BUSINESSEUROPE

COMMENTS

15 January 2019

BusinessEurope Comments on Commission Proposal on a supplementary protection certificate (SPC) manufacturing waiver for export purposes

Background

In May 2018, the EU Commission submitted a Proposal for a Regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate (SPC) for medicinal products ("Commission Proposal" or "draft Regulation").[1] The Proposal aims to introduce an SPC manufacturing waiver for the exclusive purpose of export to third countries. This would allow EU manufacturers of generics and biosimilars to produce medicines already during the SPC term (up to 5 year) exclusively for exports to third countries where patent or SPC protection has expired or never existed whilst leaving unaffected SPC protection for placing those products on the EU market.

On Intellectual Property Rights

The protection of intellectual property (IP) is key for innovation, growth, competitiveness and job creation in Europe. IP generates 39% of EU GDP. 1 in 3 jobs in Europe rely on IP-intensive industries. This is evidenced in a joint EUIPO-European Patent Office study from 2016[2].

European innovation is vital to ensure that the EU can maintain its global leading role in developing sustainable solutions to cope with mutual challenges prompted e.g. by consumer safety, climate change, lack of clean water, a growing aging population and health issues. The EU is widely acknowledged with its trading partners for its firm commitment to promote innovation and progress through, amongst others, means of strong and enforceable IP rights.

Only with a strong IP policy will Europe be able to remain competitive as well as keep its ability to generate and attract R&D investment. This would also make Europe less dependent on other parts of the world for innovative solutions.

Although BUSINESSEUROPE does not take position on sectoral issues such as health and pharmaceutical law, it finds it crucial that the EU ensures the current level of protection and efficiency of its IP landscape.

In this context, BUSINESSEUROPE would like to put forward the following considerations regarding the Commission Proposal amending Regulation (EC) No 469/2009.

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[1] Proposal for a Regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, COM/2018/317 final - 2018/0161 (COD), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A317%3AFIN .

[2] See EUIPO-EPO Joint Study, *IP rights intensive industries and economic performance in the European Union*, Industry-Level Analysis Report, October 2016, second edition, page 3, available at: http://documents.epo.org/projects/babylon/eponet.nsf/0/419858BEA3CFDD08C12580560035B7B0/$File/ipr_intensive_industries_report_en.pdf

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On the SPC manufacturing waiver for the exclusive purpose of export to third countries

There is no innovation without investment, and no investment without adequate protection of IP rights. It is therefore essential that the Commission Proposal:

1. **Prevents an erosion of intellectual property rights in the pharmaceutical sector:** the draft Regulation should make clear that the envisaged SPC manufacturing waiver for export purposes is limited exclusively to SPCs and does not affect any other IP rights.
2. **Remains limited in scope:** the SPC manufacturing waiver for export purposes should not entail any revision of the existing SPC instrument as a whole which is part of a separate discussion.
3. **Ensures legal certainty to all economic players involved (both originators and generics manufacturers):** predictability and reliance on the protection granted by SPCs should not be jeopardised; legal definitions such as "manufacturing" and "export" should be more precise.
4. **Includes strong safeguards to avoid circumvention:** a well-defined scope, as well as sufficient and efficient transparency requirements (e.g. labelling, due diligence obligations, prompt notification to the competent national authorities and to the IPR holder concerned) should be an integral part of the draft Regulation[3].

BUSINESSEUROPE calls on decision-makers to uphold these principles in order to ensure that Europe can continue to deliver on its commitment to long-term incentives for innovation to maintain a strong manufacturing industry in the European Union.

BUSINESSEUROPE also reiterates that a future unitary SPC would be key factor for the success of European unitary patent system. By harmonising the European system for obtaining both patents and SPCs, this would unify the variations between national systems and prevent fragmentation.

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[3] *Lewiatan - the Polish Confederation, MGYOSZ – Business Hungary, and CEA – the Croatian Employers' Association do not share the views on this particular point as they believe that some of these additional safeguards are disproportionate.*