ARTICLE

The SPC manufacturing waiver

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On 1 July 2019 Regulation (EU) 2019/933 ('the Regulation'), introducing the so-called SPC manufacturing waiver, entered into force across the European Union. The SPC manufacturing waiver is an amendment to existing legislation concerning supplementary protection certificates (SPCs) with the primary objective of facilitating the generic industry (within the EU) by allowing them to manufacture SPC protected medicinal products for the purposes of (i) export and/or (ii) preparing for European 'day-one launch', from 6 months before expiry of the SPC.

In this article we take a brief look at the purpose and history of the Regulation, followed by a summary of the exempted acts and the scope of the Regulation, finally concluding with some practical considerations.

Purpose and history

The considerations included in the Regulation shed some light on the underlying purpose and history of the Regulation and the amendments it introduces into the existing SPC system.

Since the inception of the SPC regime in 1992, markets have evolved significantly and there has been huge growth in the manufacture of generics and especially of biosimilars, and in the manufacture of their active ingredients, in particular in countries outside the EU in which SPC protection does not exist or has expired.

According to the legislator, those circumstances put makers of generics and biosimilars established in the EU at a significant competitive disadvantage in comparison with makers based in other countries that offer less or no protection. Diminishing generic investments, hampering job creation, reduced competition, increased prices and reduced access to affordable medicines are further mentioned as risks in the scenario that the SPC regime were not to be amended.

What is an SPC?

The Supplementary Protection Certificate (SPC) is an intellectual property right applicable to pharmaceutical and plant protection products in the EU. SPCs are granted nationally by the Intellectual Property Office in each member state. An SPC is always linked to a patent and a product which obtained a marketing authorization. An SPC confers the same protection as the patent on which it is based, but extends this only to the authorized product (and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate).

An SPC enters into force on expiry of the patent and has a duration of up to 5 years.

Although it has been established that SPCs are not available where the basic patent is a new formulation of a known active pharmaceutical ingredient, the exact scope of the SPC regulation is not established and several cases are currently pending at the Court of Justice of the European Union.

With this Regulation, the EU attempts to strike a balance between restoring a level playing field for generic drug makers and ensuring that the essence of the exclusive rights of SPC holders is guaranteed in relation to the EU market.

The fundamental aim of this Regulation is to promote the competitiveness of the EU, by allowing makers of generics and biosimilars established in the EU to make in the EU products (active pharmaceutical ingredients), or medicinal products containing those products, for the purpose of export to third-country markets in which protection does not exist or has expired, thereby also helping those makers to compete effectively in those third- country markets. The EU exemption of day-one launch stockpiling was heavily debated and was only introduced at a late stage of the legislative process.

Exempted acts

The Regulation stipulates that the SPCs within scope of the manufacturing waiver shall not confer protection for the following acts:

(Export)

(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or

(ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export; or

(EU day-one launch stockpiling)

(iii) the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or

(iv) any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than six months before the expiry of the certificate.

The Regulation defines the maker as the person established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export or storing, is carried out.

From the wording of the Regulation it follows that related acts which are strictly necessary for export or EU day-one launch are also exempted. According to the considerations of the Regulation such related acts could include: possessing; offering to supply; supplying; importing; using or synthesizing an active ingredient for the purpose of making a medicinal product; or temporary storing or advertising for the exclusive purpose of export to third-country destinations. It is further explicitly stated that the exception should also apply to related acts performed by third parties who are in a contractual relationship with the maker. It is not unlikely that the next years will see case law developed to identify which acts are classified as strictly necessary for the making.

