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The SPC 'manufacturing waiver' for export and stockpiling

The legislation enacting the SPC manufacturing waiver in the EU (Regulation (EU) 2019/933) has now been completed by the European Parliament and the Council of the European Union.

Background

The European Commission (EC) has previously published a proposed adjustment to intellectual property rules which would allow EU-based companies to manufacture generic or biosimilar versions of an SPC-protected medicine during the term of an SPC, if done exclusively for the purpose of exporting to a non-EU market where protection has expired or never existed.

Update – the published regulation

The legislative procedure enacting the SPC manufacturing waiver has now been completed. The new regulation (Regulation (EU) 2019/933)[1] will enter into force on 1 July 2019.

The new legislation provides that the availability of the manufacturing waiver depends on the filing date of an SPC application and the date on which the granted SPC takes effect, i.e. at the end of the lawful term of the basic patent. Specifically, the waiver will apply to:

(a) all SPCs applied for on or after the regulation comes into force; and also to

(b) all SPCs applied for before the regulation comes into force, but which take effect on or after that date.

There is a transitional period for SPCs under item **(b)** above, where the manufacturing waiver will initially not apply until three years after the date of entry of the regulation. This means that the transitional period for SPCs which fall under **(b)** above will extend until 1 July 2022.

Considerations for SPC holders and SPC applicants

On the basis of an earlier version of the proposed regulation, SPC practitioners previously understood that SPCs granted before the legislation came into effect would not be subject to the manufacturing waiver – accelerated prosecution was therefore considered in the context of existing SPC portfolios in a bid to secure early grant. However, in view of the amendments made to the regulation, such acceleration is no longer a way of avoiding the manufacturing waiver for SPCs.

The window to apply for SPCs so as to benefit from the transitional period will close at the end of June 2019. Any applicants who are able to file SPC applications which could benefit, i.e. which are based on patents that expire on or before 1 July 2022, should therefore consider taking action by 30 June 2019.

SPC holders and applicants should also be aware of the implications of the new legislation. In addition to allowing manufacturing for export, the new legislation also permits stockpiling during the last six months of the term of an SPC for 'day-1 entry' to the EU market immediately after SPC expiry.

The new legislation has attempted to balance this approach by stipulating a series of safeguards, which are intended to ensure transparency and avoid the possible diversion to an EU market of the generics and biosimilars that are produced for export to a non-EU market. These safeguards include the affixing of a new EU export logo to outer packaging, as well as a requirement to provide notification to national patent offices and the SPC holder no later than three months before any intended manufacture.

Please contact your usual Mathys & Squire SPC attorney if you have any questions in relation to the new legislation, or wish to discuss an existing SPC portfolio.

[1] *The official Journal in which the Regulation appears can be found* ***here****.*