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NOTE

From:	Presidency
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Subject:	Supplementary Protection Certificate (SPCs) - Presidency steering note

With a view to facilitating the discussions at the meeting of the Working Party on Intellectual Property on 5 Sepetmeber 2025, delegations will find attached a steering note from the Presidency accompanying the partial revised text of the unitary SPC proposal set out in document 12208/25.

Annex to WK 10552/2025

Supplementary Protection Certificate proposals

Steering note accompanying the partial revised Presidency text (doc. 12208/25)

Introduction

Document 12208/25 presents a revised Presidency text on a number of articles of the unitary SPC proposal on medicinal products, to be discussed with the delegations at the upcoming IP Working Party meeting on 5 September 2025. The partial revised text builds on the discussion on the joint Polish and Danish Presidency note 10909/25 outlining a possible way forward with the unitary SPC proposals in continuation of the discussions of the institutional setup of a unitary SPC regime presented on 3 July 2025.

The partial revised text fully takes into account the guidance provided by COREPER on 29 May 2024. Notably, COREPER called for a solution that would confer the competence on direct invalidity actions related to unitary SPCs to the Unified Patent Court (UPC). The provisions are drafted specifically with this mandate in mind, with additional consideration being given to creating a setup that would make the UPC responsible for remedies.

Please note, that the question on the legal basis has not been addressed at this stage. While this question is vital for the soundness of the two unitary SPC proposals, the Danish Presidency suggests addressing the institutional set-up first. In order to ensure progress in the discussions, we encourage delegations to set the question on the legal basis aside for the moment and focus on the key elements of the proposed architecture listed below for this meeting. We will return to the question of the legal basis at a later stage.

Priority has been given to establish a design for the institutional set-up and the examination procedure in a way that builds upon the already existing competences of the Member States' patent offices, for two reasons:

- First, to ensure that the system functions effectively from the onset, involvement of the national patent offices is necessary as the examination of SPC's differs substantially from patent applications, notably in that it requires a technical evaluation of what is understood as the first marketing authorisation including whether an active ingredient has previously been covered by a previous SPC.

- Second, while it is expected that there will be an increase in SPC applications, the total number of applications filed per year are expected to be less than 100. As it continues to be possible for the applicants to apply not only for a unitary SPC, but also national SPCs, it is essential to guarantee a set-up that allows for the national patent offices to retain their competences.

At the IP Working Party on 3 July, several delegations indicated that they preferred to keep the different options regarding the central authority open and not designate the EUIPO at this stage. In light of this request, we removed the reference to the EUIPO in the current text and propose a concept of a *managing office*, which is drafted in an open manner.

The articles in the partial revised text are drafted for the unitary proposals (on the basis of the unitary SPC proposal for medicinal products) but will be transposed to the SPC recast proposals with the appropriate adaptations, as the proposed architecture is intended to apply coherently across all four SPC legislative proposals. We continue to work on the basis of a single, integral compromise package for all four proposals.

This accompanying note presents the content of the articles related to the institutional set-up of the unitary SPC system, which can be divided into different blocks:

1. Conditions and scope of an SPC application

- Article 3: Conditions for obtaining a unitary certificate
- Article 4: Scope of the protection
- Article 6: Entitlement to the unitary certificate
- Article 8: Application for a unitary certificate
- Article 9: Content of the application for a unitary certificate

2. Tasks and responsibilities of the different bodies

- Article 9b (new): Managing office
- Article 9a (new): Network of competent national authorities
- Article 9c (new): Rapporteur and co-rapporteur
- Article 9d (new): Granting office
- Article 9e (new): Criteria for the designation of the granting office, rapporteur and co-rapporteurs

3. The different steps related to an SPC application

- Article 10: Lodging of an application for a unitary certificate
- Article 11: Examination of the admissibility of an application for a unitary certificate
- Article 12: Publication of the application
- Article 14: Observations by third parties

4. Tasks of the different bodies related to the examination process

- Article 17 (new): General principles of the examination procedure
- Article 17a (new): Examination by the Network
- Article 17b (new): Procedure for disagreement
- Article 17c (new): Consultation of the applicant

5. Decision on an SPC application

- Article 18: Grant of a unitary certificate or rejection of the application for a unitary certificate
- Article 18a (new): Conversion of the application
- Article 19: Grant of an extension of the duration of a unitary certificate

6. Remedies

- Article 22: Invalidity of the unitary certificate
- Article 28 (new): Appeals

7. Combined applications

- Article 32: Combined applications

1. Conditions and scope of an SPC application – Articles 3-9

The first block of articles sets out the conditions and scope of an SPC application. The articles correspond to those in the Commission proposal with only minor amendments. They are displayed for ease of reference. Please note that the revision of Articles 5 and 7 is left for a later stage, and that they have not been amended.

