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BREAKING NEWS: Draft EU legislation on unitary SPCs and new centralized SPC examination procedure unveiled

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After years of preparation, the European Union's draft legislation for a sweeping reform of the existing legal regime on supplementary protection certificates (SPCs), which includes the establishment of a centralized SPC filing and examination procedure as well as the introduction of a unitary SPC, has finally been published today on April 27, 2023.

This draft legislation is composed of the following four new Regulations proposed by the European Commission:

- Proposal for a Regulation on the SPC for medicinal products (recast)
- Proposal for a Regulation on the unitary SPC for medicinal products
- Proposal for a Regulation on the SPC for plant protection products (recast)
- Proposal for a Regulation on the unitary SPC for plant protection products

Under the new regime set out in these draft Regulations, unitary SPCs will become available – both for medicinal products and for plant protection products – on the basis of unitary patents. In the case of medicinal products, unitary SPCs will only be allowed on the basis of centralized marketing authorizations issued by the European Medicines Agency (EMA).

In addition, applicants will be able to file a single "centralized SPC application" that will give rise to a bundle of national SPCs in the designated EU member states.

It will also be possible to file a single "combined" application, consisting of a unitary SPC application and a centralized SPC application, which would result in a unitary SPC (covering all states in which the underlying unitary patent has effect) and a smaller bundle of national SPCs (in the other designated EU member states not covered by the unitary patent).

The proprietor of a unitary patent will be free to either file a unitary SPC application or a centralized SPC application (for a bundle of national SPCs) at their own choice. This means that unitary patents do not restrict their proprietors to resort to the filing of unitary SPCs.

In the case of medicinal products, the use of the new centralized SPC application procedure will be possible, and indeed mandatory, if the basic patent is a European patent (either a conventional European bundle patent or a unitary patent) and if there is a centralized marketing authorization issued by the EMA. Conversely, the filing of a national SPC directly at a national patent office will remain possible only if a national patent is used as the basic patent (which, nowadays, rarely ever

occurs in practice) or if the marketing authorization relied upon is a national MA for a medicinal product.

For plant protection products, the filing of centralized SPC applications will be possible on the basis of a European patent (with or without unitary effect) and at least one granted national marketing authorization (as well as pending MA applications in the other designated EU member states). Moreover, it will remain possible to file national SPCs for plant protection products at the national patent offices.

The agency to be entrusted with the examination of both unitary SPC applications as well as centralized SPC applications (for bundles of national SPCs) will be the European Union Intellectual Property Office (EUIPO) based in Alicante, Spain, which will establish a new SPC Division and will partially rely on SPC examiners from the national patent offices.

Unitary SPCs will be granted by the EUIPO after the issuance of a positive examination opinion.

In the case of centralized SPC applications, the EUIPO will issue a binding opinion at the end of the examination procedure. The actual grant of the corresponding national SPCs will then be effected by the national patent offices, based on a positive examination opinion from the EUIPO. In this regard, the national patent offices will be obliged to follow the opinion from the EUIPO, unless certain exceptional circumstances apply (e.g., if the basic patent has meanwhile been revoked or allowed to lapse before the end of its maximum 20-year term).

The substantive examination of unitary SPC applications as well as centralized SPC applications will be conducted under the responsibility of the new SPC Division of the EUIPO and will be entrusted to a panel of three examiners, only one of whom will actually be a member of the EUIPO. The other two examiners will be experienced SPC examiners from two different national patent offices. Such an involvement of national SPC examiners requires the conclusion of separate agreements, which implies that not all national patent offices will necessarily participate.

After the conclusion of the SPC examination procedure, the three-member panel issues an examination opinion indicating, for each of the designated EU member states, whether a national SPC should be granted or refused (or, as the case may be, whether a unitary SPC should be granted or refused). SPC applicants will be able to challenge a negative (or partially negative) opinion by filing an appeal to the Boards of Appeal of the EUIPO, and subsequently to the General Court of the EU, and ultimately, where admissible, to the Court of Justice (CJEU).

Third parties wishing to challenge a positive (or partly positive) opinion from the EUIPO can file an opposition within two months from the publication of the examination opinion. In addition, granted unitary SPCs can be challenged via an application for a declaration of invalidity at the EUIPO, and granted national SPCs can be attacked via invalidity actions to be filed at the respective national court or the Unified Patent Court (in the same manner as under the currently existing legal regime).

It is furthermore foreseen that the new centralized procedure via the EUIPO will also be applicable to the filing of paediatric extensions.

While the European Commission expressly stated that the intended draft legislation would not change the substantive features of the existing SPC regime, the current proposals do, in fact, include a few remarkable deviations from the substantive provisions of the existing SPC

Regulations.

For example, the grant of more than one SPC for the same product will be allowed if the respective SPCs are filed by different patent holders (based on their respective different patents) – but only if such patent holders are "*not economically linked*" (see Article 3, paragraph 2 or 3). Moreover, if the marketing authorization relied upon for an SPC application is held by an entity different from the patent proprietor (and thus the SPC applicant), an SPC shall only be granted *with the consent of the marketing authorization holder* (see Article 6, paragraph 2). In addition, the recitals forming the preamble of each new SPC Regulation are intended to be enriched by selected findings from existing CJEU case law.

Altogether, the currently envisaged draft legislation, if adopted, would significantly simplify and improve the existing SPC regime in the European Union. At the same time, certain aspects of this draft legislation raise concerns that merit further scrutiny and in-depth discussion, which will be the subject of future posts on this blog.

Oswin Ridderbusch *and* ***Alexa von Uexküll*** *are the editors of the handbook* ***European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe (Second Edition)****, which was published by Wolters Kluwer in 2021.*

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