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NOTE

From:	the Polish Presidency and the incoming Danish Presidency
To:	Delegations
Subject:	Supplementary Protection Certificates (SPCs) - Joint proposal by the Polish Presidency and the incoming Danish Presidency for a compromise on major building blocks of the SPC proposals

Delegations will find attached a joint proposal by the Polish Presidency and the incoming Danish Presidency on the matter in subject. The joint proposal will form the basis of the discussions at the meeting of the IP Working Party on 3 July 2025.

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Joint Proposal by the Polish Presidency and the incoming Danish Presidency for a Compromise on major building blocks of the Supplementary Protection Certificates proposals

Introduction

This joint paper of the Presidency and the incoming Danish Presidency outlines a possible compromise regarding the institutional setup for the Unitary SPC proposals and the SPC recast proposals. The paper addresses the following building blocks of the SPC systems:

(a) the central administrative body,

(b) the examination panel,

(c) the granting authority and the invalidity actions.

This joint compromise builds upon the work undertaken by the Polish Presidency and the previous Presidencies, while also taking into account the guidance provided by Coreper on 29 May 2024. Notably, Coreper called for a solution that would confer the competence to decide on direct invalidity actions in respect of unitary SPCs to the Unified Patent Court (UPC).

The proposed architecture of the SPC system, as outlined below, is intended to apply coherently to all four SPC legislative proposals. Hence, if supported by delegations, the suggested underlying principles would be transposed, with the necessary adaptations, to the SPC recast proposals. This compromise should be considered as a single, integral compromise package.

(a) Choice and role of the central administrative body

The choice of the central administrative body has been discussed at the Working Party on Intellectual Property (IP) at length since 21 October 2024, starting under the Hungarian Presidency and continuing under the Polish Presidency. These discussions centred around matters such as the design of the system, policy concerns such as governance, as well as legal issues.

In the discussions on the granting authority held during both the Hungarian and Polish Presidencies, Member States have indicated preferences for different solutions.

The choice and the role of the central administrative body remain crucial for the further progress of the SPC files as they affect the institutional setup of the granting procedure, as well as the UPC involvement in the remedy procedures under the SPC proposals.

Although not *all* Member States have expressed a preference for that option, the Polish and Danish Presidencies consider that choosing the EUIPO as the central administrative body could represent a possible way forward.

This consideration is based on the allocation of tasks to the EUIPO and the background reasoning as detailed below:

Tasks suggested to be allocated to the EUIPO

The EUIPO would be responsible for purely administrative tasks related to the processing of applications. This would include receiving applications, establishing the examination panel, collecting and managing fees and maintaining the official register and database.

Following a positive assessment of the admissibility of the SPC application, the EUIPO would forward the application to an examination panel for substantive examination of whether the application meets the applicable criteria.

Reasons why the EUIPO would be the optimal choice as the central administrative body

The EUIPO is the EU's main IP office. In this capacity, it is responsible for fostering innovation and creativity by managing a broad range of intellectual property rights, including trademarks, design rights, geographical indications for craft and industrial products. It is also tasked with strengthening enforcement, combatting counterfeiting and piracy and ensuring fair competition. More recently, the EUIPO has been allocated the task of cooperating with the Commission in developing a framework for IP valuation for IP-backed financing.

The EUIPO is an agency embedded within the EU's legal order. The SPC system would therefore operate within an already established and trusted framework, accountable to the EU institutions and the 27 Member States of the EU. By building upon a framework that is fully under the control of the EU institutions and the EU Member States, this approach would enhance the economic security of the EU and strengthen its competitive position in the global IP landscape. Placing the SPC system within the ambit of the EUIPO would in particular reduce regulatory fragmentation, and better support vital pharmaceutical innovation and investment across the EU.

The EUIPO has the institutional framework and technical capacity to take on the new SPC-related responsibilities. This was demonstrated in 2023, when it successfully assumed the assigned responsibilities related to the registration of geographical indications for craft and industrial products.

EU agencies also play a pivotal role in the broader governance system of the European Union. Through their specialised expertise, these agencies play a vital role in supporting the institutions in implementing policies and strategies. They also contribute to the enforcement of regulations and programs, helping to ensure their effective application at the national level. Furthermore, EU agencies foster cooperation among Member States, harmonising efforts across different sectors to promote efficiency and stability across the Union.

Today, the EUIPO plays this crucial role in the development of a unified European IP framework. By providing an efficient, balanced and sustainable intellectual property environment across the Member States, the EUIPO contributes to the integration of the single market, facilitating cross-border operations for businesses, while safeguarding their intellectual assets. A transparent and predictable IP framework enhances legal certainty, thereby encouraging investment and innovation within the EU.

(b) Role and composition of the examination panel

During the discussions at the Working Party, delegations emphasised the importance of a new SPC system that delivers high-quality and consistent examination of applications. This would help build trust in the new system, with the majority of delegations indicating a preference for a setup of the examination panel similar to that of the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP).

Accordingly, the examination panel would consist of one expert from the National Patent Office (NPO) of each Member State in which the unitary SPC would apply. For combined/centralised applications, the panel would also include experts from the Member States in which the SPC would have effect. This would enable the NPO experts to share their knowledge and expertise obtained in national SPC examination, contribute to developing a unified interpretation within the panel and ensure the highest possible quality of the examination.

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For each application, a rapporteur and a co-rapporteur would be appointed and at least one of them would have to be from an NPO that carries out full substantive examinations of SPCs. The rapporteur and co-rapporteur would prepare a draft assessment, which would be circulated to all NPOs for written observations.

Following the written procedure, the draft assessment would be discussed among all members in a plenary meeting. These meetings would be convened regularly, primarily online, and in English.

Although the plenary should aim for consensus, the final decision could nevertheless be adopted by simple majority.

Giving NPOs the possibility to participate in the examination process would ensure high-quality examinations by providing coherent and harmonised examinations throughout the Union, ensuring at the same time that expertise and knowledge in SPC examinations are maintained at national level.

(c) Granting authority and invalidity actions

A single designated NPO would be responsible for granting or rejecting the unitary SPC with equal effect in all Member States in which the basic patent has unitary effect, based on the opinion of the examination panel.

This would allow for the UPC to be responsible for reviewing invalidity actions concerning unitary SPCs, in line with the guidance provided by COREPER on 29 May 2024.

In addition, a minor amendment to the definition of an SPC in Article 2(h) of the UPCA would need to be made in order to explicitly include unitary SPCs.

Conclusion

Delegations are invited to provide comments and suggestions, including on whether they can support the proposed approach.

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