

ECPA, EFPIA and IFAH-Europe Joint Position Paper

Proposal for a Unitary SPC

When adopting the unitary patent package, no provisions were made on how to obtain an SPC on the basis of a unitary patent. For the pharmaceutical, crop protection and animal health industries, SPCs are of fundamental importance as they compensate the patent holder for the loss of effective patent term up to the grant of a marketing authorisation.

The significant length of time between the filing of a patent application covering a new human or veterinary medicine or a crop protection product and the marketing thereof disadvantages the pharmaceutical, animal health and crop protection industries, as they cannot benefit from the full patent term to recoup the significant investments required to bring new products to the market. This stems on the one hand from the long development process and on the other hand, from the regulatory delays in getting a marketing approval.

Given the importance and value of SPCs, the industries represented by ECPA, EFPIA and IFAH-Europe support the concept of unitary SPCs being granted on the basis of European Patents with unitary effect. This is a logical continuation of the Member States' decision and agreement to create a European Patent with unitary effect. Though we understand that there are practical legal steps that will need to be taken to progress from the current national SPCs to a single unitary SPC, we believe it is critical that the European Commission addresses these issues in order that unitary SPCs are available, preferably before the Unitary Patent System becomes operational or very soon thereafter. This will substantially enhance the attractiveness of European patents with unitary effect to ECPA, EFPIA and IFAH-Europe member companies.

There are a number of questions to be addressed with the concept of unitary SPCs. One important question is which body would be responsible for granting unitary SPCs for the 25 Member States participating to the enhanced cooperation mechanism? Article 9(1) of the SPC Regulation allows Member States to “designate another authority” for the purpose of granting SPCs. This means that there is already a legal provision to develop the current system.

Different options have been floated and discussed, including the EPO or a mutual recognition process. However, for several legal and political reasons, they may not be suitable solutions. On the contrary, a unitary SPC will improve the appeal of the unitary patent system for industries represented by ECPA, EFPIA and IFAH-Europe, which heavily rely on SPCs.

ECPA, EFPIA and IFAH-Europe consider that any body granting unitary SPCs should fulfill the following prerequisites:

- 1) The body entrusted with granting unitary SPCs should have the expertise to do so, that is both expertise with patents and regulatory and administrative procedures but also with the specific question of granting SPCs in our industrial sectors.
- 2) The decisions made by this body, e.g. not to grant a SPC, should be appealable within a court system, preferably one that has expertise in intellectual property, such as the Unified Patent Court, and that it must be possible for references on points of law under the SPC Regulation to be referable to the CJEU.

ECPA, EFPIA and IFAH-Europe understand there are other considerations to take into account, notably political issues including the distribution of fees and the language. However we believe that our proposal does not raise additional questions from this perspective.

ECPA, EFPIA & IFAH-Europe Proposal for Unitary SPCs

ECPA, EFPIA and IFAH-Europe propose that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices.

Such a body would be able to rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping or differing national practices that might occur with mutual recognition of decisions by experienced personnel from examining national patent offices. Unitary SPCs would thus be granted by this body, combining expertise and best practices from all offices, without the political sensitivity of a mutual recognition system.

As a virtual body, considerations such as the location and associated costs of a new agency are reduced. It is recognized that there might be a need for a small number of administrative staff but it is believed that these needs would be relatively light. By making the body virtual, the administrative burden is minimised and reduced to considerations of how to optimise the virtual coordination. The details of how such a body would process applications would need to be developed with input from the national offices.

It would be acceptable for appropriate filing and renewal fees to be set to finance this body. A precedent might be taken from the fees for the Unitary Patent, once agreed. At present applicants face filing and renewal fees, in each country where an SPC is filed. It is hoped that the official fees associated with a unitary SPC would be a significant saving over national filings. A unitary SPC will also benefit European industry in reducing internal time and resources needed for the SPC filings on each product.

Set up via an EU instrument, such as a dedicated Regulation, building on the existing enhanced cooperation process used for the Unitary Patent, decisions from this virtual body would be challengeable within a court system such as the Unified Patent Court which could make any references needed to the CJEU.

Practically, this new body could be a stand-alone institution or attached to an already existing EU agency or body. It could be administratively embedded within an existing EU agency, with the task and responsibilities for granting unitary SPCs entrusted to the virtual body.

From a substantive perspective, guidelines would ideally be agreed by this virtual body so that SPCs can be granted relying on consistent principles which are the best practice of current examining national patent offices. These substantive guidelines should however remain flexible and easily adaptable in response to legislative changes and CJEU decisions.

ECPA, EFPIA and IFAH-Europe would be happy to further discuss this proposal with the Commission at its earliest convenience.

Interim solution

In the interim, building on a combined reading of the SPC Regulation and Regulation 1257/2012 implementing enhanced cooperation in the area of unitary patent protection, we support the solution of national SPCs being granted by national patent offices on the basis of a European patent with unitary effect. The Commission should however provide stakeholders with certainty in that respect.

Annex 1

Suggested Functioning Principles of the Virtual Body

The details of how such a body would process applications would need to be agreed with experts from national patent offices, but building on existing systems e.g. EMA's CHMP or NRG, we would tentatively suggest the following working principles:

- SPC applications received by the virtual body could be allocated to a division of three examiners: a “principal rapporteur” from a national patent office and two co-rapporteurs from different patent offices should be appointed.
- The rapporteur would be responsible for considering the application and proposing an opinion / recommendation on the fulfilment of the conditions laid down in Regulations 469/2009 (as amended) or 1610/96 as well as calculating the term of the SPC.
- The two co-rapporteurs could then have a limited time period to concur or to object to the recommendation made by the rapporteur.
 - Absent any objection to the application from either the rapporteur or the co-rapporteur, the SPC would proceed to grant. The Applicant would be notified accordingly. Otherwise, an office action would be issued (see below).
 - In case of objections from the co-rapporteurs to the rapporteur's proposal, a dialogue mechanism should be initiated between the rapporteur and the two co-rapporteurs so as to reach a consensus or a majority decision.
- If the 3-rapporteur examining division eventually objects to the application, an office action should be issued, setting a term for the applicant to overcome the objections, in writing. Where this is not sufficient to overcome the objection, the full body should discuss how to address the issue identified and make a decision, by consensus and where not possible, by absolute majority. Further office actions can be produced as necessary with a right to an oral hearing before a refusal.
- If a refusal issues, appeal should lie to a court having the ability to make references to CJEU, the court preferably having expertise in intellectual property such as the Unified Patent Court.
- It would be appropriate for SPC applications to be made in the language of the Unitary Patent. The translation arrangements applicable to the European Patent with Unitary Effect as per Article 3 Regulation No. 1260/2012 should also apply to unitary SPCs.
- The right to act before the virtual body should belong to any person having the right to file SPCs before a national patent office.