AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

AmCham EU position on the Supplementary Protection Certificate (SPC) manufacturing waiver

Further clarity and legal certainty needed to minimise the impact on medical innovation

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2017, directly supports more than 4.7 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
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Executive summary

The American Chamber of Commerce to the European Union (AmCham EU) is concerned about the European Commission's proposal to introduce a manufacturing exemption ('waiver') to the rights of Supplementary Protection Certificate (SPC) holders. This risks sending a negative signal about Europe's (EU) attractiveness as a destination for investment and medical innovation, at a time when other global players like China are strengthening their Intellectual Property (IP) systems. In order to minimise these risks, it is essential that the scope of the proposal is not widened and that the final legislative text provides for additional legal clarity and strengthened safeguards, ensuring that innovators' rights are not weakened further.

Sustaining innovation in Europe through the value of IP

Intellectual Property Rights (IPR) are stimulating innovation, science and research across the European economy. Where markets are open and IP is effectively protected and enforced, innovators can rely on the predictability and certainty they need to collaborate with partners, compete successfully and accelerate the launch of innovative medicines. A strong and predictable IP and exclusivity-based incentives framework is key to the attractiveness of Europe as an investment location, and essential for IP intensive-industries such as the life sciences sector to continue supporting Europe's competitiveness and growth.

How different IPR and incentives reward pharmaceutical innovation

Recognising the inherent risk and amount of capital investment required for innovation in all Research and Development (R&D) intensive sectors, the EU has laid out a world leading system of IPR and incentives playing different and complementary roles. For the pharmaceutical sector, in addition to patents, different incentives and rewards that address the reality of complex biomedical R&D and medical needs have been created: Supplementary Protection Certificates (SPCs) and extension for paediatric medicines, Regulatory Data Protection (RDP) and orphan medicinal product exclusivity. All are time-limited and run next to each other but vary in the coverage and degree of protection they provide, for example whether they are indication specific and/or apply to the whole product, or whether they allow for competition under certain circumstances. These work together to provide a coherent and complementary set of incentives providing certainty and predictability for innovative biopharmaceutical companies. Continued efforts to sustain and improve the existing incentive framework for pharmaceutical R&D are crucial for the development of future innovative therapies in areas of great demand.

Why Supplementary Protection Certificates (SPCs)? What is at stake?

SPCs are essential IPR in the innovative R&D based pharmaceutical industry, which brings direct benefits to patients and helps address public health challenges. Its fundamental role is to compensate innovators for the substantial patent term lost between patent filing and the long development process as well as regulatory approval in Europe, which overall takes 10-15 years on average of a medicine's patent life. In supplementing up to a maximum of five years of patent protection and altogether allowing for 15 years of market exclusivity, it offsets some of the risks involved in investing in the lengthy, expensive, complex and highly uncertain process of developing a new medicine, giving innovators enough certainty to undertake R&D. The Commission's proposal to introduce a manufacturing waiver – which would allow companies to manufacture generic and biosimilar products in Europe for export purposes during the SPC protection period – could undercut pharmaceutical R&D investment by large and small innovators alike, and put European innovators at a disadvantage with competitors based in countries with more competitive IP systems.

Legal clarity and stronger safeguards needed

In order to minimise the risks to Europe's competitiveness and prevent the EU from losing its place as a leader in medical innovation and research, it is essential that the Commission's proposal provides for additional clarity and certainty to ensure that innovators' IP rights are not further eroded. AmCham EU welcomes the efforts to include safeguards in the Commission's proposal, but in order to be effective and ensure against any misuse or undue consequences of the waiver, these safeguards should be further strengthened and clarified.

1. Application in time

The Commission's proposal, in line with EU law, is for the waiver not to be applied retrospectively. While we support the prospective approach, the waiver should only apply to SPCs that are applied for on and after the date of implementation of the new regulation. This is essential to preserve the legal certainty and legitimate expectations that a developer of an innovative medicine had when deciding whether or not to take the risk to invest in a complex and lengthy R&D process, and to allow market players to take account of the new situation. This is also consistent with the application of other comparably significant changes to IP law introduced in Europe and internationally, including the amendment to European Regulatory Data Protection (RDP legislation proposed in 2004[1] and the introduction of SPC equivalent legislation in Canada in 2017.[2]

2. Notifying right holders of intention to manufacture for export

AmCham EU welcomes the proposal's obligation for the generic or biosimilar producer to publicly notify (ex-ante) the relevant competent authority of its intention to manufacture. However, given limited capacity of many national patent offices, the SPC holder should also in parallel be directly notified of intention to manufacture and be provided with a list of intended export markets, well in advance of the intended launch date. This would more effectively guarantee a timely and direct flow of information, limit any further reduction of rights of the innovator and allow the SPC holder to investigate and seek remedies in case the making of products under the waiver would infringe IPRs.

3. Preserving the EU and international IP framework

The proposal states the waiver applies to manufacture for the exclusive purpose of export to third countries. The final legislative text should include a specific provision in an article that this export should only be to third countries (as per recital 21 of the proposal), where there is no IP protection or where this has expired, so that European IP rights are not further eroded and international IP rights are respected. The EU should not be seen to introduce rules that encourage infringement in third county markets.

4. Preventing trade diversion

The Regulation should ensure that products manufactured under the waiver cannot be placed on the EU market or re-imported into the EU during the legal term of SPC protection. The Commission has recognised this with the initial obligation to include a logo on the outer packaging on the product intended for export. More robust

[1] https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2004_27/dir_2004_27_en.pdf

[2] https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/csp-guide-cps-ld-eng.pdf

labelling specifications are needed to ensure that this is practically workable across the various export markets, many of which may have specific labelling restrictions, including where there may be eventual repackaging. Linking this Regulation to the soon-to-be-introduced European Medicines Verification System (EMVS) would be a means to ensure products manufactured for export-only are not diverted back into the EU.

In addition, while AmCham EU supports the requirement to notify contractual partners along the supply chain about the intention to manufacture a product for export, there should be more robust compliance measures in place to align with the intention of due diligence.

Moreover, swift legal proceedings should be ensured in the event of a suspected illicit diversion within the EU of generics or biosimilars, in order to ensure legal certainty and IP rights' protection for innovators. The latter should be able to secure a rapid interim injunction against the generic company suspected of illicit diversion within the time frame of a maximum of two months following the court injunction request. This would ensure robust legal remedies, with a view to safeguarding the implementation and scope of the regulation.