



14.11.2024

epi's comments on the Proposals to introduce a more centralized granting process for Supplemental Protection Certificates in the EU/EEA

The Institute of Professional Representatives before the EPO (epi) has already provided recommendations to the EU Council and other bodies regarding the proposed Regulations regarding Supplementary Protection Certificates (SPCs)¹. We attach a copy of our letter to the Commission on this subject. We understand that the Council is now considering the SPC proposals in view of the trilogue negotiations with the European Parliament. **epi** would like to contribute to these considerations. This is therefore a good time for **epi** to repeat its position.

epi is the representative body for all ca. 14500 persons entered on the list of professional representatives before the EPO under Article 134 EPC (usually referred to as European Patent Attorneys). As such, **epi** represents the vast majority of persons responsible for obtaining the European patents on which an EU-wide SPC would be based. European patent attorneys represent before the EPO entities ranging from multinational corporations to individual inventors, not only from within the EU but also from within the non-EU member states of the EPC and throughout the world. **epi** therefore is well aware of the views of a wide variety of entities interested in the present SPC proposals.

The entities which the members of **epi** represent are generally in favour of the proposals to achieve a higher level of harmonisation and unification of the SPC processes, provided that the proposals are amended to make them practical and efficient. If the proposals are properly implemented, **epi** expects that they will greatly reduce the complexity and costs of the present EU SPC system, thus increasing efficiency of the procedure for obtaining an SPC. It will more importantly ensure that the process around SPC's will become more transparent and provide a higher degree of legal certainty to all involved parties.

epi notes that the Unitary Patent (UP) and the Unified Patent Court (UPC) entered into force on 1st June, 2023 and that both systems have proved to be well-accepted by many applicants for patents before the EPO. The take up of the UP has exceeded expectations and the UPC seems to operate efficiently and effectively. **epi** recommends that the EU bodies take advantage of these now established systems to provide an efficient and effective new EU SPC system.

As **epi** noted in its letter referred to above, it is considered that, in order to have an efficient and effective EU SPC system, the present proposals should be amended to specify first that the EPO should replace the EUIPO and second that the UPC should replace the General Court.

We find that the EPO is well equipped to become a central authority responsible for implementing the new SPC application and grant process. The EPO is already the authority for granting all

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.

European patents, with or without unitary effect, on which the SPC applications will be based. The EPO therefore already has a register for these patents and so has most of the administrative functions required to process SPC applications. Moreover, the EPO already has examiners who are skilled in the technical areas to which SPCs relate and so have a body of experts able to implement any new SPC procedure. All that would be needed is an added area for the register and rules for dealing with the SPC applications.

On the legal side, from our perspective, no changes to the European Patent Convention (EPC) would be required. Articles 149a and 63 EPC already provide a suitable legal framework for a centralized SPC-granting system. The existing Unitary Patent shows and can be a model for the type of legal basis for the EPO to perform a task of granting SPCs, within the legal framework of the European Union. The SPC procedure could be supervised by an "SPC Select Committee", similar to the Select Committee supervising the UP, and would comprise representatives of the 27 EU Member States and the Commission as observer. There is also already a model for involving experts and examiners from National Patent Offices of EU countries, who are currently dealing with SPC-applications, in a new administrative centralized process to examine and grant SPC applications: Currently at the EPO Boards of Appeal, there is a possibility to involve national judges in certain cases; thus, experts and examiners from National Patent Offices could be delegated to work on SPC-matters within an administrative-organisational framework of the EPO.

The UPC is able and competent to deal with questions around SPCs (Articles 2(h), 3(b) and 30 UPCA). It is a specialized court which has the expertise to deal with matters relating to SPCs and so would be able readily to deal also with appeals from EPO decisions regarding SPCs. It also operates very efficiently as it has, so far, shown that it is able to handle such cases at first instance within one year. In contrast, the General Court has no experience of SPCs and takes much longer to deal with cases.

