boult

Supplementary Protection Certificates and the Unitary Patent/Unified Patent Court; is a Unitary SPC also on the way?

Barbara Niemann Fadani, German Attorney-at-Law

Contents

Introduction

Supplementary Protection Certificates and the Unitary Patent/Unified Patent Court; is a Unitary SPC also on the way?

Supplementary Protection Certificates (SPCs) are a sui generis IP right available in Europe for the protection of medicinal and plant protection products. SPCs can provide up to five and a half years extra protection for such products beyond expiry of the standard 20-year patent term. The SPC system exists to compensate patentees for the effective loss of patent term resulting from the time taken to obtain the authorisations required to place medicinal and plant protection products on the market. Although SPCs can be granted on the basis of European patents obtained via the European Patent Office (EPO), SPCs are national rights, granted and enforced at a national level.

We discuss below the impact of the Unitary Patent (UP) and Unified Patent Court (UPC) on the current SPC system. In addition, we provide an update on the EU's most recent proposals for harmonising SPC law, including in particular the introduction of a Unitary SPC and/or a unified procedure for the granting of national SPCs.

The current SPC system

The requirements for obtaining SPC protection in EU member states are governed by EU legislation, specifically Regulation (EC) No 469/2009 covering medicinal products and Regulation (EC) No 1610/96 covering plant protection products.

The Regulations set out the basic conditions for obtaining an SPC which are:

a) the product must be protected by a basic patent in force;
b) a valid authorisation to place the product on the market must exist;
c) the product must not have already been the subject of a certificate; and
d) the authorisation under (b) must be the first authorisation to place the product on the market.

SPC protection is also available under the same terms in certain non-EU states including the UK, Switzerland, Liechtenstein, Norway and Iceland, based on application of the EU Regulations or equivalent national law.

Under the current system SPCs are national rights, and applications for SPCs must be filedat the national office of each country in which protection is sought. Despite the fact that the "basic patent" can be a European patent granted by the EPO and the "authorisation" can be a centralised marketing authorisation granted by the European Medicines Agency (EMA), there is no centralised or unified procedure for SPCs.

This imposes both a cost and administrative burden on patentees and the patent offices across Europe. Importantly, the current system also allows for divergent outcomes both in the granting and enforcement of SPCs between the different European countries.

This divergence has been exacerbated by difficulties in interpreting the basic requirements of the SPC Regulations. Since the entry into force of the SPC system, there have been a large number of referrals to the Court of Justice of the EU (CJEU) seeking clarification on different aspects of SPC law. Despite numerous decisions handed down by the CJEU, there remains a lack of harmonisation across Europe.

Neil Thomson, Partner

Changes following the introduction of the Unitary Patent and the opening of the Unified Patent Court

Henning Erb, Partner

Based on current time-scales, it is anticipated that the Unified Patent Court (UPC) will open towards the end of 2022 or early in 2023. European patents with unitary effect or "Unitary Patents" (UPs) will become available at the same time. For more information on UPs and the UPC system, please see our Boult Wade Tennant guide **here**.

In terms of how this new European patent system will affect SPCs, the following points are of note.

Ability to use a UP as the basis for SPC protection
It will be possible to use a UP as the basic patent upon which SPC applications are based. However, for the time being, the SPC application and grant process will remain unchanged with separate applications required at each national office.

If SPCs are to be based on a UP, it will be important to consider the territorial scope of the UP. Each granted UP will only take effect in EU countries that have ratified the Unified Patent Court Agreement (UPCA) **at the time of registering that UP**. The protection conferred by the UP will not extend to countries that ratify the UPCA after the UP has been registered.

The 16 countries that have currently completed ratification of the UPCA are: Austria; Belgium; Bulgaria; Denmark; Estonia; Finland; France; Italy; Latvia; Lithuania; Luxembourg; Malta, Netherlands; Portugal; Slovenia and Sweden. Germany must also deposit its ratification of the UPCA prior to the UPC opening.

Aside from countries that have not yet ratified the UPCA, countries outside of the EU (e.g. UK, Switzerland) and EU countries that are not party to the UPCA (Spain, Croatia and Poland) will not be covered by a UP.
SPC protection in European countries not covered by the UP will still need to be based on national patents, potentially obtained via the traditional route of validating a European patent nationally.

Jurisdiction of the UPC
The default position for all SPCs, like all European patents, is that they will fall under the exclusive jurisdiction of the UPC.

However, during a transitional period of seven years after the date of entry into force of the UPCA, it will be possible to remove certain SPCs from the exclusive jurisdiction of the UPC. This can be achieved by the "opt-out" system, which will be available for traditional European patents, i.e. European patents granted by the EPO that are subsequently validated as a bundle of national rights.

In order for patent proprietors to remove both existing and future SPCs from the UPC system, it will be necessary to register an "opt-out" for the European patent(s) on which the SPCs are based.

Importantly, it will not be possible to opt-out future SPCs granted on the basis of UPs. SPCs based on a UP will always fall under the exclusive jurisdiction of the UPC.

