Questions and Answers on the Supplementary Protection Certificates

Brussels, 27 April 2023

Why is intellectual property important and why is the Commission proposing a new initiative on patents today?

Europe has a long tradition of encouraging creativity and innovation. Intellectual property (IP) rights help companies, inventors and creators protect and valorise their intangible assets. The Commission continues to deliver on the Action Plan on Intellectual Property of November 2020 to improve the IP legal framework, notably in three patent-related fields where legislative action is required: supplementary protection certificates, compulsory licensing and standard-essential patents. Despite the strategic importance of patents, EU patent law remains fragmented. EU patent law therefore needs to be modernised to boost the resilience of our patent system, support the EU's green and digital transition and strengthen the EU's technological sovereignty, in particular in emerging technologies. With the set of proposals for a Regulation adopted today the EU shows its willingness to further reinforce the harmonisation of EU patent law and complement the Unitary Patent System, whose launch will take place in June 2023. In today's world of globalised markets and the knowledge economy, it is vital to ensure that the EU IP system is effective, transparent and future proof, setting global standards.

What is a Supplementary Protection Certificate and how does the new regime relate to the Unitary Patent?

A supplementary protection certificate (SPC) is an IP right that extends a patent by up to five years for a pharmaceutical or plant protection product that has been authorised by regulatory authorities, thereby encouraging innovation and promoting growth and jobs in these sectors. The proposed SPC reform includes the creation of a unitary SPC, complementing the unitary patent that will enter into force on 1 June 2023. The unitary SPC will also incentivise innovators to use the unitary patent. In the absence of a unitary SPC, a unitary patent could be extended only by means of national SPCs, i.e. in a non-unitary manner, leading to greater administrative burden and costs. In addition, for all SPCs based on a European patent, infringements will be handled by the new Unified Patent Court (at least for the initially 17 participating Member States), provided that the applicable conditions are fulfilled.

Who can use the new SPC centralised procedure and what are the benefits?

The SPC centralised procedure can be used by any company, start-up, research organisation, innovator, etc. that holds a valid patent on a medicinal product or a plant protection product, and a corresponding marketing authorisation in the EU. Applicants will be able to file a ‘combined application’ with a view to the grant of both a unitary SPC and national SPC for additional Member States not covered by the unitary patent.

Today, to obtain SPC protection in more than one Member States for a given product, it is necessary to file separate national applications, in the national languages of the respective Member States, with the risk of SPCs being granted in some Member States and denied in others. Once the proposed SPC reform will be adopted, it will be possible to file a single, combined, application. This application will be subject to a single examination which, if positive, will result in the grant of a unitary SPC (for those 17 Member States participating in the unitary patent system at the moment) and of national SPCs in further Member States. The cost of seeking additional protection will be greatly reduced: estimated savings of €137 000 per applicant for receiving EU27 wide, five-year-long SPC protection, bringing the EU closer to its main trading partners. The increased transparency resulting from this centralised procedure will also make it easier for generics manufacturers to be informed of the protection status of a given product across the EU, and to make business plans accordingly.

What’s the benefit of the proposal for SMEs?

SMEs are a motor of innovation in the pharmaceutical sector, playing a major role in the development of new medicines for patients. The new proposal will significantly decrease the cost and burden of SPC protection in the EU, and increase transparency and legal certainty. Therefore, it will
also bring significant benefits for both, innovative SMEs and for SMEs that manufacture generics. By simplifying the SPC procedure, the reform reduces the current cost of application and renewal fees. For instance, a five-year long, EU-wide SPC would cost 55% less than the baseline, producing savings of around €137 000 per applicant. The bulk of savings would result from the unitary SPC, as the SMEs would avoid paying high renewal fees annually in each of the 17 Member States of the unitary patent protection).

In addition, for SMEs engaged in manufacturing activities related to generics, the SPC reform will also be beneficial since the new centralised procedure will intrinsically result in more legal certainty and transparency, allowing SMEs to have a better picture of the protection status of a certain product across the EU and make adequate business plans. This will potentially speed up the availability of generic medicines. In addition, under the new procedure, SMEs manufacturing generics will be able (1) to submit observations during the examination of a centralised SPC application, and (2) to file an opposition in order to challenge in a central manner the validity of SPC protection for a given product, where this appears to be justified.