2. Tasks and responsibilities of the different bodies - Articles 9b-9e

The next section contains articles that outline the tasks and responsibilities of the various bodies involved in the process. These articles are new and differ significantly from those in the Commission proposal. They include a substantial shift of competences from the concept of a central authority (EUIPO in the Commission original proposal) to the national level.

The set-up described in Articles 9a-9e has been designed in a way to give all Member States within the unitary patent system the opportunity to be involved in the examination process, by setting up a network of competent national authorities. This enables national offices to maintain their competences, while at the same time preventing the network's recommendations from becoming Union acts, as the granting office retains full discretion on whether to grant the SPC or reject the SPC application.

Article 9a: Network of competent national authorities

This article establishes a network of competent national authorities. The network is tasked with assessing the applications. It is important to note that the network is not a formal body or an institution, but a cooperation framework between national patent offices, acting solely in their capacity as national patent offices (NPOs). The network's legal basis is therefore established in the Regulation. The network will not take decisions on whether to grant SPCs or reject applications, as this decision will be at the full discretion of the granting office. The network would only issue non-binding recommendations on the SPC applications (more details on this process is outlined in Article 17).

Participation in the network would be open to all national patent offices on an opt-in basis (Article 9a(2)). However, only NPOs of Member States in which the unitary patent has effect will be entitled to take part in the examination procedure regarding unitary SPCs (Article 17(1)), while participating NPOs of other Member States would be involved in cases of combined applications (Article 17(2)) - see for further details below. The participating offices will have to ensure that the participating examiners possess the required qualifications in a relevant technical field or in law (Article 9a(5)).

Article 9b: Managing office

This provision is drafted in a way that could accommodate either the EUIPO or the EPO as the managing office. The managing office would be given a strictly administrative role to support the network, and it would not be involved in the actual substantive examination process. Its tasks include:

- receiving and publishing applications for unitary certificates and for applications for extensions of the duration of certificates related to pharmaceuticals for paediatric use and forwarding the applications to the network;
- performing a preliminary assessment of the admissibility of applications;

- distributing recommendations, including statements of disagreement, among members of the network;
- establishing and maintaining the register and database;
- communicating with the applicants, certificate holders and third parties;
- collecting and distributing administrative fees;
- tasks related to combined applications.

Limiting the role of the managing office to mere administrative, supportive tasks ensures that the act of granting a unitary SPC or rejecting the application is not considered an EU act, which could be challenged before the Court of Justice of the European Union. Instead, the substantive decision of granting a unitary SPC or rejecting the application is left to the granting office. This secures the involvement of the UPC in the remedies process, in line with the COREPER mandate of 29 May 2024.

Article 9c: Rapporteur and co-rapporteur

For each case, two of the NPOs participating in the network will be designated as rapporteur and co-rapporteur respectively. For additional support in complex cases, an additional co-rapporteur can be designated at the request of either the rapporteur or co-rapporteur. Their principal task would be to draft a *recommendation* on whether an SPC should be granted or the application should be rejected, in accordance with the procedure described in the section concerning the examination procedure (Articles 17-17c).

Article 9d: Granting office

With the aim to establish a streamlined, least complex procedure, Article 9d foresees that the NPO acting as the rapporteur in the examination of a given SPC application will also serve as the *granting office*. This concept significantly decreases the risk that a granting office would subsequently deviate from its own recommendation when deciding whether to grant the SPC or reject the application.

Article 9d: Criteria for the designation of the granting office, rapporteur and co-rapporteurs

Both the rapporteur and co-rapporteur(s) are selected based on a set of criteria, leaving the managing office with no discretionary power in their selection. *The rapporteur* is determined by the residence or principal place of business of the applicant, provided that this is in a Member State where the basic patent has unitary effect. For joint applications, the NPO of the Member State listed first will be the rapporteur (and the granting office), again provided it is party to the unitary patent cooperation. For applicants from outside the unitary patent cooperation or third

countries, it is suggested that the rapporteur is determined by a rotation mechanism among the Member States in which the unitary patent has effect.

The selection of *the co-rapporteur* will always be done based on a rotation system. However, to ensure quality in the examination of the application either the rapporteur or the co-rapporteur must be a competent national authority not making use of the exemption for substantive examination of SPCs (Article 10(5) of Regulation [COM(2023) 231]). A possible additional co-rapporteur would be selected by the same mechanism.

