Council of the European Union

Brussels, 13 March 2026
(OR. en)

7319/26

LIMITE

PI 36

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

NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	6196/26
Subject:	Supplementary Protection Certificates (SPCs) – Discussion paper

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (22.05.2026)

SPCs – Considerations to address issues of the legal basis

Introduction

Following the exchange of views held during the Working Party meetings on 21 January and 18 February 2026 on the legal basis of the unitary SPC proposals, the Cyprus Presidency has continued to explore possible avenues to facilitate progress on this matter.

During the Working Party meeting of 18 February, a more elaborated structure of the newly envisaged model (doc. 5438/26 and doc. 6196/26) was presented, with a view to exploring the legal feasibility of relying on Article 114 TFEU, [redacted].

The feedback gathered from delegations, both orally and in writing, indicated that some of the elements of the newly envisaged model risk undermining the very objectives of the SPC reform.

Member States reiterated the need for a solution that will ensure legal certainty, reduce fragmentation and enhance the competitiveness of the Single Market, while ensuring alignment with the current EU priorities of removal of barriers and simplification of EU procedures.

The Presidency acknowledges the importance of finding an approach that fulfils the objectives of the SPC package reform.

In response to this, the Cyprus Presidency has worked on two solutions which are set out in this document as Solution A and Solution B, both of which aim to address the shortcomings Member States identified under the previous model. As several Member States requested drafting suggestions to help visualise the proposed concepts, further details on both approaches are provided below.

Solution A [redacted] draws inspiration from the concept used for the Unitary Patent Regulation. It aims to preserve the underlying philosophy of establishing a unitary SPC on the basis of Article 118 TFEU.

Solution B reflects the openness expressed by some Member States to explore potential solutions based on Article 114 TFEU. It examines to what extent the objectives of the SPC reform could be pursued within that legal framework, notably through the harmonisation of procedures and measures aimed at improving the functioning of the Single Market.

The present document sets out these two approaches for further reflection and discussion by delegations.

Delegations are invited to comment on both approaches at the next meetings of the Intellectual Property Working Party.

Solution A - [redacted]

The proposed solution A [redacted] draws inspiration from the concept established in the Unitary Patent Regulation.

[redacted]

Main Elements of solution A:

In response to several Member States underlining the importance of maintaining a genuinely unitary SPC, solution A seeks to preserve the underlying philosophy of establishing a unitary SPC based on Article 118 TFEU.

The central idea of this approach is that the Unitary SPC Regulation should apply uniformly across the Union, both in its wording and legal structure, while the factual territorial scope of the SPC protection is linked to the jurisdictional framework of the Unified Patent Court (UPC). [redacted]

[redacted]

The drafting suggestions proposed to implement solution A are presented in the context of the proposal for a Regulation on medicinal products. With the necessary adjustments, these amendments could also be applied to the proposal for a Regulation on plant protection products and aligned with the SPC recast proposals.

Summarising the core elements of solution A:

- Preserves the idea/philosophy of a Unitary SPC Regulation based on Article 118 TFEU;

[redacted]

- [redacted]

Drafting suggestions for solution A:

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.

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].

[redacted]

Solution B – Use of the harmonised centralised procedure for SPCs based on a unitary patent

Given the openness expressed by several Member States at the previous Working Party meetings to explore potentially feasible solutions to address the deadlock on the legal basis by relying on Article 114 TFEU, solution B explores how the objectives of the SPC reform could be achieved within that framework, with a focus on the harmonisation and centralisation of procedures and the improvement of the functioning on the Single Market.

As regards substance, solution B is based on the understanding that the unitary character of an SPC building on a unitary patent derives *ipso facto* from the very character of the underlying unitary patent, provided that the territorial scope of the requested SPC coincides with that of the underlying unitary patent. Even though SPCs are *sui generis rights*, a unitary SPC is intrinsically linked to the European Patent with unitary effect, builds upon it and cannot exist without it.

At the same time, it is a matter of fact that the territorial scope of the unitary patent is limited. It is therefore not the SPC Regulations themselves that are limiting the territorial scope of SPC protection based on a unitary patent. Rather, this limitation inherently results from the underlying unitary patent.

Solution B aims seeks to leverage the procedural possibilities available under Article 114 TFEU, through a harmonised and centralised procedure, to allow the effects of the underlying unitary patent to unfold *ipso facto*/automatically onto an SPC based on it, by providing, for means of procedural efficiency, a single SPC where the SPC application has the same territorial scope as the underlying unitary patent.

Main Elements of solution B:

Under solution B, a harmonised centralised procedure, with a central authority (in charge of both examination and granting), enables the grant of a **Single SPC**, which derives its territorial coverage and equal effect from the underlying unitary patent, thus mirroring them. Therefore, where the territorial scope of the SPC application is identical to that of the underlying unitary patent, the SPC would inherit both the protection and effects of the underlying unitary patent and could be conferred by a single certificate.

Where the territorial scope of the SPC application is not identical to that of the underlying unitary patent (i.e. where the applicant requests SPC protection only in some individual Member States), only the patent protection would be carried over into the SPC. In such cases, SPC protection would need to be granted through individual national SPCs issued by the relevant national patent offices (NPOs).

As regards the designation of Member States by the applicant, solution B does not oblige applicants to designate all Member States in which the unitary patent has effect. Applicants retain full discretion regarding the territorial scope of their SPC applications, in line with the choice that is given to the applicants under the original SPC recast proposals. However, obtaining a Single SPC in the harmonised centralised procedure is only possible where the territorial scope of the SPC application fully corresponds to that of the underlying unitary patent. Such a Single SPC through a centralised procedure will enhance procedural efficiency by reducing administrative burdens and limiting multiple national filings.

