

The SPC Manufacturing and Stockpiling Waiver

In the EU, Supplementary Protection Certificates (SPCs) extend the 20-year patent protection period for medicines by adding up to five additional years of protection to approved drugs and biologics. The additional exclusivity period of protection is meant to compensate for the lapse between when the patent application is filed and when marketing authorization is granted.

Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 introduces an exception to the protection conferred by an SPC for products, or medicinal products containing those products, manufactured for export purposes and/or stockpiling purposes. Under the Regulation, generic and biosimilar makers will be able to obtain a waiver to manufacture SPC-protected products for export to non-EU countries where intellectual property protections for those products have expired or never existed. The proposal will also allow for the stockpiling of generic and biosimilars during the final six months of SPC protection to enable day-one market entry for those products. The Regulation will enter into force across all Member States on 01 July 2019.

Main Provisions

The main provisions of the SPC manufacturing waiver regulation can be summarized as follows:

- The waiver will have the effect of creating an exception to the protection conferred by an SPC so as to allow the making of a product, or a medicinal product containing that product, for the purpose of export to third countries outside the EU as well as permitting stockpiling for day-1 entry to the EU market immediately after SPC expiry.
- The waiver will allow the manufacture for export of generics and biosimilars throughout the entire SPC lifetime whereas the manufacturing and stockpiling for day-1 marketing in the EU will be permitted only during the last six months before SPC expiry.
- The Regulation requires a generics or biosimilar producer intending to benefit from the manufacturing waiver to notify not only the national patent office that granted the SPC in question, using a standardized form, but must also directly inform the SPC holder and all those involved in the commercialisation of the product, no later than three months before the intended start of manufacture (or the first related act). The competent national patent office will be required to publish the notified information together with the date of notification as soon as possible.
- The information to be notified to the competent national patent office includes the name and address of the manufacturer; an indication whether the intended manufacture is for the purpose of export, storing, or both export and storing; the EU member state where

the manufacture is to take place (and, if applicable, the member state where the first related act prior to manufacture is to take place); the number of the SPC in question; and, in the case of export to third countries, the reference number of the marketing authorization in each third country of export. Any subsequent changes to this information must also be notified. The standard form provided for notifications is available [here](#).

Submission of Notifications

Notifications may be sent to the Patents Office which is the competent authority for Ireland, by email to: regadmin@patentsoffice.ie

or alternatively by post to:

Patents Office

Government Buildings

Hebron Road

Kilkenny

R95 H4XC

- The Regulation requires that the new “EU export” logo (shown below) must be affixed by the maker to the outer packaging and, where feasible, the immediate packaging of products made for the purpose of export to third countries outside the EU.

This logo shall appear in black and in such a size as to be sufficiently visible.



- Under the agreed transitional regime, the applicability of the manufacturing waiver will depend on the filing date of an SPC and the date when the SPC takes effect:
 - The SPC manufacturing waiver will apply to all new SPCs filed on or after the day of entry into force of the Regulation (i.e. 1 July 2019).
 - Conversely, the manufacturing waiver will not affect any SPCs that are already in effect on 1 July 2019.
 - For all other SPCs – i.e. SPCs that are filed before, but take effect only after, 1 July 2019 – the manufacturing waiver will initially not apply, but will become applicable after three years from the entry into force of the Regulation i.e. July 2022.