JONES DAY

COMMENTARY

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The Proposed SPC Export Manufacturing Waiver: Really a Balanced Approach?

IN SHORT

The Situation: For the pharmaceutical industry, supplementary protection certificates ("SPC") are probably the most valuable IP rights. While the scope of protection of an SPC is determined separately from the scope of protection of the underlying basic patent, it is similar to the basic patent in that it functionally does not distinguish between manufacturing for domestic use and for use in (patent free) countries. Thus, under the current law, manufacturing for export purposes infringes the rights of the SPC owner.

The Plan: To counter a perceived potential loss of export markets, the European Commission proposes to introduce an "export manufacturing waiver" that would limit the scope of SPCs in Europe where patented products are being manufactured for export to countries outside the EU.

The Lookout: The European Commission may be aware of the risks that such "export manufacturing waiver" entails. But while the proposed legislation contains some safeguards, it is questionable whether this proposal really balances the interests of both originator and generic manufacturers in the pharmaceutical industry. Therefore, it may jeopardize the IP protection of the innovative industry in Europe.

The proposed amendment to the European regulation 469/2009 concerning the supplementary protection certificate for medicinal products ("SPC Regulation") would introduce an exception to the scope of protection conferred by an SPC (Article 4 SPC Regulation).

The planned exception aims at preventing the perceived potential loss of export markets for EU-based generics and biosimilar manufacturers. It would allow the manufacture of generics or biosimilars in EU Member states while there is an SPC in force, if this manufacture is solely intended for export into (patent-free) "third countries." These target countries must be outside the European Union (irrespective of the status of SPC coverage within the European Union).

> Allowing manufacturing to take place within Europe creates the risk that products allegedly destined for export are in fact diverted to the European market.

The European Commission, in the explanatory memorandum, points to the upcoming "patent cliff" with an estimate of over €90 billion of the first generation of blockbuster biologics becoming open to biosimilar competition by 2020 after (basic) patent expiry. If biosimilar companies would be forced to shift their manufacturing outside the European Union in view of national SPCs, the European Commission argues that the EU's "pioneering competitive advantage" in the biosimilar sector might be lost and huge business opportunities foregone.

Allowing manufacturing to take place within Europe creates the risk that products allegedly destined for export are in fact diverted to the European market. Since the intended export manufacturing waiver expressly seeks to include "upstream acts" (e.g., the supply of intermediary products and active ingredients), the risk of diversion of these products along the value chain increases. To counter these potential negative effects, the proposed legislation contains three "safeguards":

(i) A requirement for the generic/biosimilar manufacturer to notify the national patent office of the country of manufacturing of the intended manufacture for export, with subsequent publication of this notification in a public register;

(ii) Affixing a logo to the outer packaging of the product indicating that it is designed for export only; and

(iii) Informing contractual partners of the manufacturer that the product is designed for export and may otherwise infringe the SPC.

The European Commission presents these safeguards as ensuring "transparency" and imposing "due diligence requirements" on the generic/biosimilar manufacturer. However, this may in practice not be the case.

The planned "transparency" only includes a notification on the identity of the maker and intended place of manufacture of the generic product, but not any disclosure on other entities involved in the

manufacture, e.g., "upstream" for manufacturing of the actual active pharmaceutical ingredient. The export logo shall only be affixed on the outer packaging of the product, but not necessarily also on its immediate packaging, so a risk of repackaging into a new outer packaging arises. The "due diligence requirement" is only a mere notification of the contractual partners of the generic/biosimilar manufacturer, without any other requirements of monitoring compliance by these contractual partners and, in particular, without imposing on the manufacturer to hold books containing relevant information (e.g., batch number and date of manufacture) regarding the products manufactured for export. Finally, no direct and immediate notification to the SPC holder is envisaged (in contrast to the notification requirements for parallel imports to the IP right holder). The SPC holder will obtain the information only indirectly and possibly with significant delay from the publication of the notification by the national patent offices. Furthermore, this notification would only inform about the intention to manufacture for export, but not on an intended launch in a EU market.

The European Commission acknowledges that allowing generic/biosimilar manufacturers to create manufacturing capabilities in Europe during the term of the SPC will easily enable them to use the same manufacturing lines to supply the EU market immediately after the SPC expiry. This facilitated "Day-1 entry" is explicitly highlighted as an intended positive effect of the new legislation, to "ensure a swifter entry of generic and biosimilar medicines onto the market." However, the very same manufacturing and logistics capabilities will similarly also make it significantly easier for generics/biosimilar manufacturers to "launch at risk" before the expiry of an SPC while at the same time challenging the validity of the SPC. As the European Commission acknowledges, it will only be the first few generics/biosimilars to enter the market that capture a significant market share and are financially viable, so that this economic incentive will amplify this risk. The contemplated safeguards in the proposed legislation, however, currently do not take this aspect into account. To allow sufficient time prior to the launch to have the matter reviewed by a court, at the very least, a notification to the SPC holder sufficiently in advance to a generics/biosimilar launch would be needed.

TWO KEY TAKEAWAYS

1. In view of the potential loss of export markets, the European Commission is pushing for quick introduction of the "SPC export manufacturing waiver."
2. In the current form, the proposed legislation would, in practice, erode the level of protection of innovative medicines in Europe, unless further safeguards are added, such as an obligation to hold accounts of the products manufactured for export enabling a compliance control to ensure that the limits of the waiver are not overcome, and a direct notification requirement to the SPC holder prior to launch.


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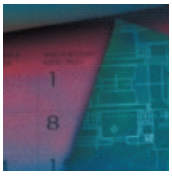
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