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NOTE

From: To:	Presidency Delegations
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Subject:	Supplementary Protection Certificates (SPCs) - Presidency discussion paper

Delegations will find attached a discussion paper from the Presidency aimed at steering the further discussions on the key institutional aspects of the set up of the SPC system.

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Supplementary Protection Certificates

Presidency discussion paper on Options 3, 4, and 5

Introduction

Following the guidance provided by **COREPER on 29 May 2024**, the Hungarian Presidency, with support of the Commission, put forward for discussion three options (Options 1, 2, and 3) aimed at fully integrating the **Unified Patent Court (UPC)** into the invalidity procedure for unitary **Supplementary Protection Certificates (SPCs)**. Among these, Option 3 has gained most support by delegations and has therefore been the main focus of discussions.

On 9 October 2024, France and Germany put forward a non-paper outlining two additional options (Options 4 and 5) alongside their commitment to further exploring Option 3. Both options 4 and 5 suggest involving the **European Patent Office (EPO)** in the SPC granting process. Option 4 would entrust the **EPO** with the responsibility for **granting or rejecting unitary SPCs**, whereas Option 5 would assign this responsibility to a **national authority**, such as a **national patent office (NPO)**, while the **EPO** would handle the attribution of **unitary effect**.

Several delegations expressed interest in further exploring these **additional alternatives**, particularly Option 4. However, concerns were raised regarding the **legal feasibility** of granting an **intergovernmental body outside the EU legal framework** the authority to issue an **EU intellectual property right** and regarding the potential implications this might have for the EU legal autonomy. The **Commission** provided a critical analysis of Options 4 and 5, noting that they diverge significantly from its original proposals.

In response to **Member States'** requests, the **Presidency** has decided to **further examine Options 3 in comparison with Options 4 and 5** to advance discussions on the substantive aspects of the SPC proposals. To facilitate this process, sections I.-VIII. of this discussion paper compare the three options and put forward some questions aimed at clarifying Member States' views and preferences on the system's future development.

The **Presidency** suggests that the discussions within the Intellectual Property Working Party on **Options 3, 4 and 5** extend to both **the unitary and recast SPC proposals**, as the issues raised may have implications for both frameworks.

I. Filing and examination procedure

(a) Filing of an application

Under Option 3, SPC applications, whether unitary, centralised or combined, would be filed with the **European Union Intellectual Property Office (EUIPO)**, which is proposed by the Commission as the central examination authority.

Under Option 4, SPC applications, whether unitary, centralised or combined, would be filed with the **European Patent Office (EPO)**, which is proposed by the FR/DE non-paper to serve as the central authority.

Under Option 5, applications for SPC with unitary effect and/or national SPCs would be filed with a designated **national patent office (NPO)**, with no apparent role for a central authority.

1. Regarding Option 4: what are the views of Member States on the **EPO** acting as the **central authority for receiving** both unitary and national SPC applications? Are Member States prepared to accept the EPO in that role?
2. Regarding Option 5: how do Member States assess the **absence of a central filing authority for** SPC applications? This option raises several questions about the designation and responsibilities of a competent NPO. Before addressing those details, should we first consider whether Member States **see any merit in an approach that does not involve a central filing authority for SPC applications**?

(b) Composition of the examination panels

As regards Option 3, the majority of Member States supported the idea that the examination panel would consist of examiners from all participating NPOs of Member States where SPCs are sought and, for unitary SPC applications, from all participating Unitary Patent-NPOs. One member would be from the EUIPO. For each application, a rapporteur and co-rapporteur would be designated to draft an assessment, which all examiners could review and provide written observations on, enabling revisions. The draft assessment would then be discussed in a plenary meeting of all panel members, which would serve as a decision-making forum. The plenary would adopt the assessment by consensus. If consensus is not reached, a [simple/qualified majority] vote of all panel members would determine the outcome. The final assessment would be formalised as the EUIPO's examination opinion, which would be non-binding.

Under Options 4 and 5, the composition of the examination panel is still to be determined.

3. Would Member States consider it appropriate to **apply a similar model for the composition of the examination panel**, as outlined in Option 3, to Options 4 and 5?
4. Regarding Option 4, how would the examination panel be integrated into the internal structure of the EPO? Furthermore, what are the views of Member States on **including EPO examiners in the examination panels**? How many examiners would be involved? Additionally, what **role could the EPO examiners play** in the examination panel: substantive, advisory, administrative, coordinating?

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(c) Nature of the examination opinion

Under Option 3, the examination panel would issue **a non-binding opinion** on the SPC application, providing comprehensive technical advice. Given the non-binding nature of the opinion, the NPO responsible for granting or rejecting the application would (only) need to take it into account when preparing its draft decision.

Under Options 4 and 5, the nature of the examination opinion is still to be determined.

5. Do Member States see merit in **maintaining the non-binding opinion** and the accompanying mechanisms, as proposed in Option 3, **also under Options 4**, or would you prefer to resume the discussion on **making the EPO opinion binding**? Would this also extend to the **recast proposals**? It is important to highlight that the review of a binding opinion could pose c**hallenges for Member States that are not parties to the Unitary Patent (UP) system**, as no avenue for review would be available to them.

