

Mr Axel Voss
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Brussels,

Dear Mr Voss,

Thank you for your letter of 14 February, in which you expressed certain concerns regarding the Commission's work on Supplementary Protection Certificates (SPCs), notably on a manufacturing waiver.

I fully agree with you that intellectual property rights (IPR) protection – and the incentive to innovation it provides – is of crucial importance for the EU pharmaceutical industry. Indeed, our SPC system is arguably the strongest such regime in the world. In addition, through our FTA negotiations, we are continually trying to convince our trade partners to introduce or upgrade their own IPR regimes to approximate to EU levels.

Regarding the EU SPC regime, it is by no means the Commission's intention to weaken the exclusive rights that SPC holders enjoy in respect of the marketing of innovative medicines in the EU during the SPC term. That being said, the Commission has, since 2015, been looking into the SPC system, which, according to EU-based manufacturers of generics and biosimilars (notably SMEs), has unintended side effects detrimental to their competitiveness that shall be addressed as a matter of urgency. In that context, I would recall the Resolution of the European Parliament of 26 May 2016 on the Single Market Strategy:

'Urge[d] the Commission to introduce and implement before 2019 an SPC manufacturing waiver to boost the competitiveness of the European Generics and Biosimilar Industry in a global environment, as well as to maintain and create additional jobs and growth in the EU, without undermining the market exclusivity granted under the SPC regime in protected markets; believes that such provisions could have a positive impact on access to high-quality medicines in developing and least developed countries and help to avoid the outsourcing of production'.

In response to this Resolution, and other Parliament Resolutions from 2014, 2015 and 2016, our legislative initiative of 28 May (COM(2018) 317) proposes a balanced, proportionate and well-calibrated exception to the current supplementary protection certificate system, by means of a targeted amendment to the existing SPC Regulation, in the form of a manufacturing exception exclusively for the purposes of export.

The objective of the manufacturing exception is to remove the current competitive disadvantage faced by EU generics and biosimilars manufacturers vis-à-vis non-EU based manufacturers, and thus support EU companies in taking part in, and becoming leaders of, the expanding global market for these products. We believe that this objective is fully compatible with maintaining Europe as an attractive location for research and innovation for innovative medicines.

Regarding your concern of a possible erosion of IP protection, the proposal – no different to the ‘Bolar’ exemption in 2001 – does not change the core of the SPC system, nor the length of the protection provided by it. The Commission remains fully committed to strong IPR and SPC protection and enforcement, both in the Single Market and in third countries. We have listened carefully to the expectations and concerns of stakeholders, and believe that the final text represents a fair balance between the different interests at stake, notably due to the limited scope of the waiver and the strong safeguards it encompasses.

To respond to your remarks about consultation and impact assessment, I would like to draw your attention to the comprehensive impact assessment adopted alongside the proposal, which draws on the extensive research undertaken. In the options considered in the impact assessment (including a soft-law approach), the impact of the waiver on all stakeholders and on EU competitiveness as a whole, innovation, delocalisation/relocalisation, SMEs and patients was thoroughly assessed, in line with our Better Regulation rules. In addition, studies carried out for the Commission by the Max Planck Institute in Munich and by Copenhagen Economics have likewise been published, as have been the results of the public consultation: the findings of all these documents fed into our legislative initiative.

As you noted, a SPC manufacturing waiver is only one of the issues the Commission is currently looking at. Consideration is also being given, for example, to the possible introduction of a unitary SPC (to complement the long-awaited unitary patent) and to an incentives review, as called for by the EU Health Council in June 2016.

Regarding the various detailed issues raised in your letter, I have asked the responsible within DG GROW, [REDACTED] (tel. [REDACTED]), to take contact with your office.

Finally, please accept my apologies for the delay in responding to your letter.

Yours sincerely,

Elżbieta BIENKOWSKA