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NOTE

From:	Presidency
To:	Permanent Representatives Committee
No. prev. doc.:	7727/26; 9218/26
Subject:	**Supplementary protection certificate proposals (SPCs):** Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for plant protection products (recast); Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for medicinal products (recast); 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 – Guidance for further work

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (26.08.2026)

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, to 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[1], and the possibility of obtaining a unitary SPC[2] complementing the Unitary Patent.

3. On 28 February 2024, the European Parliament adopted its first reading position on the four SPC proposals.

4. Under the Swedish, Spanish and Belgian Presidencies, the Council Working Party on Intellectual Property carried out a comprehensive article-by-article examination of all four proposals, as well as of the accompanying impact assessment.

5. On 29 May 2024, the Permanent Representatives Committee provided guidance for future work requesting that solutions should be explored that would confer jurisdiction over direct invalidity actions concerning unitary SPCs to the Unified Patent Court (UPC).

6. On the basis of this guidance, the Hungarian Presidency elaborated several procedural options for the institutional set-up of the SPC granting system with a view to achieving this objective.

7. In that context, 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**

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[1] 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] 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)**.

8. 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, 10 and 28 April 2025 and 5 December 2025.

II. STATE OF PLAY AND POSSIBLE WAY FORWARD

9. The Cyprus Presidency has placed particular priority on exploring possible and viable solutions to address the question of the appropriate legal basis for the unitary SPC proposals and elaborated several options[3] aimed to address the concerns raised by the CLS. Those solutions, as summarised in the three concepts listed here below, were examined by the Council Working Party on Intellectual Property at its meetings on 21 January 2026, 18 February 2026, 18 and 31 March 2026, 27 April 2026 and 22 May 2026.

(a) 'Newly envisaged model (Bundle concept)'

10. Following an exchange of views on possible alternative approaches held between the CLS and the European Commission at the meeting of the Council 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.

11. 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'.

12. 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 provide hardly any added value in comparison to the SPC recast proposals, which are based on

[3] Doc. 5438/26, doc. 6196/26, doc. 7319/26, doc. 7727/26, **DELETED**, doc. 9218/26.

Article 114 TFEU and provide for the possibility to obtain national SPCs in a centralised procedure.

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(b) Derogation solution (so-called 'Solution A')

13. 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.

14. This derogation concept preserves 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**).

15. The proposed solution builds on the concept initially presented by the **DELETED**[4]. **DELETED**[5].

16. The derogation concept was presented at the Council Working Party on Intellectual Property on 18 March 2026. 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 2026.

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4 **DELETED**

5 **DELETED**.

(c) Specific Attributes solution

17. A majority of Member States 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 solutions to achieve these objectives on the basis of Article 118 TFEU within the ordinary legislative procedure.

18. 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 situations[6], such as the establishment of the Single Resolution Mechanism[7]. On this basis, and taking into account the particular legal nature of intellectual property rights and the special characteristics of the unitary patent framework, the Council 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.

19. The 'Specific Attributes' concept presents a different situation from a derogation. Under this concept, the proposed Regulation applies to all Member States. However, certain legal effects arise only to the extent that specific attributes 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.

20. The 'Specific Attributes' concept was presented to the Council Working Party on Intellectual Property on 27 April 2026. In light of the substantial support received and having carefully considered 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), which was further discussed at the Working Party meeting on 22 May 2026.

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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

21. **DELETED**

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CONCLUSION

22. In the light of the above, the Permanent Representatives Committee is invited to provide guidance for further work on the unitary SPC proposals. In order to enable progress on the whole SPC package, the Permanent Representatives Committee is invited to confirm that:

- with a view to preserving the overall objectives underpinning the proposed unitary SPC framework, and in particular to ensure the genuinely unitary character of the SPCs complementing the Unitary Patent, further work on the unitary SPC proposals should be pursued on the basis of Article 118 TFEU and within the framework of the ordinary legislative procedure, by building on the 'Specific Attributes' reasoning (as set out in doc. 9218/26, and along the lines of the drafting suggestions set out in Annex I to this note) or, alternatively, building on the 'Derogation solution' (described in doc. 7727/26, and along the lines of the drafting suggestions set out in Annex II to this note).

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ANNEX I

Drafting suggestions for 'Specific Attributes' solution (as tabled in doc. 9218/26)

Recitals based on recitals (3) to (7) of the initial Commission proposal on unitary SPCs (medicinal products) – doc. 8869/23:

(…)

(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 Council[9], **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.**

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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) **The unitary patent system rests on the combination of participation in the enhanced cooperation in the area of the creation of unitary patent protection, implemented by Regulation (EU) No 1257/2012, and the ratification of the UPCA by Member States. As a result, unitary patents are available only in the Member States that meet both of these requirements. While** Regulation (EU) No 1257/2012 created the possibility of ~~provide~~ **obtaining** unitary patents **protection,** ~~However (EU) No 1257/2012~~ **it** does not provide for a unitary supplementary protection certificate ('unitary certificate').

