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epi comments on the Commission's Proposal for Regulations for SPCs for Pharmaceutical and Plant Protection Products

epi

epi represents the over 14,000 members of the Institute of Professional Representatives before the European Patent Office (**epi**). The members of the Institute are entered onto a list kept by the European Patent Office (EPO). The vast majority of members are qualified by an examination jointly administered by the EPO and **epi**. Our members are usually referred to as European Patent Attorneys. Our members work in private practice, industry and academia and represent enterprises ranging from individual inventors to multinational corporations. In connection with Supplementary Protection Certificates (SPCs), our members are responsible for prosecuting to grant applications for patents for relevant products and defending granted patents both before the EPO and nationally. Our members are also involved in registering SPCs and litigation regarding registered SPCs, up to and including before the CJEU. **epi** is therefore well-placed to comment on the Commission's proposals.

1. The Commission's Proposals

epi fully understands the reasons behind the Commission's proposals (the Proposals) and welcomes the rationale for revising the systems for dealing with SPCs for, on the one hand, pharmaceutical products and, on the other hand, for plant protection products.

epi agrees with the Commission that the present system needs to be revised so that it is simplified and harmonised.

epi also appreciates the opportunity to comment on the Proposals. This shows a welcome attitude of co-operation with all users of the present system.

2. The Reasons Behind the Proposals

epi agrees with the Commission that the present system for granting and litigating SPCs within the EU is fragmented within the EU, very costly and not transparent and therefore needs to be reformed. As SPCs are at present granted and litigated nationally, there is a patchwork of protection within the EU member states. The protection provided by the SPCs granted using the present national systems can vary from state to state. The result of litigation of SPCs is also very variable. Although the CJEU should be able to provide a unifying effect, cases where there have been several rounds of referrals on similar issues have shown that this is difficult to achieve. Thus, the users of the system and those who wish to challenge SPCs have a great deal of legal uncertainty.

epi agrees with the Commission that there is a need for a system where there is uniform protection across all EU member states, there is increased legal certainty about that protection and the costs for obtaining and litigating that protection are reasonable.

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epi appreciates the Commission's Proposals, which are very ambitious. However, **epi** is of the opinion that, as that Proposals stand, improvements are necessary so that any new centralised filing and examination procedure is not more complex than the existing national procedures and allows for the quick grant of valid SPCs.

3. There Should be No Change until a Single, Central Procedure is Established

It is indicated in the Proposals that there is no intention to change the established legal basis for the grant of SPCs. However, this is not the effect of the Proposals. There will inevitably be a change in the legal basis by a number of the amendments set out in the proposals and so this objective will not be achieved. **epi** therefore considers that the present procedures should stay in place until there is in place a single, centralised procedure in place for granting and litigating a single unitary SPC. This unitary SPC should cover all the member states of the EU and national SPCs would no longer be granted.

The procedure for granting the SPC should be a central authority. Any appeals from the central authority should be heard by the same court which deals with litigation of the SPCs. As part of this new system, it should be specified that the SPC can only be based on a European patent which has been validated in all EU members states or is a European patent with unitary effect (UP) for all EU member states[1]. It should be no longer possible for SPCs to be granted on national patents.

4. The EUIPO is not the Appropriate Forum for Dealing with SPCs

epi is of the view that the EUIPO is not the appropriate forum for dealing with SPCs. SPCs are based on patents, most of which are granted by the EPO. One of the reasons for considering instituting a unitary SPC is because of the existence of the newly-created European patent with unitary effect (UP). The granting of European patents and the registration of unitary effect, if requested by the patent proprietor, is carried out by the EPO under a Special Agreement by which EU Regulations are administered by the EPO. It is therefore logical that the granting of SPCs based on European patents, with or without unitary effect, should also be dealt with by the EPO under a similar Special Agreement. The EPO already has the expertise of dealing with patents, both before and after grant, and so there would be no need for any extra personnel. The EPO also has the advantage that it has a simple language regime (only three official languages) but with a very good translation tool dedicated to patent translations. Thus, the EPO could readily carry out the process for granting SPCs efficiently and at reasonable cost. Moreover, the EPO already has a register of all European patents and this could be readily amended to allow for registering of corresponding SPCs. Any appeals regarding applications should be heard by the Unified Patent Court[2].

In contrast, the EUIPO has no experience at all of dealing with patent applications or granted patents and, as the Proposals indicate, would need to recruit new personnel from national patent offices to carry out the process. The process would also involve EUIPO personnel who have no experience of patents and who would have to be trained for every new SPC application to deal with SPCs. All appeals will also be heard by the appeal bodies within the EUIPO (that currently also have no experience in patent or SPC matters). Given that the Proposals also include suggestions for pre-

[1] **epi** trusts that the Commission will be taking active steps to ensure that all EU member states ratify the Unified Patent Court Agreement so that the unitary patent will cover all EU member states.
[2] If, for any reason, it was to be decided that the UPC should not be involved, appeals could be referred to the General Court.

grant oppositions and appeals, it is clear that the system will be subject to decisions from officers of the EUIPO who are not experienced in anything to do with SPCs. This by itself means that the process will be more expensive than is necessary.

