



European
Commission

A Single Market for Patents: new EU rules on Supplementary Protection Certificates

April 2023

The new EU patent rules will help companies, especially small and medium-sized companies (SMEs), make the most of their inventions, leverage the latest technologies and contribute to the EU's sustainable competitiveness and technological sovereignty by creating a more predictable, futureproof and crisis-ready intellectual property rights framework. They will complement the Unitary Patent (UP) system entering into force on 1 June 2023.

Optimising the Supplementary Protection Certificate (SPC) system

An SPC **extends the term of a patent** by up to 5 years for a human or veterinary pharmaceutical product, or a plant protection product. Medicinal and plant protection products are often the result of long, costly research. SPCs aim to offset the loss of effective patent protection due to the compulsory and lengthy testing required in the EU for the regulatory marketing authorisation of these products and to encourage research into these products. SPC protection is currently only available at national level and **fragmented, which is burdensome, costly and difficult** to monitor. Up to 81 SPC applications are filed annually per Member State. An SPC lasting 5 years **costs € 192 000 in the EU**, compared to roughly € 3 000 in the US and € 4 200 in Japan. Nearly 1/4 of current SPC procedures have contradictory outcomes.

The new rules introduce:

- ▶ a unitary SPC to complement the unitary patent
- ▶ a centralised procedure for the grant of national SPCs





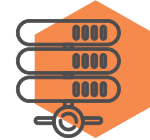
Cost savings

- ▶ Estimated savings of **€ 137 000** per applicant for receiving EU27 wide, five year long SPC protection.



Less fragmentation and more legal certainty

- ▶ Unitary SPCs to complement upcoming Unitary Patents
- ▶ Single EU-level procedure for unitary SPC and centralised procedure for national SPCs



Increased transparency

- ▶ Easier monitoring to facilitate generic entry due to a **single SPC database**



How would the new SPC procedure work in practice?

After the SPC reform, an innovative SME that carried out lengthy clinical trials for a new medicine and has the right to be compensated with a patent extension, will file just one application in a dedicated EU office, indicating all Member States for which it seeks an SPC. Through the new procedure, it will also be able to file for a unitary SPC to complement its unitary patent. Thus, instead of following up to 27 administrative procedures that were costly and sometimes resulted in uncertain or contradictory outcomes, innovative companies will be offered one transparent and more predictable process to reward them for their R&D efforts.



© European Union, 2023

Luxembourg: Publications Office of the European Union, 2023

The reuse policy of European Commission documents is implemented by Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents (OJ L 330, 14.12.2011, p. 39). Unless otherwise noted, the reuse of this document is authorised under a Creative Commons Attribution 4.0 International (CC-BY 4.0) licence (<https://creativecommons.org/licenses/by/4.0/>). This means that reuse is allowed provided appropriate credit is given and any changes are indicated.

Photos and Icons: Adobe Stock