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NOTE

From:	Presidency
To:	Working Party on Intellectual Property (Patents)
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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 17 November 2025, delegations will find attached a Presidency steering note returning to the revised texts and the questions raised in previous policy papers circulated during the Danish Presidency.

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Presidency steering note for the IP Working Party on 17 November 2025

In continuing the discussion on the SPC files, we will return to the texts and policy papers that have already been tabled during the Danish Presidency.

The Presidency acknowledges that a number of delegations have called for the pace to be reduced. We will therefore use the meeting to revisit the changes done to both the recast and to the unitary proposal and to the questions raised in the policy papers.

Amendments to the partial revised texts:

These cover the changes that have been introduced to the Presidency partial revised texts that have been published in preparation for the following meetings:

- 5 September: ST 12208/25 (unitary)
- 3 October: ST 13278/25 (unitary) and ST 13282/25 (recast)
- 20 October: ST 13924/25 (recast) and ST 13925/25 (unitary)
- 3 November: ST 14638/25 (unitary) and ST 14639/25 (recast)

Outstanding questions in relation to the introductory provisions:

Article 8 (unitary) & Article 7 (recast): Application for a certificate; Article 9 (unitary) & Article 8 (recast): Content of the application for a certificate

- Delegations are invited to indicate whether they agree that **only the patent holder** should be able to **apply** (as now clarified in Article 8(1) uSPC).
- In this context, delegations are also invited to give their views on the need of keeping the provisions in Articles 6(2) and 9(1)(ca).

Outstanding questions in relation to the provisions on the institutional set-up:

Article 9a (unitary) & Article 21A (recast): The network

As regards the **network of examiners**, delegations are invited to revisit the questions on:

- whether the examination recommendation should be **binding** or **non-binding** (and give their views on the impact the binding/non-binding character of the recommendation has on the structure of/competence for remedies);
    - What elements would need to be further elaborated in order for delegations to be able to consider a binding recommendation from the network to the EPO a viable solution? Would the answer be dependent on whether the network would be embedded within the EPO or free-floating?
- whether the network should be **embedded in the EPO**? If so,
    - whether this would imply giving more than **administrative tasks** to the EPO?
    - where in the EPO the network should be embedded?
    - whether this would be **Meroni-compliant**?
- whether the concept of a **free-floating network**, as described in the Presidency compromise text (doc. 14638/25 and doc. 14639/25) is acceptable, provided the necessary safeguards to guarantee the competences of the UPC in accordance with the COREPER guidance of May 2024 are in place?

Article 9b (unitary) & article 21b (recast): The managing office

The managing office, tentatively the EPO, would be given a strictly administrative role in the new SPC system and would not be involved in the substantive examination process.

As regards the **delegation of tasks to the EPO**, delegations are invited to share their views on:

- whether they agree with the Presidency's assessment set out in pages 2-4 of the policy paper WK 14455/2025.
- whether the EPO should have merely administrative tasks, or if it should also act as granting office for the unitary SPC's.
    - If the EPO were to act also as the granting office, would any specific measures have to be taken to guarantee that the system is Meroni compliant and that it respects the autonomy of the EU's legal order?
- whether the concept of a single Member State issuing decisions with EU-wide effect would be feasible and under which conditions (e.g. would a mutual recognition mechanism be needed)?

Article 9e (unitary) & 21c (recast): Criteria for the designation of the rapporteur and co-rapporteurs

Several delegations have supported the designation of the rapporteur and co-rapporteurs based on a pure rotational mechanism. This has been set out in Article 9e of the unitary and Article 21c of the recast proposal. The principles governing the rotation mechanism should ensure a fair distribution of the examination workload among the national offices. In order to achieve this aim, delegations are invited:

- to give their views on the **criteria** that should be used **for such rotation mechanism**; and
- to comment on the modus operandi, including on if the details of the mechanism should be established in the Regulation and which aspects could be left to an implementing act or a delegated act. (In any event, to make the EPO subject to those rules, the agreement concluded with the EPO would have to mirror those provisions (in detail or by reference to the EU Regulation/implementing or delegated acts)).

Outstanding questions in relation to the provisions on the examination procedure, and on remedies:

Article 17a-17b (unitary) & 25b-25c (recast): The examination procedure and the procedure for disagreement

The examination procedure has been significantly redrafted in an effort to design the system in a way that involves the UPC in line with the COREPER guidance of May 2024 and ensures a coherent and harmonised SPC examination procedure across the EU, while retaining expertise in SPC examinations at the national level. A further purpose of the redrafting has been to reduce the administrative burdens on the participating national patent offices (NPO's), and to have as streamlined and efficient a procedure as possible.

