Name/Title of Deputy Ambassador

RE: Discussion on the proposed SPC manufacturing waiver proposal in Coreper I

Tuesday, January 15, 2019

His/Her Excellency X,

Ahead of the discussion in Coreper I tomorrow, the American Chamber of Commerce to the European Union (AmCham EU) would like to outline some concerns regarding the European Commission's proposal to amend Regulation (EC) No 469/2009 on supplementary protection certificates (SPC) for medicinal products. This initiative proposes to introduce a manufacturing exemption ('waiver') to the rights of SPC holders for export purposes.

The European Union (EU) is among the global leaders in healthcare innovation and intellectual property (IP) protection. As a result, Europe has been a top destination for investment, clinical trials, and diffusion of medical technologies. SPCs are essential IP rights in the innovative R&D-based pharmaceutical industry, compensating innovators for the substantial patent term lost between patent filing and the long development and regulatory approval process in Europe, which on average take 10-15 years of a medicine's patent life.

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, at a time when other global players like China are strengthening their IP frameworks.

While we acknowledge that the aim of the proposed Regulation is to enable generic and biosimilar companies to increase their competitiveness outside of Europe, this should not be to the detriment of European healthcare innovation. As we understand that the proposal is moving ahead, it is important that the risks be minimised as much as possible and that a balanced approach is decided on. It is thus essential that the Commission's proposal provide for additional clarity and legal certainty to ensure that innovators' IP rights are not further eroded. In the context of the upcoming discussion at Coreper I, this applies to five key areas:

1. **Preserving the EU and international IP framework:** The final legislative text should ensure the waiver applies to manufacture for the exclusive purpose of export to third countries 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.

2. **Not extending the scope of the proposal to stockpiling for domestic use:** There no economic evidence to support the argument that manufacturing and stockpiling of medicines during the term of the SPC and for commercialisation on day-1 after SPC expiry would increase patient access to generic medicines in the EU. Allowing generic manufacturers to stockpile products for domestic use during the SPC term would create a significant precedent in IP law that would weaken IP protection for innovative medicines overall. Most importantly, this would weaken the EU's position and credibility as a trade partner throughout the world: it would mean that the EU would introduce the very measure it had launched a legal proceeding against[1], would

[1] https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm

go against what the EU agreed on in the EU-Canada Comprehensive Economic and Trade Agreement (CETA) and would contradict the current Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) interpretation by the World Trade Organization (WTO).

3. **Application in time:** the waiver should only apply to SPCs that are applied for on and after the date of implementation of the new Regulation, to preserve legal certainty and legitimate expectations of developers of innovative medicines and other market players. An earlier application date would considerably reduce legitimate expectation of innovative companies, thereby sending a negative signal for investment. It could further be interpreted as expropriation of IP rights without appropriate compensation.

4. **Appropriate notification measures:** The SPC holder *as well as* the relevant competent authority should be directly notified of the intention to manufacture for export. Both should also be provided with a list of the country our countries where the production takes place and of the export markets, well in advance of the intended launch date. This measure should ensure that the innovator can carry out an ex-ante verification of compliance with the Regulation and thus provides for more legal clarity for all involved.

5. **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, including through robust labelling requirements and potentially relying on the with the European Medicines Verification System (EMVS).

We are ready and willing to work with you and other European stakeholders to advance Europe's position as a world leader in healthcare innovation. We remain available to follow up with you to answer any questions and provide further information. In the meantime, please refer to the attached AmCham EU position paper on the SPC manufacturing waiver which provides additional detail.

Yours sincerely,

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