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WK 2110/2025 INIT

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CONTRIBUTION

From: General Secretariat of the Council
To: Working Party on Intellectual Property (Patents)

N° prev. doc.: WK 889/2025, WK 72/2025
N° Cion doc.: 8851/23, 8869/23, 8887/23, 8894/23

Subject: Supplementary Protection Certificates (SPCs)
– Register / Database
= Member States comments

Delegations will find attached the compilation of comments received from delegations on the matter in subject.

The contributions received so far are from the following delegations: CY, FR, LV and NL.

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CYPRUS (CY)

ANSWERS TO PRESIDENCY STEERING NOTE – WK 889/2025 INIT - CYPRUS

Regarding the three Options presented at the Presidency Flash (WK 72/2025 INIT), related to the structure of the Register and the Database of Unitary SPCs, Cyprus remains flexible and supports the Presidency's efforts towards moving the package of dossiers on Unitary SPC forward. Option B is considered a good basis to initiate discussions.

1. Do you consider that the entire content of the Database/Inspection File should be made available to the public without any charge, or whether some documents should be accessible only on request and for a fee?

YES, the entire content of the Database/Inspection file should be made openly available for free.

2. Do you consider that links to external databases should be included in the Register or the Database? This consideration should be made with a focus on the objectives of avoiding information duplication and minimising the financial implications associated with translation into all official EU languages.

Links to external databases should be included in the Register.

3. Do you agree that, in order to provide a single access point to information on all SPCs in the EU, the data specified in Articles 35(5) and 34(4) of the recast proposals should be shared by national offices on a mandatory basis? Furthermore, do you consider that the procedure for sharing these data should be specified at the level of the Regulation or in the implementing acts?

Yes, it should be mandatory and it should be specified in the implementing acts.

4. Can you accept that only a summary of the examination opinion shall be published in the Register, with the full document being stored in the Database. If so, do delegations consider that such a summary should have a uniform standardised form for all SPC applications?

Yes, a summary should be sufficient, and summary should have a uniform standardised form for all SPC applications.

NOTE FROM THE FRENCH AUTHORITIES

Subject: SPC reform (Supplementary Protection Certificates) – Documents from the Polish Presidency- Register and database – Comments from the French authorities

Ref. : Document WK 72/2025 “Presidency Flash - IP WP” (7th January 2025) and Annex to document WK 889/2025 “Presidency Steering note on the SPCs Register and Database” (27th January 2025)

The Polish Presidency questioned member states, during the Council working party of January 14th and 31st, 2025, on the topic of the future register and database for the SPCs’ centralised system. Initial discussions on the architecture of the registry and database have taken place, on the basis of documents elaborated by the Presidency (documents WK 72/2025 and Annex to document WK 889/2025).

The French authorities would like to thank the Polish Presidency for its consideration on the SPC file, and express a scrutiny reservation on the elements contained in the documents transmitted, concerning the future registry and database.

The French authorities wish to emphasize the difficulty of having in-depth discussions on a future information system, as the topic is closely linked to institutional issues such as the system’s governance, the overall architecture of procedures, costs, linguistic regime...

This is why the French authorities consider it a priority to focus on the fundamental institutional, structural and legal questions of the reform, within discussions at the Council.

Nevertheless, in a constructive spirit, the French authorities wish to share some preliminary thoughts relating to the future SPC register and database.

As a preliminary point, the French authorities note that the options involving the EPO have the advantage of benefiting from the existence of the EPO’s registers and databases, already containing information relating to, in particular, classic European patents and European patents with unitary effect.

The French authorities consider that it is necessary, before any detailed discussion, to clarify the definitions, contents and respective objectives of the envisaged register and the database.

In this respect, the French authorities have identified three aspects to be considered:

- 1) The creation of a legally authoritative register, containing precise and limited information on the status and procedural life of the title (equivalent, for example, to the National register for patents in France, kept by the office “INPI”).

This register should be accessible to the public. For legal certainty reasons, the information contained in this register should not be duplicated in other existing registers (national registers, European patent register, register of patents with unitary effect, etc.). However, consideration could be given to creating an information system bringing together information from all the national registers (equivalent to the EPO’s federated register).

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- 2) The creation of a public database (equivalent to Data INPI in France, or Espacenet for the EPO) fed by information from various registers and which may contain other information or documents (including exchanges with the applicant, notifications, applications for grant, etc.). At the very least, all information relating to basic patents and their legal status should be accessible in a centralised manner, alongside with information on associated SPCs.
- 3) The creation of an 'internal back-office' database for use by examiners and national offices, containing useful information for the examination of SPCs and which cannot or should not be made public on the database.

