SPC Manufacturing Waiver
CJEU Referral on the Export Exemption: Case C-371/26

EFPIA Position Paper

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Supplementary Protection Certificates and the Manufacturing Waiver

Intellectual property (IP) rights, and their effective enforcement, are fundamental to ensure continued investment in pharmaceutical innovation and the development of innovative medicines. Supplementary protection certificates (SPCs) are a key component of this incentive structure by providing a limited period of additional patent term to innovative medicinal products in order to compensate for the time lost during the long development and regulatory approval processes required for innovative medicines. As such, SPCs are a critical form of IP protection for pharmaceutical investment in Europe, supporting continued investment in new products which are the result of costly and time-consuming research

The SPC Manufacturing Waiver (Waiver), introduced by Amending Regulation (EU) 2019/933 (Amending Regulation), was created as a carefully limited exception to this important IP right. The Waiver was intended to support generic and biosimilar manufacturers established in the European Union by allowing manufacturing activities during the SPC term for two narrowly-defined purposes: (i) export to third countries where IP protection does not exist or has expired (Export Exemption); and (ii) stockpiling during the final six months of the SPC term to enable immediate market entry in the EU upon SPC expiry (EU Stockpiling Exemption).

CJEU Referral for Preliminary Ruling

The Danish Maritime and Commercial High Court has requested a preliminary ruling from the Court of Justice of the European Union (CJEU) regarding the Export Exemption under the Waiver. This referral represents the first time that the CJEU has been asked to interpret the scope of the Waiver and will set an important precedent for the enforcement of IP rights in Europe, with a significant effect on the innovative pharmaceutical industry.

Case C-371/26, brought by a group of Johnson & Johnson companies (J&J) against Samsung Bioepis NL B.V. (Samsung) and AGC Biologics A/S (AGC), concerns the manufacture and export of a biosimilar product to the UK while a SPC held by one of the J&J companies was still in force.

Samsung and AGC manufactured the product in Denmark and stored it in the EU. At the time of manufacture, Samsung could not export to or sell the products in the UK due to, *inter alia*, J&J's UK SPC and the absence of a UK marketing authorization.

According to well-established case law of the CJEU, all exceptions to or derogations from legal property rights must be interpreted narrowly and strictly. This principle should equally apply to the Export Exemption.

Importantly, the Waiver establishes two distinct exemptions: one relating to export and another relating to stockpiling. The Export Exemption only applies to manufacture for actual and imminent export and does not extend to general or strategic stockpiling. If a given generic or biosimilar manufacturer cannot carry out the intended export directly after the manufacturing has been completed, a sudden pivot to general stockpiling is not contemplated under the strictures of the Waiver. This would go against the very purpose of the Export Exemption, which was created to facilitate the export of finished and stocked products to qualifying third countries and would further undermine the careful balance of rights established by the SPC system, effectively broadening the Export Exemption beyond the limits intended by the EU legislature. Critically, if the Export Exemption, which is not limited in time, is interpreted to permit general or strategic stockpiling throughout the SPC term, it would grant broader storage rights than the EU Stockpiling Exemption itself, which is expressly limited to a maximum of six months before SPC expiry. This would render the EU Stockpiling Exemption entirely superfluous and undermine the carefully calibrated compromise that the EU Stockpiling Exemption's six-month limit represents. Furthermore, permitting prolonged storage under the Export Exemption significantly increases the risk of illicit diversion of products onto the EU market, which is precisely the concern that led the legislature to limit the EU Stockpiling Exemption to six months and to reject earlier, more permissive proposals for storage.

As the Export Exemption currently stands, generic and biosimilar manufacturers are required to serve a notification to the SPC holder, which permits manufacture for export three months after the notification. Under the terms of the Waiver, the notification should include the marketing authorization (MA) number of the generic product in the intended export country as soon as it is publicly available, presupposing that the MA has indeed been granted at the time of the notification - even if the MA number is published later. This obligation reflects a carefully considered legislative compromise to enable the SPC holder to verify - *before manufacture and export of the products* - that the products manufactured under the Export Exemption are genuinely destined for placing on the market in the given third countries. In practice, however, generic manufacturers have been serving incomplete - sometimes blank - notifications without a MA number. This practice, contrary to the compromise represented by the Waiver, erodes the effective protection of the original product. Without this critical transparency, the SPC holder is unable to verify whether the product is genuinely destined for export to a geography where IP rights are no longer in effect.

As mentioned, the Export Exemption should only apply to exports to third countries where IP protection does not exist or has expired, and where markets are open to competition at the time of manufacture. The Commission's intention from the outset was to permit manufacture exclusively for export to rights-free markets. The Amending Regulation expressly places responsibility on the EU-based manufacturer to verify that protection does not exist or has expired in the country of export. Permitting manufacture for export to countries where IP rights remain in force would place EU-based manufacturers in a more advantageous position than competitors located in the export country itself, who cannot manufacture while local rights remain in force. This goes beyond the stated objective of the Amending Regulation and is inconsistent with the principle that derogations from IP rights must be interpreted narrowly.
While this referred matter represents the first CJEU referral, various national courts have already interpreted notification under the Waiver with diverging results. This legal fragmentation creates uncertainty for both SPC holders and generic and biosimilar manufacturers. Importantly, the series of national court decisions on the Export Exemption provide no alternative explanation as to how the intended verification by the SPC holder can effectively take place without a granted and disclosed MA number for use in a given geography. It is therefore essential that the CJEU establishes a clear, predictable, and harmonized interpretation that enables effective enforcement of SPC rights while maintaining legal certainty and supporting patient access to medicines.

In this context, EFPIA urges the CJEU to hold to the legislative intent of the Waiver and find that: (1) the Export Exemption does not cover general or strategic stockpiling, and that manufacture must be for actual and imminent export; (2) a valid marketing authorization must have been granted at the time of notification, in order to permit a SPC holder to effectively verify lawfulness within the three-month notification period; and (3) the Export Exemption applies only to exports to third countries where IP protection is not currently in force and where the market is open to competition.

Conclusion

This referral to the CJEU represents an important opportunity to enhance the predictability, legal certainty, and harmonized enforcement of SPC rights across the European Union. The CJEU's interpretation will shape both the regulatory environment for pharmaceutical companies and the careful balance between innovation incentives and timely access to generic and biosimilar medicines in the long-term. The case comes at a decisive moment for the EU pharmaceutical sector, which is facing increasing global competitive pressures and significant challenges relating to investment. SPCs are a crucial mechanism for enabling re-investment into the development of innovative therapies within the EU. By adopting an appropriately narrow reading of the Export Exemption, the CJEU can ensure that the Waiver fulfils its purpose without weakening the incentives that sustain competitiveness and public health in the EU.