For traditional European patents, the opt-out process requires the patent proprietor(s) (or their appointed representative) to register an opt-out in respect of an EP patent or application with the UPC Registry. It will be possible to register opt-outs within a three-month "sunrise period" before the UPC opens. Where SPCs are already in existence at the point in time at which an application for an opt-out is filed, the opt-out will extend to all SPCs based on the European patent. Importantly however, the SPC holder, **if different from the patent proprietor(s)**, will need to lodge the application together with the patent proprietor(s). If the opt- out is being filed by an appointed representative, the representative will need to be authorised by the patent proprietor(s) and the SPC holder(s). The added complexity here is that the "proprietor(s)" are not necessarily those recorded on the EPO or national registers but are those entitled to be registered as the proprietor under the law of each Contracting Member State in which the European patent has been validated.

Where SPCs are granted **after** an application for an opt-out has been filed, the situation will be slightly simpler in that the opt-out will take effect automatically on grant of any SPCs based on the European patent.

The rules governing opt-outs will apply equally to European Patents and SPCs. In particular:

- the opt-out will apply to all Contracting Members States of the UPC;
- the opt-out will be effective for the full term of the patent and any SPCs unless the opt- out is actively withdrawn;
- once an opt-out has been withdrawn, it will not be possible to opt-out a second time; and
- an opt-out will not be possible if an action has already been brought before the UPC.

Susi Fish Partner

Proposal for a Unitary SPC/ Unified procedure for grant of SPCs

It has been noted by the European Commission (EC) that although the existing SPC regime is fit for purpose, differences between EU countries in its administration and enforcement create inefficiencies. As a result, the EC has launched an Initiative to put in place a Unitary SPC and/or a single (unified) procedure for granting national SPCs (see **Medicinal & plant protection products – single procedure for the granting of SPCs (europa.eu**)).

In March 2022, the EC published a "Call for Evidence" inviting feedback on the proposal and setting out the options being considered at this stage. These options include (amongst others):

(i) Legislative changes so as to create a centralised system for SPC protection in the EU.

This centralised system could consist of:

- a unitary SPC, complementing the future UP; - a unified procedure for granting (bundles of)

national SPCs; and

- a combination of the two.

(ii) The introduction of non-legislative instruments such as guidelines aiming to consolidate the best practices of national offices and the case law of the CJEU so as to harmonise the current system.

The period for feedback has now ended and the comments can be viewed here. Given the difficulties with the current SPC system, including issues of cost, administrative burden and diverging practice between countries, there is a great deal of industry support for both a Unitary SPC and a centralised procedure for granting national SPCs. A Unitary SPC system also has the potential to bring benefits for generics companies by improving the transparency of SPC-related information and thus simplifying the monitoring of innovator SPC portfolios.

If a Unitary SPC were to be introduced, a number of issues will need to be addressed including the following.

1. The body responsible for examining and granting Unitary SPCs – options that have been suggested already include new bodies within the EUIPO or EPO or a virtual body made up of representatives from different national offices.

2. The optional nature of a Unitary SPC – would it **only** be possible to obtain a Unitary SPC based on a UP or would national SPCs remain available even if the basic patent is a UP?

3. Related to point 2., the type of marketing authorisation that could be used as the basis for a Unitary SPC – would Unitary SPCs be limited to products granted a centralised marketing authorization by the EMA? Even if national marketing authorisations were permitted as the basis for a Unitary SPC, issues would arise if marketing authorisations did not exist in all countries covered by the UP. It is

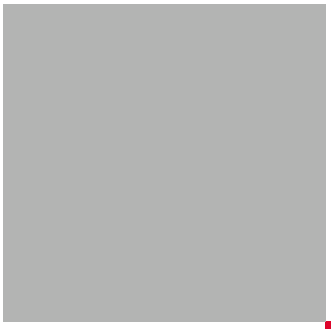
possible that a Unitary SPC would not be permitted in such circumstances or potentially, the scope of the Unitary SPC could be limited to countries in which marketing authorisations had been granted. If a Unitary SPC were not permitted without a marketing authorisation in every country covered by the UP, the option of national SPCs based on a UP would need to remain available to proprietors.

National SPCs will also remain the only option in countries not covered by the UP/Unitary SPC.

In summary, it appears that a Unitary SPC designed to match up with the UP could be on the way. In the shorter term however, a centralised/unified procedure for the granting of SPCs may be of greater interest and benefit to many. In particular, there may be reluctance from innovator companies to register their high value European Patents as UPs at the start of the new UP/UPC system. In reality therefore, there may be very few UPs to be used as the basis for SPCs in the early years of the system. Only time will tell how successful the UP/UPC will be and consequently how common Unitary SPCs (if introduced) might be in the future.

If you have any questions relating to SPC protection, including issues surrounding the UP, UPC or proposal for a Unitary SPC system, please do not hesitate to contact a member of our Biotechnology and Life Sciences team.

Sebastian Stephen, European Patent Attorney and German Patent Attorney



Boult Wade Tennant LLP
Salisbury Square House
8 Salisbury Square
London
EC4Y 8AP
www.boult.com