Spotlight on: Supplementary Protection Certificates (SPCs) in Europe

Background on SPCs and the relevant legal regime

Supplementary protection certificates for pharmaceutical and plant protection products

Supplementary protection certificates (SPCs) are an intellectual property right that provide an extension to a patent right. They apply to the patents that read on specific pharmaceutical and plant protection products that have been authorized by regulatory authorities. Supplementary protection certificates aim to offset part of the loss of the twenty years of patent protection for pharmaceutical and plant protection products due to the time it takes to secure regulatory marketing approval.

Single procedure for granting SPCs

National IP offices in EU Member States grant SPCs for specific medicinal and plant protection products. While this regime is generally considered fit for purpose, some argue that differences among EU Member States in the administration and enforcement of SPCs can create inefficiencies. The proposal for a single European procedure for the granting of SPCs would create a unitary SPC and/or a single ('unified') procedure for granting national SPCs. The rationale is that this system would make SPCs more accessible and efficient, to the benefit of innovation in the health sector.

European SPCs for medicines and phytopharmaceutical products

This additional protection applies only to **medicinal products** and **plant protection products** for which marketing authorisation must be obtained. If the chemical molecule protected by the patent has an application other than pharmaceutical or plant protection related, this application may not benefit from the extended term of protection granted by the certificate.

End of transitional period for the SPC manufacturing waiver

The transitional period for the application of the SPC manufacturing waiver has now ended. The manufacturing waiver is now operational which means that generic and biosimilar medicines companies can start manufacturing in Europe before SPC expiry for export, stockpiling, and so-called day 1 launch in Europe. The SPC manufacturing waiver was adopted to remove a perceived competitive disadvantage of EU-based generic and biosimilar medicines manufacturers compared to foreign countries, with the goal of providing better and faster patient access in Europe and abroad.

By way of background, the EU introduced the SPC manufacturing waiver back in July 2019. The waiver allows for the manufacture of medicines protected by SPCs for the exclusive purpose of export to markets outside the EEA. Stockpiling for post-expiry use in the EU/EEA is also permitted within the final 6 months of the SPC term.

The waiver does not apply to SPCs already in force on 1 July 2019. For SPCs that were applied for prior to 1 July 2019 and that came into force only after that date, the waiver will be applicable starting only from 2 July 2022. The waiver will automatically apply to all SPCs that are applied for after 1 July 2019.

Further reading: Publications about SPCs and their impact

Study on the economic impact of supplementary protection certificates, pharmaceutical incentives, and rewards in Europe

"We find that 45 per cent of the medicinal products in our dataset have obtained an SPC in at least one of the European countries. We find that the SPC has added years to the effective protection period for those innovator products where the SPC is the last measure of protection to expire. While the protection for medicinal products in the EU is amongst the strongest in the world, we find that for the medicinal products in our dataset the average effective protection period has decreased by approximately two years from 15 to 13 years since 1996 (with variations in individual cases). We find that a longer effective protection period stimulates research and development into new medicinal products."

Study on SPCs and their impact on access to medicines in Europe (case studies)

"Based on this research as to the sales revenue of and R&D investments in a limited number of medicines (sofosbuvir, trastuzumab, and imatinib), it appears that the EU SPC regime may be based on a false premise that companies need longer exclusivity periods to compensate for the 'loss' of a period of effective protection during the market approval process, to enable them to recover R&D investments.

The higher medicines prices associated with the generic competition delays caused by SPCs in relation to the three medicines analysed appears to be an unnecessary cost for society; this cost can be expressed in financial, but also 'social' terms. The SPC system can ultimately cause unnecessary suffering and/or death, as healthcare systems or patients are unable to afford essential medicines for patients."

Study arguing there are only limited benefits to European generic manufacturers of an SPC manufacturing exemption

"An argument has been made that if the European based generic industry was able to begin manufacturing (not selling) products in European countries where SPC's are still in place, these products could be exported to markets outside Europe where IP protection has expired or has never existed, bringing an economic benefit to Europe.

The timing of SPC expiry dates in Europe is not always significantly later than in the target markets – and, in several cases, is actually earlier than in non-European markets. Since European SPC / patent expiry dates are often before target export markets, this leaves limited additional opportunity or benefit from an SPC Manufacturing Exemption, as it would not be possible to sell generic products in the target export markets. In cases where the first European SPC expiry date

is later than first non-European SPC expiry date, there could be some export opportunity should an SPC Manufacturing Exemption be implemented, however, the window of opportunity is limited."

Study about the potentially "grey area" legal regime for SPCs

"Over the past five years, numerous Court of Justice of the European Union (CJEU) rulings have attempted to interpret the provisions of EU Regulation 1901/2009 and provide clarity to patent holders as well as generics manufacturers as to the protection requirements and the scope of protection awarded. This article analyses the implication of major CJEU cases concerning the interpretation of Articles 3(a), 3(d) and 1(b) of the Regulation.

The article also discusses the interrelation between the EU SPC Regulation, on the one hand, and the Market Authorization Regulation and the Market Authorization Directive, on the other, and compares the EU system with that provided by the USA. An analysis of recent case law reveals that now, some 25 years after the entry into force of the Regulation, the system is still obscure. A serious concern also arises as to whether the system as it stands today is simply inappropriate to the protection of modern pharmaceuticals and whether this is also one of the reasons for the growing volume of case law in the field."

Study about the rules re: SPCs in Europe constituting a "transitional regime"

"This article is an overview of the transitional provisions of Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (now Regulation (EC) No. 469/2009). It discusses the rationale and structure of the provisions concerning the initial entry into force of the Regulation, the subsequent enlargement of the EU and the conflict with existing national regimes for extended patent protection. An analysis of the Community legislation is carried out in the light of the national law of the Member States and the case-law of the ECJ."

Study about the consequences of Brexit for pharmaceutical patents and SPCs

"Now that the UK has left the EU, and the transition period following this departure is over, we have a clearer view on the implications of Brexit on intellectual property rights and the consequences for UK based pharmaceutical companies. Although little has changed for UK applicants wishing to obtain a European patent via the European Patent Office, the UK's withdrawal from the Unified Patent Court and Unitary Patent is a huge blow to the realisation of the long-awaited Unitary Patent system. Meanwhile, breaking away from the EU has also had effects on how UK pharmaceutical companies can apply for supplementary protection certificates (SPCs), with further intricacies due to the Northern Ireland Protocol."