II. Granting procedure

Under Option 3, a **single designated NPO** would be responsible for granting or rejecting the unitary SPC, based on a non-binding opinion from the EUIPO. To ensure harmonisation and to introduce safeguards for cases where the NPO reaches a different conclusion than the examination panel and intends to deviate from the EUIPO's opinion, a **consultation mechanism** involving all participating UP-NPOs is proposed.

In the recast proposals, a designated NPO would issue a national decision based on a non-binding opinion from the examination panel, which the office would be required to assess and internalize.

Under Option 4, the **EPO** would grant or reject the unitary SPC based on the **examination opinion** issued by a common panel of national examiners. For a centralised application for national SPC(s), the panel opinion would be implemented by the respective NPOs as a bundle of national decisions. In the case of combined applications, the two mechanisms would be combined.

Under Option 5, a **designated NPO** would decide on granting or rejecting the unitary SPC following the **panel's examination opinion**, while the **EPO** would be responsible for granting or rejecting **unitary effect**. In the case of an application for national SPC(s) based on a European patent, the respective NPO would grant or refuse the SPC, taking into account the examination conducted by the panel.

6. Regarding Option 4, what would be **the nature of the EPO's decision to grant the unitary SPC**? Would it constitute a direct unitary title providing "uniform protection" and having "equal effect" in all Member States where the basic patent has unitary effect?
7. Regarding Option 4, would NPOs from Unitary Patent-participating states have a role in the **EPO's decision-making process** for granting or rejecting a unitary SPC? Would Member States see value in applying a **consultation mechanism** similar to that in Option 3? How could the EPO be bound to follow the opinion of a panel composed of non-EPO staff?

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8. Regarding Option 5, would the **EPO play any role in granting or rejecting unitary SPCs**, or would its involvement be limited solely to deciding on unitary effect?

III. Appeals

Under Option 3, both the granting and the rejection decision of the designated NPO would be subject to **appeal before the competent national courts**, following the same procedures applicable to national SPC decisions under national law. However, if Unitary Patent-participating states so decide, the UPCA could be amended to confer jurisdiction on the UPC to review NPO decisions related to unitary SPCs. Notably, the UPC is not considered a national court in this context, as **current UPCA provisions do not grant it jurisdiction over appeals against national NPO decisions**.

Under Options 4 and 5, appeals against EPO decisions are envisaged to be brought before the **UPC**. Granting the UPC such competence would require an amendment of the UPCA. In Option 5, the decision may also originate from an **NPO**, making it subject to national appeals, even if the EPO ultimately grants the unitary effect.

In particular, since the EPO is not an EU body, its actions are not subject to Article 263 TFEU or the review mechanism under Article 256 TFEU. As a result, **the UPC cannot currently review EPO decisions on unitary SPCs,** unless the UPCA is amended to explicitly confer such authority to the UPC.

To establish UPC jurisdiction to review EPO decisions on unitary SPCs, two alternatives could be considered[1]:

(1) amending Article 32 UPCA via an **international agreement**, requiring ratification by Contracting States. While this is the most conventional approach, it is also complex and time-consuming, with an uncertain timeline for implementation;

(2) modifying Article 32 UPCA through the **Administrative Committee** under the simplified procedure set out in Article 87(2) UPCA, to align the UPCA with provisions of EU law. This option appears to be more practical and expedient, but the extent to which it could be used to also authorise the UPC to review SPC granting decisions taken at national level would require further consideration.

9. What are the Member States' views on the potential **amendment of the UPCA** to grant the UPC jurisdiction **to review EPO decisions** on unitary SPCs?
10. What are the Member States' perspectives on **amending the UPCA** to allow the UPC to **review national decisions of NPOs** concerning unitary SPCs?

[1] Max Planck Institute for Innovation and Competition, *Study on the Legal Aspects of Supplementary Protection Certificates in the EU*, 2018, point 22.2.5.3, p. 572-574, point 22.6.2 p. 595-596.

IV. Invalidity

Under Option 3, a decision by **one designated NPO** to grant a unitary SPC would be subject to the same **invalidity actions** before the competent national courts as those applicable to **national SPCs under national law**. This approach would allow the **UPC to review the validity of unitary SPCs**, provided that Article 2(h) of the UPCA is amended to include them. This aligns with the current framework for **national SPCs in UPCA Contracting States**, as long as the underlying European patent has not been opted out of the UPC's jurisdiction.

Under Options 4 and 5, invalidity actions for the unitary SPCs would be also brought before the **UPC**.

11. What are the Member States' views on the potential **amendment of the UPCA** to grant the UPC jurisdiction over actions for **invalidation of unitary SPCs**?
12. The European patent system includes a **post-grant opposition procedure**. Delegations are invited to share their views on whether a similar opposition procedure should be established for unitary SPCs as an alternative to pre-grant opposition procedure at the EUIPO.

