


18 July 2023

## Proposals on Supplementary Protection Certificates

### KEY MESSAGES

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- Following the entry into operation of the Unitary Patent and the Unified Patent Court on 1<sup>st</sup> June 2023, it is time now to create the unitary Supplementary Protection Certificate (SPC) to incentivise pharma, biotech, and agrochemical companies to also participate in the Unitary Patent system.
  - BUSINESSEUROPE generally welcomes the European Commission proposals on the Supplementary Protection Certificates, which are expected to significantly reduce administrative burdens and increase efficiency, transparency as well as legal certainty.
  - The proposals on the unitary SPCs should enter into force as soon as possible to reduce the period of uncertainty between the entry into operation of the Unitary Patent system and the availability of unitary SPCs.
  - BUSINESSEUROPE has questions on the ability and expertise of the EUIPO to perform the key tasks assigned to it in the SPC proposals, especially as this EU Agency does not have any experience on substantive patent law. Therefore, clear and transparent procedures and criteria for the selection of examiners need to be included in the legislation.
  - It must be ensured that the new SPC procedures allow the granting of unitary SPCs with the highest degree of quality.
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18 July 2023

### **POSITION PAPER ON THE EUROPEAN COMMISSION'S PROPOSALS ON SUPPLEMENTARY PROTECTION CERTIFICATES**

BUSINESSEUROPE is the leading advocate for growth and competitiveness at the European level, standing up for companies across the continent and actively campaigning on the issues that most influence their performance. We speak for enterprises of all sizes in 35 European countries whose national business federations are our direct members.

Supplementary protection certificates (SPCs) are an intellectual property right which extend the term of patent protection for medicinal or plant protection products by up to five years, in order to offset the reduced effective duration of patent protection caused by the lengthy processes for obtaining regulatory marketing approval. Currently, there is no centralised process for SPC applications in the European Union (EU), instead SPCs have to be applied for through the national patent offices throughout the EU.

On 27 April 2023 the European Commission (Commission) published several legislative proposals (so-called Patent Package), four of which cover SPCs: (i) Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast); (ii) Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast); (iii) Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013; and (iv) Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products (jointly referred to as “SPC proposals”).

One of the main objectives of these proposals is to create a new “unitary SPC” for medicinal products and another for plant protection products to complement the Unitary Patent which entered into operation on 1st June 2023 alongside the Unified Patent Court (UPC). Another objective is to introduce a centralised examination procedure for granting national SPCs based on European bundle patents (EP bundle patents). According with the proposals, the SPC examination will be entrusted to the European Union Intellectual Property Office (EUIPO).



In short, the proposed system provides that an applicant will be able to file a “combined” centralised SPC application before the EUIPO requesting the grant of both a unitary SPC (for those Member States where the basic patent has unitary effect) and, at the same time, national SPCs (for the other Member States). After examining the application, the central examination authority will issue an opinion as to whether or not the application fulfils the criteria required by the proposed regulation. The applicant will be able to file an appeal before the EUIPO’s Boards of Appeal, subsequently before the General Court in Luxembourg and, finally, assuming that the general admissibility conditions are fulfilled, before the Court of Justice. Third parties will be able to file an opposition within two months against positive opinions of the central examination authority. In view of the examination opinion, as amended following an opposition, the EUIPO will then decide to either grant or reject the SPC. If there has been an appeal before the Boards of Appeal, the grant or refusal to grant will be subject to the outcome of that appeal. After the grant, third parties will be able to bring actions for a declaration of invalidity before the EUIPO. The decisions could be then appealed before the Boards of Appeal, the General Court and, if the general admissibility criteria are fulfilled, before the Court of Justice.

As a key business stakeholder, BUSINESSEUROPE is pleased to take part to this debate and share the following comments to the SPC proposals.

## GENERAL COMMENTS

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Following the entry into operation of the Unitary Patent and the Unified Patent Court on 1<sup>st</sup> June 2023, BUSINESSEUROPE believes that it is time now to create the unitary SPC to incentivise pharma, biotech, and agrochemical companies to also participate in the Unitary Patent system.

