property at its meeting on 18 March 2026⁴. Based on the initial broad support expressed by delegations and in order to highlight the temporary nature of the derogation, the Cyprus Presidency developed the derogation solution further **DELETED**. This modified version was discussed on 31 March 2026⁵.

³ Case C-146/13, paragraphs 106-107.

⁴ See doc. 7319/26.

⁵ See doc. 7727/26.

c) Specific Attributes

15. Throughout the discussions, a majority of delegations repeatedly emphasised the need for a solution capable of preserving the genuinely unitary character of unitary SPCs in order to meet the policy objectives of creating a simple, efficient and legally sound system complementing the Unitary Patent. In addition to the derogation solution, the Cyprus Presidency therefore continued to explore other possible avenues to achieve these objectives on the basis of Article 118 TFEU within the ordinary legislative procedure.
16. To that end, the Cyprus Presidency explored a concept of differentiated application of Union law based on '*Specific Attributes*', previously developed by the CLS in earlier opinions concerning analogous situations⁶, such as the establishment of the Single Resolution Mechanism⁷. On this basis, and taking into account the particular legal nature of intellectual property rights and the special characteristics of the Unitary Patent, the Working Party on Intellectual Property examined the '*Specific Attributes*' stemming from the unitary patent framework and whether they could objectively justify such a differentiated application of the unitary SPC Regulations adopted on the basis of Article 118 TFEU within the ordinary legislative procedure.
17. The '*Specific Attributes*' concept presents a different situation from a derogation. Under this concept, the proposed unitary SPC Regulation applies to all Member States. However, certain legal effects of the SPC established by this Regulation arise only to the extent that specific attributes of the underlying patent, on which the SPC is based, are fulfilled. Those attributes need to provide a distinction in an objective and characterised manner and be relevant to the objectives pursued by the proposal and to the area of competence concerned.

⁶ See docs. **DELETED**, 5347/19, 6582/19.

⁷ Regulation (EU) No 806/2014 of the European Parliament and of the Council of 15 July 2014 establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Resolution Fund and amending Regulation (EU) No 1093/2010.

18. The ‘*Specific Attributes*’ concept was presented to the Working Party on Intellectual Property on 27 April 2026. In light of the substantial support received and carefully considering delegations’ feedback, the Cyprus Presidency further elaborated the reasoning of this concept and prepared legislative drafting suggestions to illustrate how this rationale could be reflected in the unitary SPC Regulations (see doc. 9218/26). The discussions continued in greater depth at the Working Party meetings on 22 May 2026, 4 and 22 June 2026.
19. **DELETED**

20. Based on the deliberations in the Working Party and given the importance of the matter, on 27 May 2026, political guidance was sought from Coreper on the way forward regarding the legal basis for the proposed unitary SPC Regulations. Following an exchange of views, Coreper provided guidance to continue work on the basis of Article 118 TFEU within the framework of the ordinary legislative procedure, building on the '*Specific Attributes*' reasoning and with a view to preserving the overall objectives of the proposed unitary framework and, in particular, to ensure the genuinely unitary character of the SPCs complementing the Unitary Patent.
21. Following the guidance provided by Coreper and taking into account the feedback received from the CLS, the Cyprus Presidency continued the work on the recitals underpinning the '*Specific Attributes*' concept. Based on the latest feedback received by delegations (during and after the last Working Party under Cyprus Presidency on 22 June 2026), the Cyprus Presidency submits with this stocktaking paper an updated partially revised text on the recitals, set out in the Annex).

III. CONCLUSION

22. Significant progress has been achieved during the Cyprus Presidency with regard to the legal basis of the proposed unitary SPC Regulations. The political guidance provided by Coreper on 27 May 2026 has established a clear basis for continuing work on the proposals under Article 118 TFEU within the framework of the ordinary legislative procedure, building on the reasoning of the ‘Specific Attributes’ concept. The Cyprus Presidency hopes that this will provide a solid foundation for further technical work and facilitate progress on the remaining important outstanding issues of the SPC package.
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Revised drafting suggestions for 'Specific Attributes' solution

Changes compared to the initial Commission proposal (doc. 8869/23) are indicated in **bold underlined** or in ~~strikethrough~~.

Changes compared to the previous text set out in doc. 10591/26 are highlighted in grey shade and marked by ~~double-strikethrough~~ for deletions.

(...)

- (3) Uniform patent and supplementary certificate protection within the internal market, or at least a significant part thereof, should feature amongst the legal instruments which pharmaceutical undertakings have at their disposal.
- (4) In its Communication of 25 November 2020 entitled 'Making the most of the EU's innovative potential – An intellectual property action plan to support the EU's recovery and resilience'⁸, the Commission highlighted the need to tackle the remaining fragmentation of the Union's intellectual property system. In that Communication, the Commission noted that, for medicinal products and plant protection products, supplementary protection is only available at national level. At the same time, there is a centralised procedure for granting European patents, as well as a centralised procedure for obtaining marketing authorisations for medicinal products. In addition, ~~the 'unitary patent' as laid down in~~ **pursuant to** Regulation (EU) No 1257/2012 of the European Parliament and of the Council⁹, **unitary patent protection became available** ~~enters entered into force in~~ **on 1 June 2023** in respect of ~~the~~ **seventeen** Member States having ratified the Agreement on a Unified Patent Court ('UPCA'). **Following the ratification of the UPCA by Romania, as of 1 September 2024, unitary patents are available in eighteen Member States.**

⁸ COM(2020)760 final.