How will the new regime be implemented?

Currently, the EU regime for national SPCs is covered by two different EU Regulations, one related to pharmaceutical products (for human and veterinary use – cf. Regulation (EC) No 469/2009) and another one related to plant protection products (Regulation (EC) No 1610/96), as those products are subject to different EU marketing authorisation rules. In addition, so far there is no EU legislation providing for a unitary SPC complementing the unitary patent. Hence, the new SPC rules proposed today are laid out in four proposals for a Regulation:

- Two Regulations that introduce a centralised procedure for the grant of national SPCs, by recasting and repealing the existing EU regulations (one for medicinal products and the other for plant protection products), and
- Two completely new Regulations creating a new unitary SPC (with the same centralised examination procedure), one for medicinal products and one for plant protection products.

This makes a total of four regulations which rely on the same principles (in particular the same SPC eligibility criteria) and on the same centralised examination procedure. Applicants will also be able to file a 'combined application' with a view to the grant of both a unitary SPC and national SPC for additional Member States not covered by the unitary patent.

What is the relation between the revision of the pharmaceutical legislation and the new rules for Supplementary Protection Certificates?

Intellectual property rights, in particular patents and SPCs, protect innovative medicinal products and, together with the regulatory pharmaceutical protections (such as data protection), influence the moment when competing products (generics) can come on the market. Incentivising innovation while ensuring access, availability and affordability of medicines are key considerations of both EU rules for pharmaceutical products and intellectual property. The EU's intellectual property system works in tandem with the EU system of regulatory pharmaceutical incentives (e.g. market protection, data protection), both contributing to the same objectives. The parallel proposals on the pharmaceutical legislation include enhanced provisions on the Bolar exception (allowing generics to perform research and tests for preparing regulatory approval despite a patent/SPC being in force) to IP rights, that will facilitate the authorisation of generic medicines and thus speed up their availability.

Can a product be covered by both a national and a unitary SPC?

Yes, any product that is covered by a patent and that is a (human or veterinary) medicinal product, or a plant protection product, and thus falls under the scope of the SPC regulations, can benefit from the new centralised procedure that will be implemented by the EUIPO.

The new SPC regulations foresee the possibility to apply for a “combined application” for the same product to obtain a unitary and national SPCs, for those cases where the product is protected by a European patent having unitary effect. Since a unitary SPC can only cover those (initially 17) Member States where the basic patent has unitary effect, national SPCs would be needed to ensure protection in additional Member States. That said, a given product cannot be protected by both a national SPC and a unitary SPC in the same Member State.

Does the new SPC regime replace the existing national SPC schemes?

No, the proposed SPC rules will not replace the existing national SPC scheme for human and veterinary pharmaceutical products, nor for plant protection products. That said, a centralised SPC application will need to be filed in respect of a medicinal product protected by a European patent
(including a unitary patent) and centrally authorised; the national route would be closed in such a case. The reform aims at simplifying the EU’s SPC system as regards both the application for and the examination of national SPCs, by introducing an EU centralised examination procedure, reducing divergences and improving transparency and efficiency. The new rules, however, do not alter the competence of national IP Offices in granting national SPCs, following the binding opinion issued by the examination authority, run by the EUIPO. The reform of the national SPC regime does also not alter the eligibility criteria to obtain an SPC, which remain the ones currently foreseen in Article 3 in the existing legislation for both pharmaceutical products and plant protection products.

**For More Information**

[Proposals](#) for a Regulation on Supplementary Protection Certificates  
[Press Release](#)  
[Factsheet on Supplementary Protection Certificates](#)

Press contacts:

Sonya GOSPODINOVA (+32 2 296 69 53)  
Federica MICCOLI (+32 2 295 83 00)

General public inquiries: [Europe Direct](#) by phone 00 800 67 89 10 11 or by email