Examples:

- If the applicant has its residence or principal place of business in Germany, the Rapporteur would be the German Patent and Trademark Office with the co-rapporteur being selected from the remaining 17 NPO's based on a rotational principle (details of which to be decided at a later stage).

- If the applicant has its residence or principal place of business in Slovenia, the Rapporteur would be the Slovenian Intellectual Property Office. However, as the Slovenia Intellectual Property Office make use of the exemption set out in Article 10(5) Regulation [COM(2023) 231]), the co-rapporteur would have to be from one of the Member States that do not make use of the exemption.

- If the applicant is from either a non-UPCA Member State – for instance Spain – or from a third country – for instance the United Kingdom – both the Rapporteur and Co-Rapporteur would be decided based on a rotational principle (details of which to be decided at a later stage).

- Finally, in the event of joint applications, where more than one applicant's residence or principal place of business is within a Member States in which the unitary patent has effect, for instance where the applicants would be from Japan, France, or Germany, the Rapporteur would be the NPO of the UPC-Member State listed first, in this case France.

3. The different steps related to an SPC application – Articles 10-12, 14 & 15

Articles 10-14 cover the various procedural steps involved during the assessment of an SPC application. They correspond to those in the Commission proposal with only a few minor changes, mainly of linguistic nature and related to references to other articles. Article 15 on oppositions has been deleted from the text in its entirety.

4. Tasks of the different bodies in the examination procedure – Articles 17, 17a-17c

This block of articles sets out the general principles of the examination procedure and the tasks of the different bodies (managing office, network, members of the network participating in the examination, rapporteur, co-rapporteur(s)) involved in the examination process. These provisions are drafted in an effort to design the system in a way that ensures coherent and harmonised SPC examinations across the EU, while retaining expertise in SPC examinations at the national level. The block of Articles 17, 17a-17c is meant to replace Articles 13, 16 and 17 of the initial Commission proposals.

Article 17: General principles of the examination procedure

Article 17 is a new article which outlines the general principles of how the examination procedure should be conducted within the network. It specifies that only competent national authorities from Member States where the basic patent has unitary effect can participate in the examination of unitary application. However, the national authorities from the other designated Member States would be involved in the case of combined applications.

The examination procedure is primarily conducted in writing, though plenary meetings of the network may be convened for specific cases. The network should strive to reach consensus in its assessments, but as this cannot always be achieved, a procedure to handle disagreements is proposed in Article 17b.

Article 17a: Examination by the Network

This new article describes the examination process carried out by the network. The examination would start following the publication of the application, with the rapporteur and co-rapporteur(s) examining the application according to the relevant rules and criteria in the Regulation related to the grant or rejection of an SPC. They would then prepare a written recommendation to either grant the unitary certificate or reject the application. This recommendation would be circulated among the other offices of the network particpating in the examination (so-called "examining members") with a view to receiving their written comments on the recommendation. Each examining member would analyse the application and the recommendation and consider any statements or observations by either the applicant or third parties. The examining members of the network would be able to submit a reasoned disagreement within [one month]. If no objections are raised, the granting office would proceed to adopt a final decision to grant the SPC or reject the application.

It is expected that most applications would be processed with no disagreement or objection to the recommendation of the rapporteur/co-rapporteur. Applications would proceed to examination by the granting office if no examining member objects. If any examining member of the network, within the deadline described in the proposal, submits a reasoned statement of disagreement with the draft recommendation, a written procedure for disagreement will be initiated.

Article 17b: Procedure for disagreement

This article sets out the procedure to be followed in cases of disagreement among examining members. If any statements of disagreement are submitted under Article 17a(3), the managing office shall forward them to the rapporteur and co-rapporteur(s). The rapporteur and the co-rapporteur(s) will have to either revise the recommendation to address the statements or explain to the network their reasoning for not following the statements. If the majority agrees, the recommendation will be referred to the granting office, which will – in full discretion, not bound by the network's recommendation - take a decision to grant the SPC or reject the application.

If a majority of members submit further reasoned disagreements within one month, the case will be referred to a plenary meeting for discussion. If a majority disagrees with a recommendation to reject the application, the applicant will have the opportunity to convert the application into centralised SPC applications (described in Article 18a) once the rejection of the unitary SPC application has become final.

Similar to the European Medicines Agency's (EMA) CHMP model, the plenary would be conducted online and in English.