(6) **The main objective of this Regulation is to complement the unitary patent system and, by creating a unitary certificate for medicinal products, simplify the Union's SPC framework and reduce fragmentation within the internal market.** In the absence of a unitary certificate, **the protection conferred by** a unitary patent could 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~~. **This requires separate examination proceedings in parallel in several Member States, which entails duplication of work and potential divergent decisions among Member States. As a result, holders of unitary patents cannot benefit from unitary protection throughout the entire period concerned, since any extension beyond the expiry of the unitary patent depends on separate national certificates. Such market fragmentation creates significant legal uncertainty and adversely affects the Union's competitiveness, innovation and the proper functioning of the internal market.** ~~Therefore~~**To rectify this fragmentation**, 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 and scope are intrinsically linked to the underlying basic patent it relies upon. Therefore, a unitary certificate can only be based on a unitary patent. In view of the territorial nature 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 that of the underlying unitary patent. This Regulation should therefore establish a system governing unitary certificates that is coherent with the protection provided by the underlying unitary patent. In order to ensure consistency with the unitary patent framework and improve the functioning of the internal market, while respecting the territorial scope inherent in unitary patent protection, the unitary certificate established by this Regulation should have effect in the Member States in which the underlying basic patent has unitary effect.**

(6b) **While this Regulation applies to all Member States, it should operate on the basis of the objective characteristics of the underlying unitary patent and, in particular, its territorial scope, which arises upon the registration of unitary effect of the basic patent and remains unchanged throughout the lifetime of the unitary patent, and which should objectively determine the territorial scope of the corresponding unitary certificate. The territorial scope of a unitary certificate is therefore a factual and objective consequence inherently resulting from the territorial scope of the underlying unitary patent, which depends on the Member States in which unitary patent protection was available at the time when the unitary effect of the basic patent was registered. The availability, unitary nature and territorial scope of a given unitary patent constitute specific attributes which inherently determine the territorial scope of the unitary certificate based thereon. At the same time, since this Regulation applies to all Member States, the territorial scope of protection conferred by future unitary certificates will evolve accordingly as additional Member States join the unitary patent system.**

(7) **Like unitary patents,** ~~a~~ unitary certificate**s** 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 certificate**s** should only be transferred or revoked, or expire, in respect of all those Member States.

(…)

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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 Convention[10] ('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 ~~**European**~~ patent ~~**with unitary effect**~~ 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)**;

(…)

(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;

(…)

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

Article 3

Conditions for obtaining a unitary certificate

1. A unitary certificate shall be granted by the **[office TBC]** ~~Office granting office referred to in Article 9d~~ 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 ~~granting~~ **[**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.

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ANNEX II

Drafting suggestions for 'Derogation Solution' (as tabled in doc. 7727/26)
(based on the text of initial Commission proposal on unitary SPCs (medicinal products) – doc. 8869/23)

New recital:

(xx) The Unified Patent Court (UPC) has been established to hear cases concerning European patents with unitary effect. Building on that framework, and in order to ensure an effective remedy system concerning such patents and related unitary certificates, consistency of case-law and hence enhance legal certainty, and achieve cost-effectiveness for proprietors of patents and certificates, it is of paramount importance that Member States join the Agreement on a Unified Patent Court in accordance with their national constitutional and parliamentary procedures and take the necessary measures to ensure jurisdiction for that Court regarding unitary certificates. Until the necessary measures have been taken, certain conditions and effects under this Regulation should only apply to Member States in which the UPC has exclusive jurisdiction in respect of European patents with unitary effect and unitary certificates.

Article 2
Definitions

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

(…)

(5) 'basic patent' means a ~~unitary~~ **European** patent **with unitary effect** which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder ~~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)**;

(…)

Article 3

Conditions for obtaining a unitary certificate

1. A unitary certificate shall be granted by the ~~Office~~ **central office (tbc)** 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.

(…)

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 Member States.

Article 7

The unitary certificate as an object of property

A unitary certificate or an application for a unitary certificate as an object of property shall be treated in its entirety~~, in each Member State in which the basic patent has unitary effect,~~ in accordance with the national law applicable to the basic patent as an object of property.

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Article 55
Committee procedure

1. The Commission shall be assisted by a Committee on Supplementary Protection Certificates established by Regulation [COM(2023) 231]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

(New) Article XX
Reporting on national measures

Member States shall notify the Commission of any national measures taken in relation to Article 57(3) and (4). Each Member State shall designate one or more national authorities responsible for matters relating to the implementation of the measures provided for by this Regulation and it shall communicate the details of that national authority or authorities to the Commission.

Article 56
Evaluation

By xxxxxx [OP, please insert: five years after the date of application], and every five years thereafter, the Commission shall evaluate the implementation of this Regulation. **The evaluation shall take into account any information received under (New Article XX).**

Article 57
Entry into force and application

1. 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].

2. It shall apply from xxxxx [OP please insert first day of the ~~12th~~ **24th** month after the date of entry into force] **or the date on which the UPC has jurisdiction in respect of unitary certificates, whichever is the latest.**

3. The conditions set out in Article 3(1) shall only apply in respect of those Member States in which, at the date of lodging of an application for a unitary certificate in accordance

with Article 10, the UPC had exclusive jurisdiction in respect of the basic patent and of unitary certificates.

4. A unitary certificate granted under this Regulation shall have the effects referred to in Articles 5(1), 5(2) and 20(1) only in those Member States in which, at the date of lodging of an application for such certificate in accordance with Article 10, the UPC had exclusive jurisdiction in respect of the basic patent and of unitary certificates.

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