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**NOTE**

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Subject: Supplementary Protection Certificates (SPCs)  
- Stocktaking paper

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In view of the Council Working Party on Intellectual Property on 5 December 2025, delegations will find in the Annex a stocktaking paper on the progress of the discussions on the SPCs proposals during the Danish Presidency and questions on remaining open issues.

This paper is to be read in conjunction with the partial revised texts on the proposals for a Regulation on the SPCs (recast) (doc. 16177/2025) and on the unitary SPCs (doc. 16178/2025), and the note describing the functioning of the rotation mechanism for the designation of the rapporteur and the co-rapporteurs set out in WK 16641/2025.

## **Supplementary Protection Certificates (SPCs)**

### **PROGRESS DURING THE DANISH PRESIDENCY**

In an effort to progress the SPC files, the Danish Presidency has included the topic on the agenda of seven IP Working Party meetings. The discussions have focused on: (a) draft proposals on the institutional set-up and the examination procedure, including the concepts of a rapporteur, co-rapporteurs and the network of national patent offices (NPOs); (b) policy papers on the political and legal implications of the involvement of the EPO.

#### ***The institutional set-up and examination procedure for the SPC-system***

The Danish Presidency has prioritised a text-based approach in the negotiations. To this end, several partially revised Presidency texts have been presented for both the unitary and recast SPC proposals.

The drafts have revised and elaborated on an institutional framework and examination procedure that could function irrespective of which institution, the European Union Intellectual Property Office (EUIPO) or the European Patent Organisation (EPO), would ultimately be selected as a managing office. A main focus has been on designing the system based on the guidance provided by Coreper on 29 May 2024, to achieve that the jurisdiction in invalidity proceedings for the unitary SPC is conferred to the Unified Patent Court (UPC).

Delegations have repeatedly stressed that the granting procedure for SPCs should draw on the expertise of national patent offices, which currently handle SPC examinations. Therefore, a second focus point has been to involve the Member States' patent offices in the substantive examination of applications, in order to guarantee the quality of examinations and to allow for the system to function effectively from the onset, while also retaining national expertise in the sphere of SPCs.

Based on these considerations, the proposed institutional framework will consist of a network structure comprising competent NPOs. A rapporteur and two co-rapporteurs will prepare a recommendation to grant an SPC or reject the application, which will be presented to the network for a collective assessment. It will not be the network that takes the formal decisions on whether to grant SPCs or reject applications, as this would be at the discretion of the granting office.

A further element of the proposal has been the deletion of the pre-grant opposition procedure.

In order to keep the package character of the four SPC proposals, and following a call from some of the non-UPC Member States not to overlook centralised and combined SPC applications, the Presidency has also presented revised texts of the recast proposal on medicinal products, incorporating the changes introduced in the unitary proposal, along with the necessary adjustments to render the Regulation operable.

Based on feedback received from the Working Party, the Presidency has revised the proposals, including by:

- making direct references to EPO as the managing office,
- allowing for a central authority, potentially also the EPO, to carry out the task of the granting office,
- providing for an option for a pure rotational principle for the designation of the rapporteur and co-rapporteurs as an alternative to a seat-based principle,
- as well as improving the wording of the articles in general.

In addition, the Presidency has revised the majority of the procedural provisions in an attempt to align them with the proposed institutional set-up.

A significant number of delegations have voiced preference to exclude the pre-grant opposition procedure. The delegations have also expressed an overall support for the network structure of national patent offices as presented in the revised Presidency texts.

To draw a preliminary partial conclusion from the discussions held so far on the above issues, the Presidency invites delegations to confirm that the overall building blocks of the SPC system should include the following elements:

- An examination procedure that shall inherently draw on the already existing expertise in national patent offices.
- No pre-grant opposition in the unitary and centralised SPC proceedings.

### ***The political and legal considerations in the choice of granting office***

Although a majority of delegations have expressed a wish to explore solutions that could incorporate the EPO in the future SPC system, many emphasised that EPO's role should be purely administrative so that the examination of SPCs would rely on the assessment from the network of national IP offices as presented in the revised Presidency texts and, so far, the Working Party remains divided on the exact scope of the EPO's involvement.

A number of delegations have indicated a preference for the EPO to act as an integrated *one-stop-shop* for both the unitary applications, centralised applications, and combined applications, arguing that this would be the most effective solution to achieve the desired level of integration and harmonisation. Under this solution, the EPO would not only be the managing office but would also – with the assistance of the network of competent NPOs that would be embedded within the EPO – perform the examination, and ultimately also act as the granting office.

Other delegations have also expressed openness for conferring a role to the EPO in the future EU SPC system. However, due to concerns regarding the autonomy of the EU's legal order and the Meroni doctrine, several of those delegations called for caution against the “full” EPO solution. Instead, these delegations expressed preference for a solution in line with the initial Danish Presidency proposal, where the EPO would only act as the managing office, and where the national patent offices act as granting offices.

Finally, a third group of delegations have been calling for a return to the concept of the initial Commission proposal with the EUIPO acting as the central and granting authority, as this would place the future SPC system most coherently within the EU's legal order.