The Unitary Patent system is a key development with a significant potential for businesses.<sup>1</sup> An EPO study suggests that the Unitary Patent could significantly enhance technology transfer in the EU through more trade and foreign direct investment (FDI). Improved harmonisation of Europe’s patent system is expected to increase trade and FDI in high-tech sectors by up to 2% and 15% in the EU, leading to annual gains of EUR 14.6 billion in trade and EUR 1.8 billion in foreign trade investment.<sup>2</sup>

In the absence of unitary SPCs, it would be uncertain how SPC protection could work for unitary patents. National SPCs based on a unitary patent would open the possibility for

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<sup>1</sup> This statement and the positions reflected in it are not supported by the Spanish Confederation of Employers and Industries (CEOE), Confederação Empresarial de Portugal (CIP), the Confederation of Industry of the Czech Republic (SPCR), Polish Confederation Lewiatan and MGYOSZ – BUSINESSHUNGARY.

<sup>2</sup> EPO, “Patents, trade and foreign direct investment in the European Union”, October 2017, available at <https://www.epo.org/service-support/publications.html?pubid=162#tab3>



different national interpretations of SPC validity. Businesses would also be required to enforce these SPCs country-by-country.

BUSINESSEUROPE believes that the proposed central SPC examination procedure may also bring advantages in terms of simplification as regards SPCs based on EP bundle patents.

Therefore, **BUSINESSEUROPE generally welcomes the SPC proposals**. They are expected to significantly reduce administrative burdens and increase efficiency, transparency as well as legal certainty.

The proposals on the unitary SPC should enter into force as soon as possible to reduce the period of uncertainty between the entry into operation of the Unitary Patent system and the availability of unitary SPCs.

## SPECIFIC COMMENTS

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Although BUSINESSEUROPE generally supports the SPC proposals, some amendments appear necessary for the SPCs to become a workable instrument which could really benefit European businesses. These will be presented in turn.

### **EUIPO as central examination authority**

Under the proposed centralised procedure, the SPC application could be filed in any official EU language and then a central examination authority will carry out the examination of the application. The Commission proposed that the EUIPO would be the appropriate body for this role.

BUSINESSEUROPE questions whether the EUIPO would have the required expertise to perform these key tasks, especially as it does not have any expertise on substantive patent law. There is a potential increase of legal uncertainty in the way SPCs and unitary SPC applications will be handled and decided in Europe. These concerns also cover the EUIPO Boards of Appeal's expertise to deal with appeals on SPCs as these are likely to involve substantive matters as well.

BUSINESSEUROPE acknowledges that the Commission indicated that patent examiners from the national offices would be chosen to sit on both the central examination authority and the EUIPO Board of Appeal. However, we believe that this does not necessarily mean that the examiners will have the required qualifications and expertise to deal with the proposed centralised system. Thus, it should be clarified how the examining teams would be composed, and how it can be ensured that the patent



examiners from the experienced patent offices are selected as part of the examining panels.

In addition, it is not clear how the EUIPO could face the costs of the new tasks relating to SPCs. In the Explanatory Memorandum accompanying the SPC proposals, the Commission indicates that “[t]he necessary set-up costs of the tasks conferred to the EUIPO, including the costs of new digital systems, will be financed from the EUIPO’s accumulated budgetary surplus”. However, recent data from the EUIPO<sup>3</sup> show that “the EUIPO surplus would be exhausted by 2025”. If this surplus is going to expire, how does the Commission expect to finance these new tasks and still argue that the SPC proposals will have no impact on the EU budget, since the system will remain fully self-funded by applicants’ fees?

The SPC proposals relate to SPCs based on European patents which may or may not be unitary patents. Thus, these SPCs are narrowly related to European patents, which are granted by the European Patent Office (EPO) and have no relation to EU trademarks and/or designs, which are handled by the EUIPO. This is stressed by the fact that, if an SPC applicant needs to be represented, the representative should be a patent attorney (or an attorney-at-law) rather than an EU trademark / design practitioner registered on the lists of the representatives maintained by EUIPO. This point should be clarified in the SPC proposals.

