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NOTE

From:	Presidency
To:	Delegations
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Subject:	Supplementary Protection Certificate (SPCs) - Presidency Policy Paper

With a view to facilitating the discussions at the meeting of the Working Party on Intellectual Property on 3 November 2025, delegations will find attached a Presidency Policy paper which further elaborates on the potential conferral of tasks regarding SPCs to the European Patent Office (EPO) and on the feasibility of a binding opinion issued by the network .

This policy paper is to be read in conjunction with the Presidency revised texts set out in doc. 14638 /25 and doc. 14639/25.

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Policy paper on the institutional set-up for the Unitary SPC

This paper elaborates on the discussions at the IP Working Party meeting on 20 October 2025 and on the basis of the feedback on how an **institutional setup for the Unitary SPC (uSPC) system** could be constructed.

So far, delegations have emphasised that if SPC-related **tasks** are to be **delegated to the EPO** (European Patent Office), these tasks **should remain purely administrative**, and the EPO itself should not be involved in the substantive examination that leads to a grant or refusal of the uSPC.

The paper is drafted on the premise that the EPO would act as managing office and ultimately also as the granting office for the uSPC. The EPO would grant a uSPC based on a **potentially binding recommendation from a "free-floating" network of competent authorities** (i.e. that is not embedded within the EPO). The Unitary SPC system will rely on the structure and procedures set out in the PCY revised text (doc. doc. 14638/25 and doc. 14639/25).

The concept outlined in this paper therefore relies on a network structure of national authorities presented in the previously revised draft PCY texts.

The paper aims to explore the feasibility of a concept under which the EPO would be bound by the examination of the network or where the network would be embedded in the EPO.

Nature of the Supplementary Protection Certificate under EU Law – *sui generis rights*

Supplementary Protection Certificates (SPCs) have been established within the EU by Regulation (EC) No 469/2009 (for medicinal products) and Regulation (EC) No 1610/96 (for plant protection products). While an **SPC** may colloquially be described as an extension of the patent, it **is a *sui generis* intellectual property right** (as also outlined by the explanatory memorandum of the first SPC Regulation) — and therefore a legally autonomous right.

SPCs lie right **at the interface between the marketing authorisation and the underlying patent**: the grant of an SPC and the protection conferred by an SPC depend on distinct substantive conditions (besides a basic patent in force, most importantly a marketing authorisation covering the product protected by the basic patent is needed). The scope of the SPC is also limited to the product authorised, and both the invalidity of the patent or the marketing authorisation will render the certificate void.

Concept of Supplementary Protection Certificates and the possibility to base an SPC on a Unitary Patent – Article 63(2) and (3) of the European Patent Convention

SPC's are also not considered a patent term extension for the purpose of the European Patent Convention (EPC).

Article 63(2)[1] of the EPC concerning the term of European Patents makes an explicit distinction between an "*extension of the patent term*" and the "*grant of corresponding protection*".

[1] As amended by the Act revising Article 63 EPC of 17.12.1991, which entered into force in 1997 (OJ EPO 1992, 1 ff).

While the EPC does not explicitly mention **SPCs**, it therefore seems clear from a literal and ordinary understanding of the wording of Article 63(2), that they are not to be understood as mere patent term extensions but as **a grant of corresponding protection**.

Article 63(2) reads:

> *"(2) Nothing in the preceding paragraph shall limit the right of a Contracting State to **extend the term** of a European patent, **or to grant corresponding protection**, which follows immediately on expiry of the term of the patent, under the same conditions as those applying to national patents:*
> *(a) …;*
> *(b) if the subject-matter of the European patent is a product or a process for manufacturing a product or a use of a product which has to undergo an administrative authorisation procedure required by law before it can be put on the market in that State."*

The wording of the provisions outlines two distinct legal concepts: a Contracting State to the EPC may either: **(1)** extend the term of a European patent or **(2)** provide corresponding protection.

The distinction between a "patent term extension" and "corresponding protection" lies in their legal nature; a patent term extension prolongs the duration of the original patent itself, maintaining its legal identity and rights, whereas corresponding protection refers to a separate legal right, such as an SPC.

As briefly outlined in the previous section, an SPC does not extend the protection conferred across the entire scope of the patent claims, but will only protect the product covered by the authorisation to place the corresponding medicinal product (or plant protection product) on the market and any use of that product as a medicinal product (or plant protection product) that has been authorised before expiry of the SPC[2]. Moreover, the rights conferred by an SPC may be subject to additional limitations compared to the basic patent (e.g. the SPC waiver for manufacturing and stockpiling), thus further highlighting its *sui generis* nature.

