Supplementary protection certificate for medicinal products. Recast

2023/0130(COD) - 27/04/2023 - Legislative proposal

PURPOSE: to simplify the EU's supplementary protection certificates (SPC) system as regards national SPCs for medicinal products and improve its transparency and efficiency.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: a **supplementary protection certificate** (SPC) is an intellectual property right that extends the term of a patent (up to five years) for a human or veterinary pharmaceutical or plant protection product that has been authorised by regulatory authorities, thereby encouraging innovation and promoting growth and employment in these sectors.

However, SPC protection is only available at national level. As a result, the current system suffers from fragmentation, leading to complex and costly procedures and legal uncertainty.

The unitary patent will enter into force on 1 June 2023, allowing for a single patent that covers all participating Member States in a unitary manner.

The Commission's intellectual property action plan of November 2020, which builds on the SPC evaluation, highlighted the need to tackle the remaining fragmentation of the EU's intellectual property system.

Pharmaceutical research plays a decisive role in the continuing improvement in public health. Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

This proposal is part of the 'EU patent package' announced in 2023 which, besides the **revision, modernisation and introduction of a system for unitary SPCs**, includes a new initiative on compulsory licensing and legislation on standard-essential patents. The proposal also complements the unitary patent system, which is a major step towards the completion of the single market for patents.

In addition to this proposal, parallel proposals are being made to create a centralised procedure for the grant of national certificates for medicinal products, a unitary certificate for plant protection products and a unitary certificate for medicinal products.

CONTENT: this **proposal for a recast of Regulation (EC) No 1610/96** lays down the rules on the supplementary protection certificate for medicinal products protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure.

The SPC reform introduces a **centralised examination procedure**, implemented by the EU Intellectual Property Office (EUIPO), in close cooperation with the EU's national intellectual property (IP) offices. Under this scheme, a single application will be subject to a **single examination** process which, if positive, will result in the **grant of a unitary SPC and of national SPCs** in further Member States.

While that examination would be conducted by a centralised authority, the actual granting of SPCs would be done by the respective national offices of the designated Member States, based on a positive opinion from the central examination authority. The opinion of the central examination authority would be binding upon the national offices of the designated Member States.

The core substantive features of the proposed centralised procedure – i.e. the conditions for obtaining certificates, as well as their legal effect – are the same as those of the existing SPC regime. This proposal introduces new procedural provisions as regards the centralised examination and is not intended to modify the scope nor the effect of the rights conferred by national SPCs currently granted according to Regulation (EC) No 469/2009.

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.