Medicines for Europe's comment on the CJEU Referral on the Export Exemption Case C-371/26

Intellectual Property (IP) Rights represent the main tool to protect and foster innovation in the pharmaceutical field, ensuring investments and the development of innovative medicines. Supplementary Protection Certificates (SPCs) were introduced to provide the originator industry with a limited additional period of market protection for a specific authorized medical product, to compensate for the time elapsing between the patent filing and the grant of the Marketing Authorization. However, European SPCs have had the consequence of delivering the longest IP protection worldwide, and produced unintended results: not only did they not help close the R&D gap with the United States, which was of the main reason for introducing an SPC in Europe, but the absence of any exemption for manufacturing during SPC term, has forced generic and biosimilar manufacturers to delocalize production outside Europe to enable launch of their products in export markets and in the EU immediately after the expiration of IP rights. For this purpose, the Supplementary Protection Certificate Manufacturing Waiver was introduced.

The Supplementary Protection Certificate (SPC) Manufacturing Waiver Regulation (Amending Regulation 2019/933 (EU), henceforth also "The SPC Waiver Regulation") has been applicable since 2 July 2022 and was introduced in order to remove the competitive disadvantage faced by European manufacturers of generic and biosimilar medicines vis-à-vis third countries' manufacturers who can start manufacturing generics and biosimilars much earlier due to shorter IP protection.

CJEU Referral for preliminary ruling

The Danish Maritime and Commercial High Court requested a preliminary ruling (Case-371/26) from the CJEU on April 10th 2026, pursuant to Article 267 TFEU, concerning the correct interpretation of the scope of the exemption laid out in Article 5 SPC Waiver Regulation.

The case involves a group of Johnson and Johnson companies (J&J) against Samsung Bioepis NL B.V. (Samsung Bioepis) and AGC Biologicals A/S (AGC) and the aim is to assess whether Samsung Bioepis and AGC infringed the Danish SPC granted to J&J by making and storing ustekinumab between January 24th 2024, and July 20th 2024. Samsung Bioepis and ACG

manufactured and stored it to export it to the UK following the expiry of the UK SPC on 19 July 2024.

In view of the hearing before the CJEU, EFPIA drafted a Position Paper in which they advocate for a restrictive reading of the SPC Waiver Regulation, seeking to artificially restrict the export exemption by introducing non-statutory hurdles concerning storage, Marketing Authorizations in third countries and foreign patent landscapes, that were not intended by the SPC Waiver Regulation.

The SPC Waiver Regulation should be interpreted in line with its wording, purpose and practical effect, so that EU-based manufacturers of generic and biosimilar medicines can compete globally without artificial or additional constraints and the threat of unjustified litigation.

1. **Systematic distinction of the exemptions laid down in the SPC Waiver Regulation**

The SPC Waiver Regulation provides for two distinct and separate exemptions:

- The "**export exemption**", **applicable throughout the SPC term and not limited to the final six months before the expiry of the certificate, subject to the Regulation's notification requirements**, comprising *(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;*
- The "**stockpiling exemption"**, comprising *(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.*

According to EFPIA's position paper, storage of products intended for export must be temporary with export imminent, because prolonged storage would be a way to bypass the 6-month limit of the stockpiling waiver and it would increase the risk of illicit diversion into the EU market. For that reason, EFPIA advocates a strict and narrow interpretation of the exemptions laid down in the Regulation.

While it is undisputed that CJEU case law maintains that all exemptions from intellectual property rights must be interpreted narrowly and strictly, such exemptions **must not be interpreted in a way that deprives them of practical effectiveness or is contrary to the intentions behind its implementation**.

After all, the SPC Waiver Regulation was introduced to restore a global level playing field between generic and biosimilar manufacturers established in Europe and outside of Europe as well as between originators and European generic and biosimilar manufacturers. An ultra-restrictive interpretation would unfairly defeat the very goal of the SPC Waiver Regulation, actively harming European industrial competitiveness and its economy. Furthermore, this restrictive interpretation is without basis: while the stockpiling waiver is unnecessarily linked to a 6-months period before SPC expiry, the export waiver has no such time limitations. There is no need for any interpretation as to the timing of the export waiver, as it is explicitly permitted in order to bring the EU manufacturer on the same playing field as a manufacturers established outside of Europe. With the suggested restrictions, this goal would not be achieved and would only add another unnecessary limitation against the spirit of the legislation. Therefore, it is senseless.