Moreover, the EUIPO has a more complex language regime and the use of such a complex and cumbersome language regime would be contrary to one of the reasons for the new system. There are five official languages (English, French, German, Italian and Spanish) but, according to the proposals, a centralised SPC application could be filed in any one of the 24 EU languages. Any application filed in a non-official language would then need to be translated into an official language. This would also be the case for the proposed Third Party Observations (TPO). Moreover, the proposed examination opinion (EO) would also need to be translated into all 24 EU languages. The EUIPO does not have the tools for carrying out all the required translations at low cost.

epi therefore considers that the process for granting SPCs should be entrusted to the EPO under a Special Agreement.

5. The Proposals Need To Be Simplified and More Clearly Defined

It is the view of **epi** that the Proposals solve some of the issues encountered with the current SPC Regulation but, on the other hand, they add complexity in the centralised procedure as proposed which can create new legal uncertainties and legal delays.

epi believes that the proposed centralised procedure should be reviewed and clearly defined, with strict and short deadlines to be met by applicants, third parties and examiners.

The proposed centralised procedure requires:

1) Filing an application with the central authority;

2) Examination of the application, the production of an examination opinion (EO) and the publication of the EO;

3) The possible filing of TPO by a third party;

4) A possible appeal by the applicant (to the Boards of Appeal of the central authority, a possible further appeal to the General Court of the EU and possibly a yet further appeal to the CJEU, giving three possible levels of appeal) against a negative EO, which may result in the EO being changed;

5) Within 2 months of publication of the EO, a third party may file a pre-grant opposition, which may result in the EO being changed (again);

6) Any change in the EO as a result of the pre-grant opposition may be appealed (to the Boards of Appeal of the central authority, further appealed to the General Court of the CJ-EU and possibly further appealed to the CJEU, again giving three possible levels of appeal); and

7) Forwarding a final binding opinion to national offices.

epi understands that this model is supposed to be based on the current "EPO model" for examining and granting patents. However, the EPO model does not include pre-grant opposition proceedings. Moreover, as the purpose of the SPC Regulation is to deal with the validity of a supplementary protection certificate and not with the validity of a patent, **epi** suggests designing a simpler and less fragmented system, so as not to run the risk of the examination and granting procedure for the SPC taking longer than the additional time that could be granted to the holder of the MA. Such a situation would inevitably undermine the predictability and value of the SPC regime in Europe.

epi considers that two procedures available to third parties to try to prevent the grant of an SPC, the TPO procedure and the pre-grant opposition procedure, will result in endless delays in the process of examining and granting SPCs and in the *de facto* non-useability of the centralised SPC system. **epi** therefore considers that the pre-grant opposition procedure should be abandoned and that there should be strict time limits for filing TPO.

epi also considers that having three levels of appeal is not required. Rather than having a first level of appeal within the central authority, any appeals should go directly to the General Court with a possible further level of appeal to the CJEU.

epi is also concerned that there will be undue complexity because of the availability of a number of different, possibly co-existing systems [i.e.: National SPC procedures (for European patents with or without unitary effect and national patents) based on national marketing authorisations (MAs); and a centralised SPC application for European with or without unitary effect based on a centralised MA procedure]. **epi** considers that the present system should continue unchanged until a single, central procedure for granting unitary SPCs is brought into effect and the Proposals should therefore have clearly defined transitional measures leading to a single, simple, centralised procedure for all SPC applications.

Regarding invalidity actions, with the entry into force of the UPC, which is competent to deal with SPCs based on UPs (uSPCs) and is a specialized court in Europe, **epi** considers it makes no sense to permit the filing of invalidity actions before the central authority. Furthermore, taking into account that all uSPCs will fall within the jurisdiction of the UPC, the possibility to file invalidation actions before the central authority is improper and ignores the exclusive jurisdiction of the UPC precisely for such actions.

There is also the question of representation before the EUIPO. Those who prosecute the patents on which SPCs are granted may not be representatives before the EUIPO. It is considered that it should be possible for those who prosecuted the patent on which the SPC is based also to represent the patent owner in all proceedings relating to the SPC at all levels, including the final appeal stages.

epi considers, in light of the comments given above, that the application procedure should not provide for pre-grant oppositions but should, as the EPO does, only provide for the TPO procedure before grant. Any appeal by the applicant should go direct to the UPC with no intervention by an appeal board so that there are only two levels of appeal. Actions to enforce or revoke centrally-granted unitary SPCs should be filed directly with the UPC.

As noted above, **epi** considers that the applications should be filed at the EPO as the EPO already has the necessary familiarity with patents. Moreover, there are only three official languages at the EPO and so the language problems would be significantly reduced. Further, those who prosecuted the patent on which the SPC is based would be able to represent the patent owner in all the SPC proceedings before the EPO and, with the relevant amendments, should be also able to represent the parties in any subsequent appeals as proposed herein.

epi considers that it would be preferable not to refer in the new Regulations to the decisions of the CJEU but to have this information set out into specific guidelines relating to the examination of the SPC applications to be put in place by the central authority in the future.

epi considers that the proposed changes to Article 3(2) of all four Regulations makes that Article further unclear. The phrase "where they are not economically linked" is unclear and needs further explanation.

epi also considers that there should be provisions to enable an authority to order the third party referred to in Article 6(2) to provide the required consent in situations where there is a dispute as to the protection afforded by the patent owned by the third party on which the unitary certificate is based.

Finally, **epi** would like to highlight that there is no central EU body for providing MAs for Plant Protection Products and so considers that it would be advisable to set up such a central body before making any changes to the SPC Regulations for Plant Protection Products.

Yours sincerely,

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President