The SPC Regulation should govern the information that must be contained in the register and the minimum information that must be shared (*via* a public database). The creation of an internal database (or back office) or a federated register does not need to be provided for in the Regulation.

In addition, the French authorities wonder what the European Commission meant, during the meeting of 31 January 2025, when it mentioned 'procedural language' (in reference to the language of the database). The French authorities would like clarification on this point and on the languages of the register and the database.

The French authorities wish to stress that the linguistic regime of future centralised SPC procedures, the working language, as well as the language of proceedings, notifications, exchanges and decisions, will inevitably have an impact on the different aspects of the register and the database.

Paris, 11 février 2025

NOTE DES AUTORITÉS FRANÇAISES

Objet : Propriété Intellectuelle - Réforme des Certificats Complémentaires de Protection (CCP) – Documents de la Présidence Polonaise - Registre et base de données – Commentaires des autorités françaises

Ref. : Document WK 72/2025 “Presidency Flash - IP WP” (7 janvier 2025) et Annexe au document WK 889/2025 “Presidency Steering note on the SPCs Register and Database” (27 janvier 2025)

La Présidence polonaise a interrogé les Etats membres, lors des groupes de travail des 14 et 31 Janvier 2025 au Conseil, sur la question du futur registre et de la base de données du système centralisé pour les CCP. Des premières discussions sur l’architecture du registre et de la base de données ont eu lieu, sur la base des documents élaborés par la Présidence (documents WK 72/2025 et Annexe au document WK 889/2025).

Les autorités françaises remercient la Présidence polonaise pour la considération qu’elle porte au dossier CCP et expriment une réserve d’examen sur les éléments contenus dans les documents transmis, concernant le futur registre et la base de données.

Les autorités françaises souhaitent en effet souligner la difficulté d’échanger de manière extensive sur un futur système d’information dans la mesure où le sujet est intimement lié à des questions d’ordre institutionnel telles que la gouvernance du système, l’architecture globale des procédures, les coûts, le régime linguistique...

C’est la raison pour laquelle les autorités françaises estiment qu’il est prioritaire de se concentrer sur les questions fondamentales d’ordre institutionnel, structurel et juridique de la réforme dans les discussions au Conseil.

Dans un esprit constructif, les autorités françaises souhaitent néanmoins partager certaines réflexions préliminaires relatives aux futurs registre et base de données CCP.

A titre liminaire, les autorités françaises relèvent que les options impliquant l’OEB présentent l’avantage de bénéficier de l’existence des registres et bases de données de l’OEB, contenant déjà des informations relatives notamment aux brevets européens classiques et aux brevets européens à effet unitaire.

Les autorités françaises estiment qu’il est nécessaire, avant toute discussion détaillée, de clarifier les définitions, les contenus et les objectifs respectifs du registre et de la base de données envisagés.

A cet égard, les autorités françaises relèvent trois aspects à considérer :

- 1) La création d’un registre faisant foi juridiquement et contenant des informations précises et limitées sur le statut et la vie procédurale du titre (équivalent par exemple du Registre National des brevets en France, tenu par l’INPI).

Ce registre devrait être accessible au public. Pour des questions de sécurité juridique, les informations dans ce registre ne devraient pas avoir de doublon dans d'autres registres existants (registres nationaux, registre européen des brevets, registre du brevet à effet unitaire...) ; le registre devrait donc renvoyer vers les autres registres existants pour les informations sur les titres afférents. Il pourrait néanmoins être envisagé de créer ensuite un système d'information rassemblant les informations de l'ensemble des registres nationaux (équivalent du registre fédéré de l'OEB).

- 2) La création d'une base de données publique (équivalent de Data INPI en France, ou Espacenet pour l'OEB) alimentée par les informations de différents registres et pouvant contenir d'autres informations ou documents (y compris les échanges avec le déposant, les notifications, les requêtes en délivrance...). *A minima*, toutes les informations relatives aux brevets de base ainsi que leur statut juridique devraient être accessibles de manière centralisée avec celles des CCP associés.
- 3) La création d'une base « interne » de type « back-office » à destination des examinateurs et des offices nationaux, contenant des informations utiles à l'examen des CCP et qui ne peuvent pas ou n'ont pas d'intérêt à être rendues publiques sur la base.

Le règlement CCP devrait régir les informations qui doivent être inscrites au registre et les informations minimales qui doivent être diffusées (*via* une base de données publique). La création d'une base de données interne (ou back office) ou d'un registre fédéré n'a pas à être prévu dans le règlement CCP.

Par ailleurs, les autorités françaises s'interrogent sur ce que la Commission européenne entendait, lors du groupe du 31 janvier 2025, lorsqu'elle parlait de « langue de procédure » (en référence à la langue de la base de données). Les autorités françaises souhaiteraient avoir des précisions sur ce point et sur les langues du registre et de la base de données.