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 responsible for appeals from EPO decisions in respect of its handling of SPC applications, in the same way that the UPC is responsible for appeals against EPO decisions in respect of applications for unitary effect. Article 21 UPCA already provides that the UPC can refer questions to the Court of Justice of the EU so as to ensure that EU law prevails and is applied in a harmonized way. All EU Member States are free to join or the UPCA or recognize the jurisdiction of the UCP even if they do not participate in enhanced cooperation on the Unitary Patent.

epi therefore requests the EU Presidency to work towards implementing the amendments to the SPC proposals set out above to ensure that the new SPC granting system provide an efficient, effective and legally secure system for this economically so important IP rights. This will ensure that innovation in the fields covered by SPCs is encouraged and third parties benefit from an enhanced degree of legal certainty.

Yours sincerely,



Peter R. Thomsen
President



Institut der beim Europäischen Patentamt zugelassenen Vertreter
Institute of Professional Representatives before the European Patent Office
Institut des mandataires agréés près l'Office européen des brevets

European Patent Institute · Bayerstrasse 83 · 80335 Munich · Germany

General Secretariat of the Council

By e-mail only to: LIFE.3@consilium.europa.eu

05 April 2024

epi Position paper on jurisdiction of uSPC

Dear General Secretariat of the Council,

In view of the current discussion on the revision of the EU Regulations regarding Supplementary Protection Certificates and Unitary Supplementary Protection Certificates in the areas of pharmaceuticals and plant protection products we would like to provide you with the attached **epi** position paper.

Please feel free to contact us if you have any questions with regard to our submission.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Peter R. Thomsen', written in a cursive style.

Peter R. Thomsen
President

Attachment: **epi** Position Paper on Proposed EU Regulations regarding Supplementary Protection Certificates and Unitary Supplementary Protection Certificates in the areas of pharmaceuticals and plant protection products, issued on 5th April 2024.

President • Peter R. Thomsen

epi Secretariat · Bayerstrasse 83 · 80335 Munich · Germany

Phone +49 89 242052-0 · Fax +49 89 242052-220

info@patentepi.org · www.patentepi.org

Direct Phone: : +41 79571 0076

president@patentepi.org



05.04.2024

epi Position Paper on Proposed EU Regulations regarding Supplementary Protection Certificates and Unitary Supplementary Protection Certificates in the areas of pharmaceuticals and plant protection products

About epi

The Institute of Professional Representatives before the European Patent Office (**epi**) is the professional body representing all European Patent Attorneys, many of whom are also very familiar with matters relating to SPCs within the EU and in the other 12 member states of the European Patent Convention wherein SPCs are available. Currently the Institute has about 14,200 European Patent Attorneys as members coming from all the 39 Contracting States of the European Patent Convention and who work either in industry or in private practice. European Patent Attorneys help their clients and employers, which include multinational corporations, SMEs and private inventors, to create value from their inventive ideas, thus providing jobs and strengthening the European economy.

epi as an organisation deals primarily with the development and implications of patent law. **epi** is at the forefront of patent law developments and regularly serves public policy leaders by issuing legal opinions and highly specialised advice.

Introduction

epi has been aware of the proposals from the EU for amending and bringing into force Regulations regarding Supplementary Protection Certificates (SPCs) and Unitary Supplementary Protection Certificates (uSPCs) in the areas of pharmaceutical products and plant protection products. **epi** has already commented on these proposals, which **epi** considers are likely to have the opposite effects to those desired by the EU. Our views on the proposals were communicated to the EU by our letter of 18th September 2023.

