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Dear Ms Niebler,

I would like to thank you for your e-mail addressed to Vice-President Katainen on the SPC manufacturing waiver. I am pleased to respond to you on his behalf.

I fully agree that intellectual property right (IPR) protection, and the SPC in particular, is of crucial importance for the biopharmaceutical innovation, and this is why the EU introduced SPCs as far back as 1992, with features that make it virtually the strongest such regime in the world. Moreover, the EU is actively trying to convince its trade partners (through FTA negotiations) to upgrade or introduce IPR regimes similar to our own, including as regards SPC-like protection, something we recently succeeded in achieving in Canada.

As you are probably aware, on 28 May 2018 the Commission adopted a legislative proposal (COM(2018) 317) to amend the existing EU SPC Regulation by introducing a manufacturing 'exception' for export purposes. The objective is to remove the current competitive disadvantage faced by EU-based manufacturers of generics and biosimilars vis-à-vis non-EU based manufacturers, an issue that was stressed in your letters. The initiative will thus support EU companies to take part in and become leaders of the expanding global market for these products.

Finally, please rest assured of our commitment to ensure that the EU IPR framework carefully balances the interests of all stakeholders, not least through effective incentives for the EU biopharmaceutical industry.

Yours sincerely,

Elżbieta Bieńkowska