The EPO rather than EUIPO could be appointed as central examination authority for handling the new SPC procedures. Since the EPO already grants European patents, including both EP bundle patents and unitary patents, it should be able to also grant their extensions. To this end, no changes to the European Patent Convention (EPC) would appear to be required. The legal basis could be Article 149a and Article 63 EPC. An *ad hoc* SPC Select Committee comprising representatives of the 27 EU Member States and the Commission as observer could oversee any SPC operations entrusted to the EPO.<sup>4</sup>

Further, from a procedural perspective, the Unified Patent Court could also deal with SPCs based on Articles 2(h), 3(b) and 30 of the Agreement of the Unified Patent Court (UPCA). As Article 20 UPCA provides that “[t]he Court shall apply Union law in its entirety and shall respect its primacy”, EU regulations can provide that the UPC will be in charge of handling appeals from EPO decisions regarding SPC examinations, just like the UPC is in charge of appeals against EPO decisions regarding unitary patents. Any necessary referrals to the Court of Justice under Article 267 TFEU are already covered by Article 21 UPCA. Entrusting the UPC with SPC examination appeals would ensure that a specialised court already handling SPCs will also handle SPC examination appeals, instead of the General Court which has no experience regarding the SPCs. All Member

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<sup>3</sup> EUIPO, Midterm financial sustainability of the Office, MBBC/23/S15/6/EN(O).

<sup>4</sup> This paragraph and the positions expressed therein are not supported by Croatian Employers' Association (Croatian Association of Employers) - HUP and by Polish Confederation Lewiatan.



States are free to join the UPCA even if they do not participate in enhanced cooperation on the Unitary Patent.<sup>5</sup>

In its Recommendation on the IP Action Plan,<sup>6</sup> the EU Parliament proposed to entrust the EPO with the role of central examination authority. More precisely, it suggested the Commission to “*give consideration to extending the European Patent Office’s mandate, so that examination of SPC applications could be carried out on the basis of unified rules*”. The Commission clearly disregarded these EU Parliament’s recommendations.

BUSINESSEUROPE therefore calls the co-legislators to look into the open points mentioned above regarding the Commission proposal to entrust the EUIPO and the Court of Justice of the EU with the new SPC procedures.

### **High quality examiners**

If, however, it is concluded that the EUIPO is the only body which could deal with the SPC centralised procedure, then the competence of EUIPO examiners must be ensured to achieve harmonisation in the granting process of unitary SPCs with the highest degree of quality. Examination should be carried out by the patent examiners from experienced national patent offices, who should be selected exclusively on the basis of objective and predetermined quality criteria.

### **Pre-grant opposition proceedings**

The SPC proposals introduce a relevant change in the granting procedure. They formalise the right for third parties to make observations during examination and include a new opposition procedure whereby a positive grant opinion could be challenged through the central examination authority within a two-month period after issue and with rights of appeal up through the EUIPO Boards of Appeal and potentially on to the Court of Justice of the EU. Currently, the validity of SPCs has to be challenged through the individual national courts. The proposed new oppositions would introduce a significant change for, and so the threat of, central and early challenge to SPCs.

Legal certainty, quality and timeliness of SPCs, as well as of the basic patents, are in the interest of the whole industry, patients and society as a whole. Thus, it must be ensured that pre-grant opposition proceedings do not create unnecessary delays and do not result in delaying the grant of SPCs even after expiry of the underlying basic patent.

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<sup>5</sup> This paragraph and the positions expressed therein are not supported by Croatian Employers' Association (Croatian Association of Employers) - HUP and by Polish Confederation Lewiatan.

<sup>6</sup> European Parliament resolution of 11 November 2021 on an intellectual property action plan to support the EU’s recovery and resilience (2021/2007(INI)), P9\_TA(2021)0453.



## **Transparency**

To ensure the highest level of transparency in the system, BUSINESSEUROPE is in favour of the creation of an SPC register where SPC applications, all legal documents relating to the granting process, and SPC case reports are uploaded in a timely manner, and can easily be downloaded by third parties.

## **SPC Proposal on plant protection products: conditions for obtaining unitary certificates**

The proposed Regulation on the unitary SPC for plant protection products sets several conditions that must be fulfilled in order for the unitary certificate to be issued.

Among these requirements, Article 3(3)(a) provides that a unitary certificate shall be granted by the central examination authority on the basis of a basic patent if, *in each of the Member States* in which that basic patent has unitary effect, at the date of the application, a valid marketing authorisation has been requested. The requirement to have a marketing authorisation in all Member States participating in the Unitary Patent system does not take into account the specificity of the sector and is detached from reality.

We therefore consider that the wording “in each of the Member States” in Article 3(3)(a) should be replaced with the “in relevant Member States” only.

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