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Innovation and Advanced Manufacturing
Intellectual Property and Fight Against Counterfeiting
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Dear Dr Resch, Dear Dr Nake,

Thank you for your letter of 15 March 2018 to Commissioner Bieńkowska (related to *Supplementary Protection Certificates* ergänzende Schutzzertifikate – SPCs), who asked me to reply on her behalf.

I fully agree that intellectual property right (IPR) protection, and SPCs in particular, is of crucial importance for research and innovation in the medicinal field, and especially for related 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 introduce or upgrade IPR regimes similar to our own, including as regards SPC-like protection, something we recently achieved in Canada.

So far the Commission has not taken any decision regarding a possible proposal for the introduction of an 'SPC manufacturing waiver' into EU legislation, and is still assessing the consequences this might have on various stakeholders. Let me clarify that such a waiver would not affect the SPC term or other fundamental features of the SPC regime. Under such a waiver – should it be proposed – the manufacturing of generics and biosimilars would only be allowed for very limited purposes and subject to a number of safeguards. However, the fundamental, exclusive right for SPC holders to place their products on the EU market during the term of the SPC would not be affected in any way.

The Commission is currently looking at other issues that are also relevant to the EU medicinal 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 medicinal landscape.

Best regards,

[redacted]

CC: [redacted], Cabinet of Vice-President Katainen;
[redacted], Cabinet of Commissioner Bieńkowska