V. Language regime

Under Option 3, **all official EU languages** may be used for documents and information submitted to the EUIPO. Also, **the register** would be available in **all these languages**, with verified machine translations used as needed.

Under Option 4, where the **EPO** would act as the central authority, considerations on the language regime for unitary SPCs would need to take into account that, at present, the EPO procedures are conducted in **its three official languages** only: German (DE), English (EN), and French (FR).

Under Option 5, where a single designated NPO would be involved, the language in which the documents and information would be submitted remains unclear.

13. Regarding Option 3, do Member States see merit in/the possibility for **limiting the language regime** for the documents and information sent to the EUIPO to:
    a) **Three languages**, based on the UPC language regime?
    b) **Five languages**, as provided for under the EU Trade Mark Regulation?
    c) **English only**?
    d) **Other options,** for example, the language of the applicant or the language of the basic patent?
14. Regarding Option 4, what are the views of delegations on the possibility of applying the **restrictive language regime of the EPO** to unitary SPCs, given that this would require a further Regulation to be adopted by unanimity[2]?

[2] It is noted that according to Article 118(2) TFEU if specific language arrangements for the European intellectual property rights are to be adopted, they require unanimity after consulting the European Parliament.

15. Regarding Option 5, what are the views of the Member States regarding the **language** in which documents and information would be submitted to the **designated NPO**? How would this work for Member States that do not have any of the three working languages of the EPO as their official language?

VI. Fees

Under Option 3, **the application fee and other procedural fees** would be paid to the **EUIPO**, with fee levels set in implementing acts. A portion of these fees would be retained by the EUIPO to cover expenses related to their role in the examination and registry of the SPCs. NPOs involved in the substantive examination of unitary SPCs would receive additional remuneration, and all NPOs would receive a share of the fees collected, following a distribution mechanism similar to that of unitary patents.

16. Do Member States consider that a **similar mechanism** would be applied under Option 4, where the EPO would act as the central authority? How is this to be seen in light of the fact that the EPO is not subject to EU secondary legislation?
17. How do Member States view the **fee structure under Option 5**, where no central authority is involved?

VII. Role of the central authority

Under Option 3, the EUIPO would serve as the central authority, playing a **key role in the management and coordination** of the new SPC system. It would be entrusted with **administrative and supervisory responsibilities**, including receiving SPC applications, assessing their formal admissibility, overseeing the establishment and operation of examination panels, each of which would include a representative from the EUIPO. Furthermore, the EUIPO would be responsible for collecting and managing fees and for maintaining the official register and database, ensuring transparency and efficiency within the system.

Under Option 4, the **EPO** would assume the role of the central authority.

Under Option 5 **no central authority** appears to be envisaged but the involvement of a national IP Office is foreseen.

18. Do Member States consider that under Option 4, the **EPO would have similar tasks and competencies as the EUIPO** under Option 3? If so, what specific responsibilities and tasks would the EPO hold?
19. Under Option 5, who would **be responsible for coordinating the overall process**, ensuring transparency and efficiency within the system, managing fees, and maintaining the register and the database?

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VIII. Pending legal questions concerning EPO's accountability to EU institutions and integration in the EU legal order

Under Option 3, the **EUIPO**, as part of the EU legal order, would be **accountable to EU institutions** and subject to the jurisdiction of **EU Courts**. In addition, implementing rules relating to unitary SPC would be set out in EU legal acts.

Under Option 4, the **EPO**, which is not an EU body, would not be subject to Article 263 TFEU or the review mechanism under Article 256 TFEU. Nor would it be bound by EU law in its practice for examining and granting unitary SPCs (which would entail interpreting EU acts, e.g. the marketing authorisation and following the principles established by CJEU case-law) or when establishing the implementing rules for the unitary SPC system. From an EU law perspective, the EPO's role would need to align with case law on the interinstitutional balance and the delegation of powers to non-EU institutions while ensuring respect for the autonomy of the EU legal order.

20. How can powers such as **granting EU intellectual property rights** be conferred on an intergovernmental organisation like the EPO while ensuring compliance with the **EU legal order and its autonomy**? How is this to be seen in light of the fact that the unitary patent Regulation only delegates limited administrative tasks to the EPO?
21. How could the EPO **be made accountable to EU institutions** (including the European Parliament) for the implementation of its SPC-related tasks and powers?
22. How, and to whom, would the EPO **be held liable** under Option 4?
23. Would the **EPOrg Administrative Council** oversee the governance of SPC-related tasks performed by the EPO? From a political standpoint, **would such governance be acceptable** given that non-EU countries are represented within the EPOrg Administrative Council? If not, how could a dedicated governance structure be established for unitary SPCs under the current legal framework of the European Patent Convention (EPC)?
24. Would the EPC as it stands provide a sufficient basis for the EPO to perform all the SPC-related tasks? If so, which provisions would be the basis for the EPO being bound by an opinion of national examiners, performing the task of granting SPCs, and establishing the fee systems both in respect of unitary and national SPCs, etc.?