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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Innovation and Advanced Manufacturing  
Intellectual Property and Fight Against Counterfeiting  
Head of Unit

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Dear Prof. Dr. Domdey,

Thank you for your e-mail of 12 February 2018 on Supplementary Protection Certificate (SPC) addressed to President Juncker, Vice-President Katainen, and Commissioner Bieńkowska who have asked me to reply on their behalf.

I fully agree that intellectual property right (IPR) protection, and the SPC in particular, is of crucial importance for the biotech innovation, and especially for biotech SMEs. This is why the EU introduced SPCs for pharmaceutical products as far back as 1992, and for plant protection products in 1996, with features that make it virtually the strongest such regime in the world. Moreover, as you probably know, 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.

The Commission has so far not taken a decision regarding a possible proposal for the introduction of an SPC manufacturing waiver into EU legislation, especially since its impact on all stakeholders is still in the process of being assessed. The Commission is currently looking at other issues that are also relevant to the EU biotech sector such as the possible introduction of a unitary SPC – to complement the future unitary patent.

In conclusion, 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 biotech landscape.

Best regards,