Council of the European Union

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NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	9270/26
Subject:	Unitary Supplementary Protection Certificates (uSPCs) – Specific Attributes = Partial revised text

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (26.08.2026)

Following the guidance provided by COREPER on 27 May 2026, which confirmed the clear support for continuing work on the unitary SPC proposals on the basis of the 'Specific Attributes' concept, the Cyprus Presidency continued work on the recitals underpinning that concept.

Taking into account the feedback received from the CLS, recitals (3) to (7) of the unitary SPC proposal on medicinal products have been revised as set out in the Annex. Please note that no further changes have been made to the Articles at this stage.

Changes compared to the initial Commission proposal (doc. 8869/23) are indicated in **bold underlined** or in ~~strikethrough~~. Changes compared to the text submitted to Coreper (Annex I of document 9270/26) are highlighted in grey shade and marked by ~~double strikethrough~~ for deletions.

Delegations are invited to examine the revised drafting and provide feedback and any drafting suggestions they may have at the Intellectual Property Working Party meeting on 22 June 2026.

ANNEX

Revised drafting suggestions for 'Specific Attributes' solution

(…)

(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'[1], 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[2], **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.**

(5) **DELETED**

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1 COM(2020)760 final.

2 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).

DELETED

(6) **The main objective of this Regulation is to complement the unitary patent system** ~~**and,**~~ **by creating a unitary certificate for medicinal products, thereby simplifying the Union's SPC framework and** ~~**reduce**~~ **reducing fragmentation within the internal market. Currently,** ~~**In**~~ in the absence of a unitary certificate, **the protection conferred by** a unitary patent ~~**could**~~ **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**

~~Therefore~~**To rectify** ~~**fragmentation**~~ **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 ~~**and,**~~ **scope and protection are intrinsically linked to the underlying basic patent it relies upon. Therefore, a unitary certificate** ~~**can**~~ **should only be based on a unitary patent.**

(6b) 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 ~~**territorial nature**~~ **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** ~~**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 consisteney with the unitary patent framework and improve the functioning of the internal market, while respecting the territorial scope inherent in unitary patent protection~~ **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.**

(6~~b~~c) DELETED

(6d) DELETED

(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.

(…)

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 Convention[3] ('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)**;

(…)

(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;

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

(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.

PUBLIC