



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Innovation and Advanced Manufacturing
Intellectual Property and Fight Against Counterfeiting

Head of Unit

Brussels,
Grow F5 - [REDACTED]
[grow.ddg1.f.5\(2018\)3179827](mailto:grow.ddg1.f.5(2018)3179827)

Mr Cezary Kaźmierczak
President
Mr Marcin Nowacki
Vice-President
Union of Entrepreneurs and Employers (ZPP)
ul. Nowy Świat
00-029 Warsaw
Poland

a.boutanos@zpp.net.pl

Dear President, dear Vice-President,

Thank you for your letters of 11 May 2018 to First Vice-President TIMMERMANS, Commissioner BIENKOWSKA and Commissioner ANDRIUKAITIS¹, in which you expressed your strong support for a Commission initiative on Supplementary Protection Certificates (SPCs), and in particular the introduction of a manufacturing waiver. I have been requested to respond to you on behalf of all three Commissioners.

I am pleased to inform you that the Commission adopted, on 28 May 2018, a legislative proposal (COM(2018) 317) to amend the existing EU SPC Regulation. This envisages 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, to which you refer in your letters.

It will thus support EU companies in taking part in, and becoming leaders of, the expanding global market for these products. We consider it a balanced, proportionate and well-calibrated adjustment to the current SPC system, which keeps intact the exclusive rights that SPC holders enjoy in respect of the marketing of innovative medicines in the EU during the SPC term.

¹ Our internal references: ARES(2018)2501980 and ARES(2018)2481896.

You will find the text of the proposal, and all relevant background documentation, at:

http://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates_en

(Please note that the Polish version of the legal text will be available on this site within the coming days.)

The proposal is now with the European Parliament and the Council of the European Union for consideration. The Commission has called on them to adopt the proposal before the European Parliament elections, which are due to take place in May 2019. In this context, the support of ZPP to the work of those EU institutions over the months ahead would be valuable.

Yours faithfully,

[Redacted signature]

Contact:

[Redacted contact information]