⁹ Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, 31.12.2012, p. 1).

(5) **DELETED**

(6) **The main objective of this Regulation is to complement the unitary patent system by creating a unitary certificate for medicinal products, thereby simplifying the Union's SPC framework and reducing fragmentation within the internal market. Currently, ~~in~~ in the absence of a unitary certificate, the protection conferred by a unitary patent can only be extended in a non-unitary manner, by applying for several national certificates granted in each Member State where protection is sought. preventing the holder of a unitary patent from obtaining unitary protection during the whole combined protection period conferred by that unitary patent and subsequently by these certificates. DELETED. ThereforeTo rectify this situation**, a unitary certificate for medicinal products should be created, that ~~would~~**will** allow a unitary patent to be extended in a unitary manner. Such a unitary certificate should be applied for on the basis of a unitary-(basic) patent and a centralised **marketing** authorisation **and be subject to a centralised examination**; ~~it would have the same legal effects as national~~

~~certificates in all Member States in which that basic patent has unitary effect. The main feature of such a unitary certificate should be its unitary character.~~

(6a) Although a supplementary protection certificate is a *sui generis* right, its existence, validity, scope and protection are intrinsically linked to the underlying basic patent it relies upon. Therefore, ~~a unitary certificate~~ this Regulation should provide for the establishment of a unitary certificate that can only be based on a unitary patent.

(6b) Accordingly, this Regulation should ~~therefore~~ create a system for unitary certificates that is coherent with the unitary character and territorial scope of the underlying unitary patent. In view of the territoriality of intellectual property rights and the fundamental principle that a supplementary protection certificate cannot have a broader territorial scope than the underlying basic patent on which it is based, the territorial scope of a unitary certificate intrinsically results from the underlying unitary patent. As a result, the unitary certificate established by this Regulation should have effect in the Member States in which the underlying basic patent has unitary effect.

(6c) DELETED

(6d) DELETED

- (7) **Like unitary patents,** a unitary certificates should provide uniform protection and **should** have equal effect in all Member States where the underlying basic patent **they rely** it relies upon has unitary effect. Consequently, a unitary certificates should only be transferred or revoked, or expire, in respect of all those Member States.

(...)

Articles 2, 3, 4 and 5

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(...)

- (3) 'European patent' means a patent granted by the European Patent Office ('EPO') under the rules and procedures laid down in the European Patent Convention¹⁰ ('EPC');
- (4) 'unitary patent' means a European patent which benefits from unitary effect ~~in those Member States participating in the enhanced cooperation laid down in~~ **pursuant to** Regulation (EU) No 1257/2012;
- (5) 'basic patent' means a unitary patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by the applicant ~~for the purpose of the procedure for grant of~~ **in an application for** a unitary certificate **or in a combined application (in accordance with Article 32);**

(...)

¹⁰ Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000.

- (8) 'centralised application' means an application made before the ~~European Union Intellectual Property Office~~ [office TBC] pursuant to Chapter III of Regulation [COM(2023) 231]-with a view to the grant of certificates, for the product identified in the application, in the designated Member States;

(...)

Article 3

Conditions for obtaining a unitary certificate

1. A unitary certificate shall be granted by the [office TBC] ~~Office~~ on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, at the date of the application, all of the following conditions are fulfilled:
 - (a) the product is protected by that basic patent in force;
 - (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;
 - (c) the product has not already been the subject of a certificate, nor of a unitary certificate;
 - (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.
2. The holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State.

Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending ~~in a given Member State~~, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the [office TBC], as applicable.

Article 4

Scope of the protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a unitary certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the unitary certificate.

Article 5

Effects of the unitary certificate

1. The unitary certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations, ~~in all Member States in which the basic patent has unitary effect.~~
2. A unitary certificate shall have a unitary character. It shall provide uniform protection and shall have equal effect in all Member States in which the basic patent has unitary effect. The unitary certificate may only be limited, transferred or revoked, or lapse, in respect of all those Member States.

(Paragraphs 2 to 10 of Article 5 remain unchanged, as set out in the initial Commission proposal doc. 8869/23)

Article 57 remains as in the initial Commission proposal (doc. 8869/23), except for the application period which is still to be discussed:

Article 57

Entry into force and application

This Regulation shall enter into force on XXX [*OP – please insert the date - the 20th day following its publication in the Official Journal of the European Union*].

It shall apply from xxxxx [*OP please insert first day of the [12th - TBC] month after the date of entry into force*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.