The Present System

We confirm that **epi** agrees with the Commission that the present system for granting and litigating SPCs within the EU is fragmented and very costly with low transparency and therefore needs to be reformed. As SPCs are at present granted and litigated nationally, there is a patchwork of national protection across the EU member states. The protection provided by the SPCs granted using the present national systems can vary from country to country depending on how national patent offices

President • Peter R. Thomsen

epi Secretariat · Bayerstrasse 83 · 80335 Munich · Germany
Phone +49 89 242052-0 · Fax +49 89 242052-220
info@patentepi.org · www.patentepi.org

Direct Phone: +41 79571 0076
president@patentepi.org



interpret and put into practice the currently existing two SPC Regulations and various relevant decisions of the CJEU. Thus, the users of the current 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. This is particularly relevant in connection with the European Patent with Unitary Effect (UP), introduced in 2023, which now provides uniform patent protection for the territory of 17 participating EU states. In our view, if there is unitary patent protection for that territory, there should also be a uniform partial extension of that protection effect for pharmaceutical and plant protection products via a unitary SPC (uSPC). It should not be forgotten that, although the SPC is a sui generis title, each SPC is based on a specific patent (the “basic patent”) and prolongs a certain portion of the protection provided by the basic patent.

The EUIPO is Not the Correct Forum

One of the points we raised in our previous letter relates to the **unsuitability** of the EUIPO as an organisation to grant and administer uSPCs. It appears that the desire to use the EUIPO arises from a perceived requirement to use EU institutions to administer and decide on matters related to uSPCs. However, we consider that there is no such absolute requirement. **epi** is therefore of the view that the proposals should be amended so that the EUIPO is not involved in anything to do with uSPCs. The EPO should be the relevant authority for dealing with the granting of uSPCs. The EPO already has the relevant technical expertise and competence for dealing with patent-related matters. Also, the EPO is the instance that would have processed the European patent with Unitary Effect providing the basis for the related uSPC and therefore the EPO already has the technical and legal expertise to handle matters arising on the related uSPC. Additionally, the EPO already administers the register for the UP. Should the EUIPO need to administer uSPC matters, there would be a need for close connection between the UP register at EPO and the SPC register at EUIPO.

There is no general requirement for matters relating to EU instruments to be dealt with solely by EU Institutions

The fact that there is no general requirement for only EU institutions to be involved in dealing with EU Regulations is illustrated by the existence of the UP and the Unified Patent Court (UPC). The UP is an EU instrument governed mainly by two EU Regulations, but the grant of patents which are eligible for unitary effect and the processing of requests for unitary effect are carried out by the EPO, which is not an EU institution. Any appeal regarding Unitary Patents is dealt with by the UPC, which

also is not an EU institution. Moreover, any actions relating to Unitary Patents are dealt with by the UPC by its Court of First Instance and its Court of Appeal. If there is a matter of EU law on which the UPC requires an opinion, questions can and must be referred to the CJEU.

During the extensive work which was carried out before the UP and the UPC came into effect, the CJEU was given the opportunity to investigate and found that the UP / UPC system meets the requirements of the EU's legal framework and is not in conflict with EU law. This system is already in effect and, as shown below, is competent to deal with SPC matters. It therefore cannot be seen why the EPO / UPC system cannot be used for all matters related to SPCs, particularly uSPCs.

A Divided Jurisdiction for SPCs is Illogical and leads to an increased level of fragmentation in the internal market

The proposal in the Regulations regarding jurisdiction for uSPCs is set out in its Article 23, which gives exclusive jurisdiction to an invalidation division of the EUIPO for revocation actions where there is no corresponding infringement action. Any appeal from that EUIPO division will be dealt with by the Board of Appeal of the EUIPO. Any further appeal will be dealt with by the General Court of the EU. Under exceptional circumstances, there may be a further appeal dealt with by the CJEU.

epi would strongly advise against such a jurisdictional system. Such a jurisdictional system would lead to even more fragmentation and a higher level of legal uncertainty for all involved parties. More over the UPC Agreement, which has been fully in force since 1st June 2023, has already given to the UPC the competence to decide on actions for declarations of invalidity of SPCs (i.e. direct revocation actions – see Article 32(1)(d) UPCA) as well as for counterclaims for declarations of invalidity of SPCs (Article 32(1)(e) UPCA). It would be totally illogical and detrimental to legal certainty to have two different authorities for dealing with legal actions concerning uSPCs.