The understanding that SPC's are not patent term extensions, but separate – *sui generis* – IP-rights that come into effect upon expiry of a patent is also confirmed by interpretation provided on the EPO's website[3].

As follows from Article 63(3) of the EPC, a patent term extension or the grant of corresponding protection (such as by an SPC) can be provided for by Contracting States (also) in relation to Unitary Patents ("European patents granted jointly for a group of Contracting States in accordance with Article 142"). This paragraph solely clarifies that providing corresponding protection on the basis of a unitary patent is compatible with the EPC, and, like paragraph 2, does not lay down any further modalities of such an extension.

Article 63(3) reads:

> "(*3) **Paragraph 2 shall apply** mutatis mutandis **to European patents granted jointly for a group of Contracting States** in accordance with Article 142*."

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[2] See Articles 4 and 5 of Regulation (EC) No 469/2009 and recital (10) of the draft (recast) Medicinal SPC Regulation.

[3] From the EPO's website (https://www.epo.org/en/searching-for-patents/helpful-resources/patent-knowledge-news/protection-beyond-20-years-data-spcs):

> *"Unlike regulations in the U.S., South Korea or Japan, **SPCs are not term extensions by strict definition, but rather separate IP rights that come into effect once the related patent expires**."*

Delegation of tasks and possibilities under the EPC

In setting up the regulatory framework for the new SPC system and in conferring the necessary tasks related to uSPCs to the EPO, several delegations have suggested to consider a model that follows the approach of Article 9 of the Unitary Patent Regulation (Regulation (EU) No 1257/2012). It has also been suggested to explore whether a uSPC Regulation could be considered a special agreement under Article 142(1) of the EPC, as this would allow assigning certain tasks to the EPO in relation to the Unitary Patent, based on Article 143 of the EPC.

As described above, there are provisions in the EPC that allow for its Contracting States to establish a corresponding protection scheme, such as SPCs, and those SPCs can be based on both "normal" European Patents and Unitary Patents.

Moreover, the same Article of the EPC in its paragraph 4 provides also for the possibility to entrust tasks associated with such corresponding protection schemes to the EPO.

Article 63(4) reads:

> *"(4) A Contracting State which makes provision for extension of the term or* ***corresponding protection*** *under paragraph 2(b) may, in accordance with an* ***agreement concluded with the Organisation, entrust to the European Patent Office tasks associated with implementation*** *of the relevant provisions*."

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Free-floating network issuing a binding opinion to the EPO

Another issue that has not been exhaustively discussed at previous meetings is the concept of a free-floating network. A free-floating network, as described in the Presidency compromise text (doc. 14638/25 and doc. 14639/25), could issue a binding recommendation to the EPO, while the recommendation would, on the other hand, be non-binding towards the competent national authorities (NPOs) designated in the centralised procedure, and would be appealable before national courts.

It is the understanding of the Presidency that such a construction could be valid under Union law and would also preserve the Coreper mandate, provided that appropriate safeguards are included. Given their binding effects and to clarify the availability of remedies, it appears necessary to include an explicit provision in the uSPC proposal to confer to the UPC the competence over the binding opinion. This would need to be adequately reflected in the UPC agreement as well. After their adoption, the uSPC Regulation could serve as a legal basis for a fast-track amendment of the UPC Agreement (cf. Art. 87(2) UPCA).

> *Delegations are invited to indicate if they could accept a free-floating network, or if and, if so, how the network should be embedded into the EPO.*

Appeals

Several delegations have proposed that not only invalidity actions but also appeals against decisions on the grant or refusal of uSPCs should fall under the jurisdiction of the Unified Patent Court (UPC).

As mentioned above, this would likely require an amendment to the UPCA, potentially under Article 87. Member States are 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.

Delegations are invited to indicate if they would be favorable to explore such an amendment of the UPCA, and if such an amendment should also extend to the referral of appeals on decisions on grant or refusal on national level for the UPC contracting Member States for SPCs they may be granted on the basis of a unitary patent or a European patent, where the right holder has not opted out of the UPC in the transitional period.

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 procedural/administrative, with no discretionary competences, policy-making or core decision-making power being conferred regarding the right itself (i.e., the creation, scope, term of the SPC) – hence "executive" rather than "substantive". The substantive conditions would need to be clearly defined in the USPC Regulation and the EPO should have no policy discretion over those.
- They would need to be clearly defined in the EU legislation (or 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.