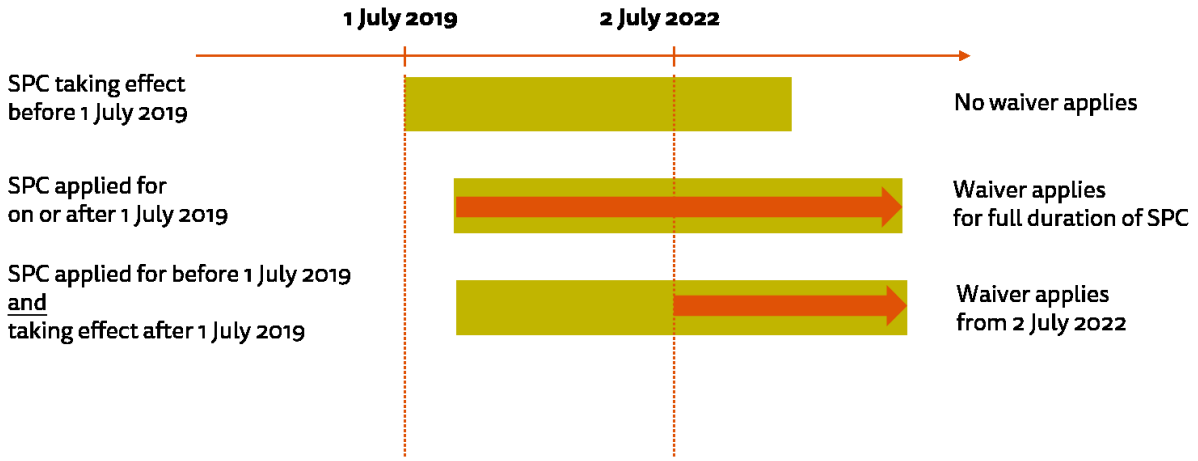
Importantly, the Regulation explicitly states that the manufacturing waiver shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the Union merely for the purpose of repackaging, re-exporting or storing.

Finally, it is noted that storing for EU day-one launch stockpiling needs to happen in the member state of making.

Scope

The SPC manufacturing waiver shall apply to:

- SPCs that are applied for on or after 1 July 2019; and
- SPCs that have been applied for before 1 July 2019 and that take effect on or after that date, but only from 2 July 2022.



Practical considerations

Notification: The Regulation imposes on the maker an information obligation requiring the maker to provide certain information to the authority who granted the SPC in the EU member state where the making is to take place, as well as to inform the SPC holder of this information. This notification needs to take place no later than three months before the start date of the making in that Member State, or no later than three months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier. The authority has to publish this information as soon as possible, together with the date of notification.

The Regulation includes a list of items to be included in the notification and, in the Annex, a standardized form for supplying the required information. It is currently not clear which authorities will charge a fee for processing the notification, but the fee may in any case not exceed the actual costs incurred by the authority for the administrative procedure. The Regulation does not provide for the authority to undertake any form or formal or substantive examination of the information provided in the notification.

As mentioned earlier, the Regulation defines the maker. However, the Regulation does not define which act(s) constitute the *making* of a product or medicinal products. In case different steps in the manufacturing process of a product of medicinal product take place in different EU member states, it thus does not appear unambiguously clear which steps constitute the *making* of the product or medicinal products and thus which authority needs to be notified.

Updating the notification: The Regulation requires the notification to be updated if any of the information listed in the notification changes. It is currently assumed that an update of a notification does not trigger a new 3-month waiting period.

For medicinal products to be exported to outside the EU, the Regulation further requires the notification to include (or be updated with), the reference number of the marketing authorization, or the

equivalent of such authorization, in each country of export, as soon as it is publicly available. Failure to comply with this requirement for a specific country will cause (only) the export to that country to no longer be exempted. It is currently assumed that as long as no marketing authorization number is publicly available (yet), the making for export to that country is exempted.

Due diligence: The Regulation also requires the maker to inform (and appropriately document) any person in a contractual relationship with the maker who performs exempted acts that those acts are performed under the manufacturing waiver and that the market, import or re-import of the product, or the medicinal product could infringe the SPC where, and for as long as the SPC applies.

Presentation: The Regulation requires the products or medicinal products produced under the manufacturing waiver for export purposes to carry the following logo on its outer packaging and, where feasible, on its immediate packaging. These products are also not allowed to carry a so-called active unique identifier.

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