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Manufacturing and stockpiling waiver set to limit rights of holders of SPCs for medicinal products

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Europe is on the verge of introducing an important legislative limitation to the rights of Supplementary Protection Certificate ("SPC") holders.

On 17th April 2019, a large majority of the Members of European Parliament approved a proposed Regulation that would exempt from infringement inter alia the export-bound manufacturing or end-of-term storage of SPC protected (medicinal) products. This controversial proposal, which met with strong resistance from different sides of the pharmaceutical and biotech industry sector, is now due to be endorsed by the Council in the coming weeks, after which it will come into force

Background

SPCs are *sui generis* intellectual property rights that award (patent-like) exclusivity for a given medicinal product for a maximum of up to five (5) years after expiry of the basic patent.¹ This prolonged exclusivity is aimed at compensating right-holders for the loss of effective patent protection before completion of the lengthy EU marketing authorisation procedure and actual commercialisation of the patented medicinal product. This piece of legislation seeks to promote the research and innovation that is necessary to develop medicinal products, and to prevent the relocation of pharmaceutical research to countries outside the EU which offer greater protection.

Over time, it was felt that the SPC regime provoked unwanted side-effects, in particular for EU-based manufacturers of so-called generic and biosimilar medicines. Firstly, the fact that the protection conferred by an SPC prevents EU-based medicine manufacturers from making them in EU, even for the purpose of exports to third countries. Secondly, the fact that it prevents them from starting to build up production capacity for market entry after the SPC would have expired. As it appeared in practice, this effectively delayed EU-based manufacturers' market entry until some time after expiry of the legal term of the SPC. In other words, protection conferred by an SPC in practice lasted longer than the legal term and it had a broader geographical effect than just the EU, placing local manufacturers in a competitive disadvantage (manufacturers based in third countries face no such constraints). The European Commission was concerned that this situation would encourage manufacturers of generic and biosimilar medicines (in particular) to relocate their activities outside of the EU.

As part of its Single Market Strategy, the Commission has announced several initiatives to boost the competitiveness of the generic and biosimilar industry sector.² The latest on the European legislator's

¹ Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, COM/2018/317.

² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Upgrading the Single Market: more opportunities for people and business, COM/2015/550

drawing board is an amendment of the SPC Regulation, introducing a waiver that - by way of derogation - would exempt certain acts from a finding of SPC infringement (hereinafter: the "Waiver Regulation").³

Scope of the waiver goes beyond mere manufacturing

Under the terms of the Waiver Regulation, right holders of valid and enforceable SPCs will no longer be able to block third parties from manufacturing products (or pharmaceutical products containing that product) for the purpose of export to third countries. Although the example usually given relates to generic or biosimilar companies, this exemption should also cover originator companies that would otherwise fall within the scope of the SPC right.

The Waiver Regulation not only exempts the manufacturers, but it also covers third parties that are involved, either on their own account or on behalf of the pharmaceutical company, in the production (e.g. a contract manufacturer of the active ingredient) or the exporting of the product at issue (so-called "Related Acts"). The possession, supply, offering to supply, import, using or synthesis of an active ingredient for the purpose of making a medicinal product containing that product, or temporary storage of the product or advertising for the exclusive purpose of export to third country destinations are cited as Related Acts in Recital 8 of the Waiver Regulation.

The manufacturing exemption applies for the purpose of export to third countries. The provisions of the Waiver Regulation do not appear to require that the import of the product in those countries is lawful. Indeed, while mention is often made (also in the Recitals) of export to countries "where there is no or no more exclusivity", this may in fact be a practical consideration rather than an actual legal requirement to apply the waiver in a given EU Member State. Notably, the waiver only applies to exports directed outside the EU; not to those directed to other EU Member States, even if there is no SPC in force and, as such, no means of legally preventing imports in such Member State.

Compared to the Commission's initial proposal, the Waiver Regulation introduces a significant further exemption. The holder of the SPC would also be obliged to tolerate the manufacture and storage of SPC protected products in the Member State of making, as well as all Related Acts necessary for such manufacture and storage, in the last six (6) months before expiry of the SPC. This so-called stockpiling exemption - contrary to the manufacturing waiver *supra* - covers products destined for commercialisation in the EU, once the SPC expires (so-called day-1 entry).

These waivers represent a considerable limitation to the rights of holders of SPCs for medicinal (not plant protection) products. Moreover, there was a concern that the purpose of the Waiver Regulation would be frustrated by creating the risk that products manufactured under the waiver would be placed or re-imported on the EU market during the term of SPC protection.

Anti-diversion measures to mitigate concerns

A series of additional measures are proposed for a successful appeal to the manufacturing and stockpiling waiver. These serve to limit the concern that the waiver would be used for unauthorised commercialisation of SPC protected products within the EU.

Dual notification

Makers can only benefit from the waiver if, prior to initiating any manufacturing in a given Member State, they have notified not only the national authority responsible for granting the SPC right in the Member State (or States) at issue, but also the SPC holder(s) directly. This will give SPC holders some comfort, not having to monitor the national registers. These notifications should occur at least three (3) months before any manufacturing or Related Act.

³ Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, COM/2018/317, the most recent version can be found [here](#).