The proposed jurisdiction from EUIPO invalidation panels to EUIPO Board of Appeal to the EU General Court would unduly prolong the way to legal certainty because there would be up to 4 instances to a final decision (involving the CJEU), whereas there would be only 2 instances if the UPC were to have jurisdiction on invalidation of uSPCs. Since there were and likely will still be in future important question on interpretation of the EU-SPC Regulations, it is of high importance to have sooner rather than later during the legal proceedings the possibility to have those questions decided by the CJEU. Neither the EUIPO invalidation panels nor the EUIPO Boards of Appeal have the possibility to refer questions on interpretation of the EU SPC Regulations to the CJEU. Even the General Court would not refer questions but would issue a decision and then the parties could further



appeal fundamental questions of law finally to the CJEU under the limitations of Art. 58a lit. a of the CJEU Statute.

In contrast to that long proceedings, the central division of the UPC in first instance would have the opportunity under Art. 267 TFEU to refer such questions at an early stage of the proceedings to the CJEU. The UPC Court of Appeal would even be under an obligation to do so, being a highest Court of last instance. Thus, we would expect that it would take significantly less time to reach legal certainty using the existing UPC procedure than using the jurisdictional system proposed in the Regulations.

The UPC Has the Required Expertise

Any panel of the Central Division of the UPC Court of First Instance comprises a technically qualified judge with qualifications and experience in the field of technology concerned. The UPC Court of Appeal comprises panels composed of three legally qualified judges and two technically qualified judges (Article 9(1) UPCA). This ensures the UPC's competence to deal with SPCs as well as with uSPCs as it already has the appropriate expertise.

The UPC jurisdiction on uSPCs is fully in line with principles of EU law

Should it, against our suggestion above, be decided nevertheless that the EUIPO will be the institution to examine, issue and administer uSPCs, there may be some arguments under the principles of primary EU law that the EUIPO, its Board of Appeals and the General Court must have jurisdiction over isolated revocation actions because the uSPC will be a legal title issued by an EU agency. However, in our view, one should not neglect that the SPC is a legal title, that although of sui generis nature, cannot exist without its basic patent. The basic patent will be based on a European Patent that was granted by the EPO, which is not an EU institution, but where the CJEU found no violation of EU law in letting the EPO also issue and administer the Unitary Patent. In our view, in particular the uSPC has such a close connection and dependency with the European patent on which it is based, that it would be justified and in compliance with Union law to allow an institution other than an EU agency, which may technically granted the uSPC, to deal with isolated revocation actions.

We take the view that the UPC Agreement in its present wording already includes legal basis for the UPC to decide on revocation actions of uSPCs, because uSPCs would just be a special type of SPCs that are subsumed under the current wording of the UPC Agreement. If it is felt that uSPCs should be expressly mentioned in the UPC Agreement, a practical way to confirm that would be an

amendment to the definitions of SPC or to the jurisdiction provisions based on Article 87(2) UPCA by way of explicitly adding uSPCs to the competence of the UPC.

Representation before the EUIPO

As we highlighted in our previous letter, 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 the patent attorneys who prosecuted the patents on which SPCs are based should also be able to represent the patent owner in all proceedings relating to the SPC at all levels, including the final appeal stages. This is sensible for reasons of technical expertise as well as cost efficiency for SPC holders who otherwise may be forced to spend money and time in instructing and briefing new representatives to act before the EUIPO.

Summary

Setting up a new and very complex system for uSPCs as proposed by the proposed regulations would increase bureaucracy and complexity and require huge institutional costs and unnecessary costs for SPC holders. There is already a clear and competent system available in the forum of the UPC. **epi** considers that there is now an opportunity to leapfrog from the current system, with its complexity, cost and legal uncertainty, to using the existing EPO / UPC system which would deliver to all users of the SPC system, including SPC holders and third parties, clarity, legal certainty and cost efficiencies. The use of the existing UP / UPC framework for UPs (on which the uSPCs will be based) will ensure that the expertise required is already available both from the EPO / UPC authorities as well as the representatives qualified to act before the EPO / UPC.

Yours sincerely,



Peter R. Thomsen
President