Unitary supplementary certificate for medicinal products

2023/0127(COD) - 27/04/2023 - Legislative proposal

PURPOSE: to simplify the EU Supplementary Protection Certificate (SPC) system and improve its transparency and efficiency, by creating a unitary certificate for medicinal products.

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 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.

There is a clear need to **complement the unitary patent ('European patent with unitary effect') with a unitary SPC**. The proposed creation of a unitary SPC will be fully compatible with the unitary patent system provided for in Regulation (EU) No 1257/2012 and the Unified Patent Court Agreement (UPCA). The unitary patent will enter into force on 1 June 2023, allowing a single patent covering all participating Member States in a unitary manner.

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 centralised procedure for the grant of national certificates for plant protection products, and a unitary certificate for plant products.

CONTENT: this proposal lays down rules on the **unitary supplementary protection certificate for medicinal products** protected by a European patent with unitary effect and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure.

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.

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.

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.** 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 currently participating in the unitary patent system) and of national SPCs in further Member States.