Indeed, there is no basis for an interpretation which imposes a time limit on storage for export. The time limit on the stockpiling waiver is to prevent *manufacture* for EU entry until 6 months before SPC expiry. This is because that product cannot be sold in the EU until the SPC expires and 6 months' manufacturing time was considered (incorrectly) to be long enough to be ready for a day 1 launch. As such, longer storage under the stockpiling exemption is not required because manufacture cannot take place – contrary to what EFPIA suggest, it is not indicative of and has no relevance to the legislature's position on storage duration under the export waiver.

In addition, pharmaceutical manufacturing requires lengthy campaign-based and complicated production processes, particularly for biosimilars. **Artificially forcing immediate export after manufacture is not foreseen in the SPC Waiver Regulation and is industrially unviable. Storage is necessary for batch-release testing and for aligning shipping schedules and supply chains, which may have different timelines**.

Furthermore, the alleged phantom risk of illicit diversion deriving from a prolonged storage under the export exemption is not a compelling argument. The Regulation already imposes strict and unnecessary rules for labelling and packaging of products manufactured for export, alongside the Pharmaceutical Legislation and the IP enforcement system, rendering such illicit diversion practically unfeasible. **Additional and unnecessary limitations imposed on the export exemption would only undermine the EU single market and the free movement of goods and seems to reveal the intention to actually block the genuine use of the SPC manufacturing waiver by the European generic and biosimilar medicines industry**.

2. **Marketing Authorization**

It has been argued that a manufacturer may rely on the export exemption only if they already hold a valid Marketing Authorization (MA) in the country of export at the time of the initial notification under Article 5.

The SPC Waiver Regulation explicitly states that manufacturers must provide the reference number of the third country Marketing Authorization *as soon as it is publicly available*. In a Regulation that is very prescriptive and detailed in relation to the safeguards and limitations of the exception, the legislator would have been explicit in case it intended to include additional limitations. The wording of the Regulation would be completely redundant if the Marketing Authorization had to be active and public at the time of the initial notification. This limitation would also go against the whole purpose of the legislation as there is nowhere a limitation to start production only upon approval of a Marketing Authorization.

3. The principle of territoriality on IPs

According to EFPIA's paper, the export exemption should only apply to exports to third countries where IP protection does not exist or has expired. The paper also suggests that the SPC Waiver Regulation imposes an obligation on EU-based manufacturers to verify that protection does not exist, or if it has expired in the country of export.

The IP status of an export market is obviously something the manufacturer has to take into account in terms of whether a launch would trigger any infringement litigation in that export country. But this is unrelated to whether the SPC manufacturing waiver can be used in Europe, like the EFPIA paper seems to suggest.

This reading would infringe the principle of territoriality and EU national courts do not have the competence to assess patent validity or infringement of foreign rights, particularly not for the purpose of manufacture under the SPC Waiver in the EU. It is in the export country that any rights which may be alleged to infringe should be enforced.

Moreover, contrary to what has been argued in the EFPIA's paper, the reference to *countries where the protection does not exist or has expired* was only introduced in the Regulation to stress that while the SPC would have ensured a longer protection in Europe, by not having an SPC other regions could have had a shorter period of protection that would cause a competitive disadvantage.

Conclusion

The export exemption was expressly designed to facilitate manufacturing for export and not to impose conditions as to the position in the export country – such as the prior grant of a Marketing Authorization in the export country or the verification of the existence of IP (eg. any secondary patents, etc.). These alleged conditions are absent from the Regulation's text because they are not intended and are incompatible with the principle of territoriality of IP rights.

In this context, Medicines for Europe urges the CJEU to safeguard the rationale and the intention behind the SPC Waiver to ensure a fair competition for European based

manufacturers and a level playing field between originators and generic and biosimilar manufacturers and EU and non-EU manufacturers, by:

i) confirming that the export exemption allows production and export to take place within timelines that are consistent with the industrial manufacturing needs and in any case without any limitations not prescribed in the law;

ii) confirming that the SPC Waiver Regulation does not require the manufacturer to have already obtained an MA in the export country in order to rely on the export exemption. Imposing such requirement would contradict the literal wording of the Regulation and undermine its intended function as a facilitative instrument for EU-based manufacturers;

iii) confirming that the export exemption under the SPC Waiver is not subject to verifying the existence, validity or expiry of intellectual property rights in the country of export. Any requirement of that sort would be incompatible with the fundamental principle of territoriality governing intellectual property rights and would extend EU-based obligations beyond the Union's legal framework.

To complement the position expressed in this document, the 2026 Industry Report on the SPC Manufacturing Waiver includes further information on the functioning of the SPC waiver, a number of court decisions in the EU which support the interpretation that Medicines for Europe explains above, as well as proposed measures on how it should be improved to exploit its full, intended potential.