Summarising the above, solution B confirms that the SPC Regulation does not determine the nature, character or effects of the protection. It clarifies that the effects of SPC protection correspond to those of the underlying unitary patent, with its scope being determined, on the one hand, by the underlying unitary patent and, on the other hand, by the designation made by the applicant in the SPC application.

Summarising the core elements/the core drafting suggestions of solution B:

- Solution B aims at clarifying the scope of protection and the effects of SPCs that are based on a unitary patent.
- To implement this solution the following drafting suggestions are put for consideration:
    - equal wording of Article 3(1), Article 4 and Article 5(1) could be used for both recast and uSPC texts (or the text could potentially be merged into one single Regulation to emphasise that this procedure applies equally to all Member States);
    - a clarifying provision for SPCs that are "*based on a unitary patent*" in Article 5(2) (see drafting suggestion below, which incorporates also the provision of Article 7 of the uSPC proposal);

- replace the term "*unitary SPC*" by another term, such as "***Single SPC***" in the relevant procedural provisions;

- the granting of such single SPC, whose territorial scope is identical to the underlying unitary patent, would for procedural efficiency, be done centrally (see drafting suggestion for new Article 32a based on latest DK Presidency revised text of Article 18 of the uSPC text doc. 16178/25);

- regarding designation, the proposed solution does not *oblige* the applicant to designate all UP-Member States in the application; it rather leaves the choice to the applicant. Based on the applicant's designation, there are two factual scenarios:

  - Where the applicant in the application requests SPC protection for only some Member States in which the basic patent has unitary effect, then application and examination would be done via the centralised procedure, but SPCs would be granted individually by NPOs (Article 32(2) below)

  - Where the applicant requests SPC protection for all Member States in which the basic patent has unitary effect, then not only the application and examination would be done via the centralised procedure, but also the certificate would be issued centrally, hence the procedure would make available a Single SPC.

- on this basis, the Regulation could also provide for centralised appeals and remedies.

Drafting suggestions for solution B:

Article 3

Conditions for obtaining a ~~unitary~~ certificate

1. A ~~unitary~~ certificate shall be granted ~~by the Office~~ on the basis of a basic patent if, in each of the Member States ~~in which that basic patent has unitary effect~~ **for which a certificate is applied for**, 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, 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 **that is based on a unitary patent and on an application that designates all Member States in which the unitary patent is in force** ~~shall have a unitary character. It~~ shall provide ~~uniform~~ **the same** protection and shall have equal effect in all Member States in which th**at** ~~e basic~~ **unitary** patent ~~has unitary effect~~ **is in force**. ~~The unitary~~ **Such a** certificate may only be ~~limited,~~ transferred or revoked, or lapse, in respect of all those Member States. *(Following sentence is taken from Article 7 uSPC Regulation)* ~~A unitary~~ **Such a** certificate or an application for **such** 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.

Chapter III
Centralised procedure for certificates

Article 20 (based on text of latest DK Presidency recast text doc. 16177/25)

~~Scope of the c~~Centralised applications

1. Where the basic patent is a European patent, including a unitary patent, and the authorisation to place the product on the market has been granted through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply.

2. ~~When~~ **Where** the conditions under paragraph 1 are met, the filing of national applications **under Chapter II** shall be prohibited, in respect of the same product, in those Member States in which ~~that~~ **the** basic patent **referred to in paragraph 1** is in force.

3. A centralised application shall be lodged with the ~~European Union Intellectual Property Office established by Article 2 of Regulation (EU) 2017/1001 ('the Office')~~ **managing office referred to in Article 21b**.

4. Articles 1 to 7 and 13 to 18 shall apply to centralised applications.

5. The centralised application shall be lodged by using a specific application form **and shall contain the information referred to in Article 8(1)** ~~**and 8(1a)**~~ ***(Article 8(1a) moved back to Article 21)***.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used to lodge a centralised application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

Article 21

~~Content of~~ Designation of Member States in the centralised application

~~*(deleted)*~~

The centralised application shall ~~contain the following:~~

(a) ~~designation of~~ **designate** the Member States in which certificates are sought under the centralised procedure; ~~*(moved to new paragraph (1a) of Article 8)*~~

(b) ~~the information referred to in Article 8(1).~~ *(moved to Article 20(5))*

new Article 32a

(based on Article 18 of latest DK Presidency uSPC text doc. 16178/25)

Grant of a ~~unitary~~ certificate or rejection of the application for a ~~unitary~~ certificate based on a unitary patent

1. Where the application for a ~~unitary~~ certificate, which is based on a unitary patent and which designates all Member States in which the basic patent has unitary effects, and the product to which it relates meet the conditions laid down in this Regulation, the ~~granting~~ central office shall grant [the ~~unitary~~ certificate][a single certificate as referred to in Article 5(2)].

2. Where the application for ~~a unitary~~ such a certificate, or the product to which it relates does not meet the conditions laid down in this Regulation, the ~~granting~~ central office shall reject the application.

3. **When deciding whether to grant the ~~unitary~~ certificate or reject the application for a ~~unitary~~ certificate, the ~~granting~~ central office shall take utmost consideration of the recommendation and any related statements of disagreement or comments submitted by examining members in accordance with Articles 17a and 17b.**

4. **The ~~granting~~ central office shall notify the applicant of the decision. The ~~granting~~ central office shall transmit the decision to the network ~~[and the managing office]~~.**