Labelling

In the case of products manufactured for the purpose of export to third countries, the maker must ensure that a specific label is affixed to the outer or immediate packaging of the (medicinal) product.



packaging logo

Obligation to inform those involved

While the Waiver Regulation applies to makers as well as third parties contractually involved in Related Acts, there is a specific obligation on the makers to ensure, through appropriate and documented means, that all their related contract partners are fully informed and aware of the nature and limits of the waiver, notably of the fact that the products benefit from an exemption and can only be put on the market outside the EU.

Commentary

In general

The proposal to introduce the aforementioned waiver has been strongly criticised throughout the legislative process, by representatives of originator companies (e.g. European Federation of Pharmaceutical Industries and Associations) and also the generics industry (e.g. Medicines for Europe). Clearly, the stakes are high for all involved. Nevertheless, the European legislator appears well-determined to go ahead with its plan. Noteworthy in that regard is that the Waiver Regulation calls for a re-evaluation of the waivers after five years.

Is a three (3) month prior notification period sufficient?

As mentioned earlier, makers are required to notify the SPC holders and are required to do so at least three (3) months before the start of the manufacturing or, if earlier, before the first Related Act. Although previous drafts of the Waiver Regulation foresaw even shorter notification periods, there is a fear that three (3) months may still be insufficient to allow the SPC holders to effectively verify and react (possibly, through court proceedings) to non-compliance by the maker.

What in case of paediatric SPC extensions?

To recall, under the provisions of the Paediatric Regulation,⁴ the SPC term of protection can be prolonged with a six (6) month extension if the SPC holder's medicinal product has been part of a paediatric investigation plan. For makers wishing to rely on the stockpiling exemption, that may be a cause of concern. The availability of this exemption depends on the end date of the SPC protection, which may be in flux due to a paediatric extension request. While applications for such extension must be filed no later than two years before the expiry of the SPC, the actual grant may occur significantly later. Similarly, difficulties may arise in case of so-called "negative term" SPCs serving as a starting point for a short paediatric extension. Especially since makers wishing to rely on the SPC waiver are required to notify in advance.

Geographical reach?

It is not clear how the waiver will play out in some of the European Union's neighboring countries. Norway and Iceland are already, by virtue of their membership of the European Economic Area (EEA), subject to similar rules as EU Member States, *inter alia* in relation to exhaustion of IP rights. Yet they are not EU

⁴ Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

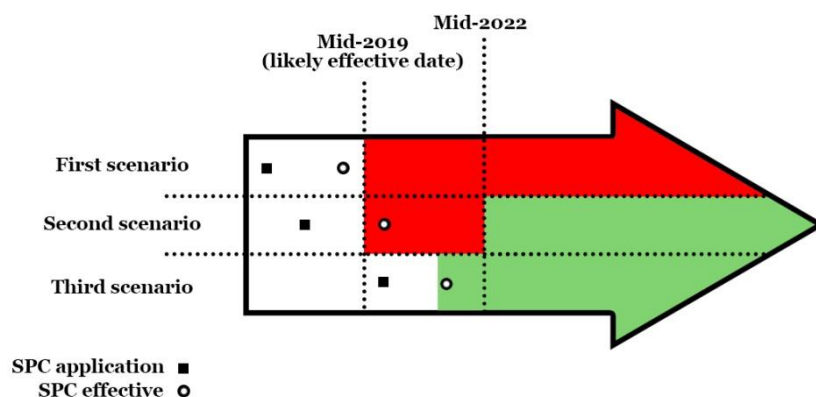
Member States. The Waiver Regulation does not automatically extend to EEA countries, and will at least be subject to further legislative initiatives.⁵ This process may take some time as well.



In our view, this will cast doubts on (i) whether and until when exporting EU products to those EEA countries will be exempted under the Waiver Regulation and (ii) whether and as of when manufacturing in those EEA countries will be exempted under the Waiver Regulation. There is also an open question about the impact of the waiver on Switzerland, which of course has a significant footprint in the pharmaceutical industry and is an important business partner of the EU. Finally, it is unclear at this stage whether the Waiver Regulation (or an equivalent thereof) will have an effect in the United Kingdom at all (after its departure from the EU)..

Next steps and application in time: which SPCs are affected?

The text of the Waiver Regulation will be close to the provisional trilogue agreement reached in February 2019. The European Parliament has approved the SPC Regulation at the first reading without substantial amendments. Now, the only outstanding act is a formal approval of the Council, before the Waiver Regulation will enter into force throughout the EU on the twentieth day following its publication in the Official Journal of the European Union. The likely effective date of the Waiver Regulation is mid-2019.



Whether the Waiver Regulation will apply to your SPC depends on two factors, namely the filing date and the effective date of the SPC in view of the effective date of the Waiver Regulation. The waiver will affect the SPCs that are applied for on/after the effective date of the Waiver Regulation, obviously. However, it will also affect SPCs that are already filed but not granted and effective before the effective date of the Waiver Regulation, be it only as of three (3) years thereafter. In those situations, the Waiver Regulation may have some retro-active effect on past SPC applications. For already granted, effective SPCs, the situation remains the same.

⁵ See <https://www.efta.int/eea-lex/319360>.

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