Article 17c: Consultation of the applicant

This new article provides for the consultation of the applicant during the examination procedure, safeguarding their right to be heard. The rapporteur and co-rapporteur may invite the applicant to submit comments at any stage, and any such comments must be shared with the examining members of the network. Before any decision is taken that could negatively affect the applicant, the applicant shall be given an opportunity to comment within two months. The rapporteur and co-rapporteur may consult the examining members on the applicant's submissions before proceeding.

This ensures that applicants have a fair opportunity to present their case and address any concerns raised by the network or third parties.

5. Decisions on the SPC application – Articles 18, 18a & 19

Article 18: Grant of a unitary certificate or rejection of the application for a unitary certificate

This article covers the granting or rejection of SPC applications. The granting office would be appointed according to Article 9d (see above).

The granting office is responsible for granting or rejecting an application for a unitary certificate. When deciding whether to grant the unitary certificate or reject the application for a unitary certificate, the granting office shall take utmost consideration of any statements or comments related to the recommendation submitted in accordance with Articles 17a and 17b. However, all the steps leading up to the granting (recommendation, any statements of the examining members) are non-binding, and the granting office has full discretion to grant the SPC or reject the application.

While the system is designed to reduce the risk of divergence between the examination phase and the granting phase, it cannot be ruled out that, in some cases, the granting office's final decision is not supported by the other examining members of the network. Against this background, a safeguard mechanism for the applicant is needed in case of rejections not supported by the network, whereby the applicant can request that the application is converted into a centralised application.

The new Article 18a establishes the conditions under which an applicant may request the conversion of a rejected application for a unitary SPC into a centralised application. This option is available in two scenarios:

- if the rejection of the unitary SPC deviates from the initial recommendation to grant the SPC where no disagreements have been submitted regarding the initial recommendation, or
- if the rejection of the unitary SPC deviates from the majority view of a plenary meeting.

The request for conversion must be filed with the managing office within two months of the rejection decision having become final. The managing office then forwards the converted application and related documentation to the relevant Member States, which will decide on the granting of national certificates in accordance with Regulation [COM(2023) 231]. We would welcome the delegations' views on the concept of the conversion mechanism, including if there could be other scenarios that could call for the right of the applicant to convert.

Article 19: Grant of an extension of the duration of a unitary certificate

This article sets out the conditions under which the duration of a unitary certificate may be extended for medicinal products intended for paediatric use. It outlines that the application must meet specific formal and substantive requirements, and if these are fulfilled, the extension is granted. If not, the applicant is given a chance to correct the deficiencies. Failure to do so results in rejection of the application. This step of the process does entail less involvement of NPOs as this is a rather straight forward formality check and does not include substantive examination.

6. Remedies – Invalidity actions and appeals – Articles 22 & 28

The Working Party has not yet had a political discussion on appeals. Appeals are currently dealt with at the national level before a competent body in the Member State of the granting office. The establishment of a Board of Appeals with the EUIPO has been deleted from the text, and it is not foreseen to introduce an appeal body with the managing office. We would value Member States views on our Presidency text of new Article 28.

Article 22: Invalidity of the unitary certificate

This article is drafted with inspiration from the corresponding Article 15 of Regulation (EC) No 469/2009. It sets out the grounds for invalidating a unitary certificate, including if it was granted in breach of the Regulation, if the basic patent has lapsed or has been revoked, or if it no longer protects the relevant product. It also provides that any person may initiate proceedings for invalidity before the competent national authority responsible for revoking the corresponding basic patent.

Article 28: Appeals

This is a new article outlining that decisions by the granting office, specifically those concerning the grant or rejection of a unitary certificate or an extension of its duration, may be appealed before the competent body under the national law of the Member State where the granting office is located. This provision allows for the possibility of amending the UPCA to also cover granting decisions by national offices, provided that there is a consensus to do so.

A key goal of this proposal has been to create an institutional set-up that would ensure that the UPC is the only competent court in the area of invalidity actions and counterclaims for unitary SPCs, in line with the COREPER mandate from 29 May 2024.

It is still an open question how appeals of national decisions to grant or reject applications should be handled. However, regardless of whether the UPC will be conferred the competence also in the area of appeals of national decisions, invalidity actions over unitary SPCs fall fully within the exclusive competence of the UPC.

7. Combined applications – Article 32

Article 32: Combined applications

This article allows applicants to include a request for a unitary certificate within a combined centralised application that also seeks national certificates in designated Member States. The text of this provision corresponds to the initial Commission proposal.