To support the Working Party's deliberations on what it would involve moving in the direction of the EPO, the Presidency has identified and explored various options for a system that could include the EPO. Subject to the condition that any option must be designed in a politically acceptable and legally sound way, the options put for consideration include:

- (i) a single NPO granting the SPC or rejecting the application based on a non-binding recommendation by the network,

- (ii) the EPO, acting as granting office, issuing decisions on SPCs based on either a binding or non-binding recommendation from a network of national examiners that is not embedded within the EPO (“free-floating” network), or
- (iii) a fully integrated EPO solution, where the EPO would decide on whether to grant the SPC or reject the application based on a recommendation of the network that would be embedded or integrated in the EPO.

While the extent of the possible EPO’s involvement remains unresolved given the divergent views of delegations on this question, there seems to be broad agreement in the Working Party that the option ultimately chosen should preserve the full competence of the Member States over the governance of the network and the examination procedures, and build upon the network structure and the concept of the examination procedures as set out in the Presidency revised texts.

To clarify the possible legal means and ways of involving the EPO in the SPC procedures, the Presidency has provided an analysis of the legal basis in the European Patent Convention (EPC) for entrusting the EPO with tasks in the field of SPCs. This analysis also includes considerations on the potential need of negotiations between the EU and the EPO. While it seems clear that the EPC does allow entrusting the EPO with tasks relating to SPCs, the Presidency’s analysis and the views expressed by several delegations in the discussions in the Working Party suggest that an agreement with the EPOrg is necessary for conferring such tasks to the EPO. Therefore, the Presidency further provided preliminary considerations on the type and content of such an agreement and who could conclude such an agreement within the EU and the EPOrg.

It is undisputed that any transferral of tasks to an EU-external body also must take into account the Meroni doctrine and respect the principle of the autonomy of the EU’s legal order. The Presidency summarised the necessary elements to be considered, namely that only non-discretionary powers that are clearly defined and based on objective criteria in a Regulation and subject to the full review of the Court of Justice of the EU, and which contain adequate oversight mechanisms, can be conferred to institutions outside the EU.

In order to make further progress on the open issues, the Presidency would like to invite delegations to reflect on the questions that were also raised in the steering note WK 15318/25 before the meeting on 17 November. Delegations are invited to share their views on:

- Whether the Meroni doctrine and the principle of autonomy of the EU's legal order is fulfilled, and if not, what would need to be further clarified in the Regulations?
- How compliance with EU law could be ensured under the EPO options?
- How should the oversight be designed:
  - to what extent would regulatory oversight need to be addressed in an international agreement with the EPOrg;
  - to what extent could any additional measures be addressed by other means, for example a governance structure similar to the Select Committee for Unitary Patents?
- How are necessary amendments to any related administrative provisions or rules of procedure of the EPO envisaged to be adopted?
  - And more specifically: for potentially making use of the procedure referred to in Articles 35(3) and 33(1)(b) of the EPC, what rules and what level of detail would be needed in the EU Regulations in order for the requirement “bringing the EPC in line with EU law” to be met?
- What role – if any – should relevant EU institutions play in supervising the SPC-related activities if delegated to the EPO?
- Do delegations agree on the legal analyses provided in WK 13518/2025 on the legal basis for conferring EPO the necessary SPC related tasks and on the negotiations with the EPOrg?
  - In this context, delegations are also invited to give their views regarding the potential timeframe for accomplishing the steps necessary for concluding an agreement with the EPOrg and the feasibility of accomplishing the necessary steps timely.

## ***Future work in the Council: the role of the UPC, discussions on the modalities of the rotation mechanism and the language regime***

### **Role of the UPC**

Delegations have repeatedly emphasised the importance of securing the involvement of the Unified Patent Court (UPC) in line with the guidance from Coreper of 29 May 2024. In addition, several delegations have proposed that not only invalidity actions but also appeals against decisions on the grant or refusal of unitary SPCs should fall under the jurisdiction of the UPC.

- In order to get a clearer picture of Member States' positions on this question, delegations are invited to share their preferences for the role of UPC and on any legal or administrative steps that would have to be made in order to make the UPC responsible for appeals, both for SPCs granted nationally and, as the case may be, by the EPO.

### **Modalities of the rotation mechanism**

The Danish Presidency is proposing that the main principles of the selection criteria are regulated in the Regulations with the specific modalities being elaborated in an implementing act. This would allow for the key objectives to be included in the Regulation, while at the same time allowing for the detailed procedure to be re-adapted quickly without re-opening the SPC Regulations, should such a need arise. However, it has been noted, that some delegations have called for the criteria to be fully explained in the base Regulations. The Presidency has prepared a separate document which could be used as a basis for discussions for the design of such a rotation mechanism (see WK 16641/2025).

### **Languages**

At the Working Party meeting on 17 November 2025 delegations were invited to share their preferences for the language regime to be applied if the tasks of administering both the unitary and centralised SPC's were conferred to the EPO.

While some delegations have indicated value in promoting linguistic diversity, noting also that establishing special language arrangements for a proposal based on Article 118 TFEU would require a new Commission proposal for a Regulation that would require unanimity to be adopted in the Council, there seems to be consensus that a language regime for the Unitary SPC should follow the official trilingual language regime of the Unitary Patent cooperation.

The picture for the centralised procedure and combined applications is, however, a bit more mixed, with several delegations expressing a preference to allow all official EU languages for national applications.

The delegations were also asked whether they could accept machine translations to limit the need to restrict the language regime, considering the technical nature and limited amount of text of SPC applications. The delegations overall seem to be able to accept such a solution, provided that the quality of translation is guaranteed.