



Mr Marton Nagy

Minister for National Economy of Hungary
Chair of the EU Competitiveness Council
Vám utca 5-7
1011 Budapest
Hungary

30 October 2024

Dear Minister,

BusinessEurope has been following the developments with regard to the Commission proposals on the supplementary protection certificates (jointly referred to as “SPC proposals”).¹ from their inception. The European business community generally welcomes the SPC proposals as they are expected to significantly reduce administrative burdens and increase efficiency, transparency as well as legal certainty. We also believe that, following the entry into operation of the Unitary Patent and the Unified Patent Court on 1st June 2023, it is time now to create the unitary SPC to incentivise pharma, biotech, and agrochemical companies to also participate in the Unitary Patent system.

We understand that the Council is now considering the SPC proposals in view of the trilogue negotiations with the European Parliament. This is therefore a good time for European businesses to reiterate their positions.

Although BusinessEurope supports the SPC proposals, some amendments appear necessary for the SPCs to become a workable instrument for European businesses:

- The EPO rather than EUIPO should be appointed as central examination authority for handling the new SPC procedures. Since the EPO already grants European patents, including both classic EP 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.²
- 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

¹ 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.

² This paragraph and the positions expressed therein are not supported by Croatian Employers' Association (Croatian Association of Employers) - HUP and by Polish Confederation Lewiatan



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 States are free to join the UPCA even if they do not participate in enhanced cooperation on the Unitary Patent.³

BusinessEurope urges the Presidency to consider these necessary changes to ensure that the SPCs become a workable instrument which could benefit European industry. Only an improved version of the SPC proposals could bring the value added at EU level, and that Member States are well-placed to ensure such an improvement.

Yours sincerely,



Markus Beyrer

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