As most SPC applications are expected to be processed with no disagreement or objection to the draft recommendation within the network, it is proposed that the examination procedure is conducted primarily in writing. However, the possibility of convening an online plenary meeting is provided for, if the rapporteur requests it, or if, following a second written draft recommendation having been presented to the network, there are dissenting opinions within the network on whether to grant the SPC or reject the application.

Some delegations have expressed the view that the proposed procedure could be burdensome.

- Delegations are invited to give their views on whether they consider the proposed concept practical or whether they would consider further adjustments necessary to establish a procedure that is as efficient as possible, and if so, which adjustments would need to be done.

Article 28 (unitary): Appeals

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 Unified Patent Court (UPC).

- Delegations are invited to share their views on the competent authority to decide on appeals over the grant or rejection of a unitary certificate or an extension of its duration.
- Delegations are further invited to reflect on any legal and/or administrative steps that would have to be made in order to make the UPC responsible for appeals, both for SPCs granted nationally and by the EPO.

Political and legal questions raised in Presidency Policy Papers

In preparation for the meetings in the IP Council Working Party held on 20 October and 3 November, the Presidency provided two policy papers raising a number of legal and political questions:

- WK 13518/2025
- WK 14455/2025

Legal basis in the European Patent Convention to confer tasks regarding Supplementary Protection Certificates to the EPO and on the negotiations between the EU and the EPO

The Presidency has provided legal analysis of the relevant provisions in the European Patent Convention (EPC) on whether the EPO can be tasked with issuing unitary SPCs, without needing to amend the EPC.

While it was held that the EPC does allow entrusting the EPO with tasks relating to SPCs, an agreement with the EPOrg is still necessary.

The Presidency further provided an assessment of the type and content of the agreement needed between the EU and the EPO and who could conclude it within both the EU and the EPOrg.

See pages 1-3 in WK 13518/2025.

- Delegations are invited to reflect on the legal assessment provided in WK 13518/2025 and on the points related to the Union competence.
- Delegations are also invited to give their views regarding the feasibility and the potential timeframe for accomplishing the steps necessary for concluding an agreement with the EPOrg.
- Delegations are invited to share their views on the extent to which the examination procedures, rules of procedure, network structure, and timelines should be regulated by EU law.

Regulatory Oversight

The EPO is not a Union body subject to EU law or accountable to the EU institutions. Any agreement would therefore need to include provisions on the governance and oversight.

Neither Articles 63 and 142-145 of the EPC, nor the Rules of Procedure of the EPOrg Administrative Council currently provide adequate regulatory oversight for a network as envisaged in the revised Presidency text or include any details on the governance arrangements.

Delegations are invited to share their views on:

- How compliance with EU law could be ensured?
- How should this oversight be designed:
    - to what extent could regulatory oversight be addressed in an international agreement with the EPOrg; and
    - would any additional measures be needed, 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 envisaged to be adopted?
    - And, for potentially making use of the procedure referred to in Articles 35(3) and 33(1)(b) of the EPC for bringing the EPC in line with EU law, what rules and what level of detail would be needed in the EU Regulations?
- What role – if any – should relevant EU institutions play in supervising the SPC-related activities if delegated to the EPO?

Meroni compliance

As regards the question to what extent conferring administrative tasks to the EPO could be considered compliant with the Meroni-doctrine, the following criteria have been mentioned in the discussions, so far:

- The delegated powers would need to be strictly "executive" rather than "substantive". The substantive conditions would need to be clearly defined in the uSPC Regulation and the EPO should have no discretion power.
- The tasks would need to be clearly defined in the EU legislation (and reflected in an agreement) in clear, precise terms, with objective criteria guiding their exercise.
- They are subject to judicial review and adequate oversight mechanisms (so the delegating entity retains ultimate responsibility).

If these safeguards are built in, then the architecture mirrors many modern EU delegations of power and should appear compatible with the Meroni doctrine as currently construed.

- Delegations are invited to share their views of these issues.

Languages

Delegations are invited to share their preferences for the language regime to be applied if the task of administering SPC's is conferred to the EPO, for both the recast and the unitary SPC proposals. Limiting languages under Article 118(2) TFEU would require a new Commission proposal for a Regulation, that would require unanimity to be adopted in the Council.

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- Should the system use
    - the 3-language regime of the EPO,
    - all official EU languages, or
    - a completely different regime?
- Would this be the same for both the unitary and the recast proposal?
- To what extend would delegations be able to accept machine translations to limit the need to restrict the language regime, considering the technical nature and limited amount of text of SPC applications.

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