

Considering the proposed Supplementary Protection Certificate (SPC) manufacturing waiver

The Supplementary Protection Certificate¹ (SPC) is an essential intellectual property (IP) right for the innovative R&D-based pharmaceutical industry². The adoption of an SPC manufacturing waiver – i.e., allowing a manufacturer to produce for export or stockpiling purposes a generic or a biosimilar of an original product still under SPC protection – would not only weaken the overall IP regime in the European Union (EU) but it would also have very limited potential benefits for the economy and for patients.

The proposed SPC waiver would weaken Europe's IP regime and harm innovation in Europe:

- With the potential adoption of an SPC waiver, SPCs would no longer confer the same exclusionary rights as patents. This contradicts the fundamental purpose of the SPC – that is, to compensate innovators for the substantial patent term lost due to regulatory delays.
- Instead, **the SPC regime would weaken IP rights, and the consequent innovation incentives, to become an instrument of industrial policy and localisation** which would send a negative signal internationally as localisation policies – which the European Commission (EC) consistently fought against – are multiplying worldwide.
- This would put Europe at a disadvantage when compared with systems in the United States, Japan and other markets that restore complete patent rights. It would also send a signal of weakening IP protection when emerging markets such as China³ are considering a new patent enforcement mechanism and increased regulatory data protection.
- **The potential adoption of an SPC waiver would further harm European innovators by encouraging some jurisdictions to adopt similar measures, and even during the 20-year patent term,⁴ and imperil existing international jurisprudence on early manufacturing and stockpiling.**

The proposed waiver puts thousands of research-based jobs and investment at risk while providing little, or no, potential economic benefit:

- **The potential negative impact of the adoption of an SPC manufacturing waiver on the R&D-based pharmaceutical industry has been underestimated⁵.** Recent studies find that the adoption of such a measure would lead to the loss of between 4,500-7,700 direct jobs in the industry with an additional loss of between 19,000 and 32,000 indirect job losses. It would also result into a decrease of between EUR215 million to EUR364 million in R&D investment⁶.
- **The number of direct and indirect jobs that may potentially be created by the adoption of an SPC manufacturing waiver⁷ was largely overestimated.** When parameters of economic uncertainty are taken into consideration, the estimate of the number of direct and indirect jobs created is not statistically distinguishable from zero⁸.

¹ The SPC is an intellectual Property right designed to compensate for the erosion of patent term due to the lengthy development and regulatory timelines in the biopharmaceutical sector, in recognition of the need to guarantee continuous funding for future biomedical research.

² "Approximately 19,000 SPC were filed in Europe over the period 1991 to 2014, confirming the importance for the pharmaceutical industry of this protection right." European Commission, Inception Impact Assessment, *Optimising the Internal Market's industrial property legal framework relating to supplementary protection certificates (SPC) and patent research exemptions for sectors whose products are subject to regulated market authorisations*, 2017

³ Statement of the China Food and Drug Administration (CFDA), <http://www.cfda.gov.cn/WS01/CL1746/178364.html>

⁴ Seuba, X. et al, *A manufacturing for Export Exception*, forthcoming publication in B. Mercurio (Ed), *Contemporary Issues in Pharmaceutical Patent Law and Policy*, Routledge, 2016

⁵ Logendra, R. et al, *Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU*, QuintilesIMS, 2017

⁶ Pugatch Consilium, *Unintended Consequences, How introducing a manufacturing and export exemption to supplementary protection certificates would weaken global standards of IP protection and result in direct losses to Europe's research-based biopharmaceutical industry*, 2017, Pugatch Consilium. Available at: http://www.pugatch-consilium.com/reports/Unintended_Consequences_October_%202017.pdf

⁷ Vicente, V. et al, *Manufacturing and export provisions: Impact on the competitiveness of European pharmaceutical manufacturers and on the creation of jobs in Europe*, Journal of Generic Medicines, 2014, Vol. 11(1–2) 35–47

⁸ Sussell, J. et al, *Reconsidering the economic impact of the EU manufacturing and export provisions*, Journal of Generic Medicines, 2017, 0(0) 1–17

- **An SPC manufacturing waiver would only create very limited commercial opportunity for EU generic manufacturers in export markets and it would not improve its competitiveness globally because:**
 - **SPC patent expiry dates in Europe are often before target export markets, therefore leaving limited or no additional benefit from an SPC Manufacturing Exemption** as it would not be possible to sell generic products in the target export markets⁹;
 - **Regardless of the adoption or not of an SPC manufacturing waiver, there are many environmental factors impacting a potential export strategy to the target countries**, such as trade barriers, price levels, ability to manage local commercial relations locally, and increasingly, incentives for domestic producers (such as localisation measures)¹⁰.

The proposed SPC manufacturing waiver puts healthcare sustainability and patient access to new therapies at risk for no apparent benefit to Europe:

- **The EU IP incentives framework, including the SPC, has generated a healthy ecosystem of innovation and generic competition where:**
 - Small and Medium Size Enterprises (SMEs), for which a strong IP portfolio is a primary and often the only asset to attract investments, develop 27% of all new medicines and up to 61% of innovative orphan medicinal products¹¹.
 - Innovative medicines of today are the generics and biosimilars of tomorrow: by weakening the current EU IP framework, and potentially the long-term flow of pharmaceutical innovation in the EU, it is the future of the generic and biosimilar offer overall that is at stake.
 - Unmet medical needs of critical importance to ageing societies, including potential treatments for Alzheimer's and other neurological conditions, include areas of complex research and development require reaffirming, not weakening incentives for long-term research; a manufacturing waiver would undermine these incentives and goes exactly in the wrong direction¹².
- **An SPC waiver allowing stockpiling of generics and biosimilars in the EU would not "level the playing field" with foreign sourced generics or biosimilars. It is also unlikely that the adoption of an SPC waiver would result into an increased market share of EU-produced generics in EU markets as it is often European generic companies that are first to market in the EU under the current system¹³.**

⁹ Logendra, R. et al, *Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU*, QuintilesIMS, 2017

¹⁰ Logendra, R. et al, *Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU*, QuintilesIMS, 2017

¹¹ Lincker, H. et al, *Where do new medicines originate from in the EU?*, Nature Reviews: Drug Discovery, 2017

¹² Lietzan *The Innovation Drug Paradox: Why Complex Drug Research is not Being Rewarded*, Life Sciences Intellectual Property Review, 2017

¹³ Logendra, R. et al, *Assessing the impact of proposals for a Supplementary Protection Certificate (SPC) Manufacturing Exemption in the EU*, QuintilesIMS, 2017