Les autorités françaises souhaitent souligner que le régime linguistique des futures procédures centralisées CCP, la langue de travail, ainsi que la langue de procédure, des notifications, échanges et décisions, impacteront de manière inévitable les différents aspects du registre et de la base de données.

LATVIA (LV)

Latvian written comments concerning SPC Register and Database

Do you consider that the entire content of the Database/Inspection File should be made available to the public without any charge, or whether some documents should be accessible only on request and for a fee?

We maintain flexibility on this issue. We support transparency and are committed to serving the public interests, which is why we could support public access to the Database. However, we could agree to withhold certain documents from the public for confidentiality reasons, at the applicant's request, or to impose fees for full document access if the majority of member states decide so.

Do you consider that links to external databases should be included in the Register or the Database? This consideration should be made with a focus on the objectives of avoiding information duplication and minimising the financial implications associated with translation into all official EU languages.

We could agree that links to external databases are included only in the Database, keeping the Register simple.

Do you agree that, in order to provide a single access point to information on all SPCs in the EU, the data specified in Articles 35(5) and 34(4) of the recast proposals should be shared by national offices on a mandatory basis? Furthermore, do you consider that the procedure for sharing these data should be specified at the level of the Regulation or in the implementing acts?

We could agree to the mandatory sharing of information on national SPCs, provided there is a straightforward and convenient method for data submission that does not place an undue burden on national IP offices. The technical implementation is critical here (whether it involves periodic submissions of data tables or an automated solution that should be integrated into our system). It could be specified in the implementing acts.

Can you accept that only a summary of the examination opinion shall be published in the Register, with the full document being stored in the Database. If so, do delegations consider that such a summary should have a uniform standardised form for all SPC applications?

We could agree to the summary being published in the Register if the full document is available in the Database. A standardised form of summary would be beneficial.

Written answers to questions in WK 889/2025 INIT from The Netherlands

In the Presidency steering note of 27 January 2025 (WK 889/2025 INIT) the Presidency asked four additional questions.

The response on behalf of The Netherlands is provided below.

Answers to questions

1. Do you consider that the entire content of the Database/Inspection File should be made available to the public without any charge, or whether some documents should be accessible only on request and for a fee?

All documents should be available free of charge on a website without the need for a request.

This is already currently the case with the Inspection files of patents and SPCs at the national level and those of European Patents in the databases of the EPO.

2. Do you consider that links to external databases should be included in the Register or the Database? This consideration should be made with a focus on the objectives of avoiding information duplication and minimising the financial implications associated with translation into all official EU languages.

The Netherlands would like to emphasise that currently the European Patent Registry already provides a lot of the required features. It is therefore useful to take the set-up of this system as a starting point.

For each patent the European Patent Registry provides, under the heading 'Legal Status', direct links the entries of that particular patent in the national patent registries, and those entries provide links to any national SPC based on that patent. Most patent offices also supply information on national SPC applications (filings, grants, lapse etc.) to the EPO and this is included in the European Patent Registry under the same heading 'Legal Status'.

So the national and European patent and SPC registries are already linked and the new system should provide at least the same level of integration.

The Netherlands question the need for a link to the EMA database and are concerned about the associated costs. The necessary documents (marketing authorisation, summary of product characteristics, compliance statement) are already part of the SPC file due to formal requirements. Occasionally an examiner may consult the Public Assessment Report but this is easily retrievable from the EMA website.

So it is unclear to us what the purpose for such link would be. In the Presidency paper it is suggested that this may lower translation costs but under the proposal the necessary documents do not need to be filed in all the EU languages.

3. Do you agree that, in order to provide a single access point to information on all SPCs in the EU, the data specified in Articles 35(5) and 34(4) of the recast proposals should be shared by national offices on a mandatory basis? Furthermore, do you consider that the procedure for sharing these data should be specified at the level of the Regulation or in the implementing acts?

Yes, see our written comments. Take note of the fact that the last national SPC under the current Regulation may expire 15½ years after the new Regulation has come into force. We should remove the burden on third parties to search in multiple databases as soon as possible.

4. Can you accept that only a summary of the examination opinion shall be published in the Register, with the full document being stored in the Database. If so, do delegations consider that such a summary should have a uniform standardised form for all SPC applications?

The Netherlands questions the need for a summary of the examination opinion when the full document is available in the database. If necessary a button for a machine translation of that document can be included. Drafting the summary is also more work for the examination panel and not a straightforward matter. Rejections usually involve a careful legal analysis of the case law and the arguments of the applicant and/or very technical discussion on the product and how it is identifiable in the patent. These considerations are hard to accurately summarise in a few words.
