ZPP

Warsaw, May 11th, 2018

List of recipients:

President Jean Claude Juncker

First Vice-President Frans Timmermans

Vice-President Jyrki Katainen

Commissioner Elżbieta Bieńkowska

Commissioner Vytenis Andriukaitis

Dear President,
Dear Vice-Presidents,
Dear Commissioners,

We have been closely following the recent discussions on the supplementary protection certificate for the medicinal products. We welcome the European Commission's work towards providing the sufficient protection to medicinal products and intellectual property in the interest of public health, so the encouragement for innovation, smart growth and new jobs creation. In this letter we would like to express our concerns in regards to limitations that the supplementary protection certificate causes for export outside of the EU and propose a legislative solution.

The supplementary protection certificate in its current form deepens disproportions between the European pharmaceutical companies and their global counterparts. SPC regulation in force allows entrepreneurs from outside the European Union to start production of generics and biosimilars shortly after the patent protection expiry, which is not the case for the European Union based enterprises. In practice even 25 years after obtaining the patent protection, European pharmaceutical companies are not allowed to produce generic and biosimilar drugs based on it in the European Union.

ZPP

Beginning with Council Regulation (EEC) No 1768/92 of June 18th, 1992, followed by Regulation (EC) No 469/2009 of the European Parliament and of the Council of May 6th, 2009, concerning supplementary protection certificates for medicinal products, the EU legislator introduced into the legal order an instrument to extend the protection of medicinal products beyond the duration of basic patent protection. In accordance with Article 2 of this Regulation, any medicinal product protected by a patent within the territory of a EU Member State and before being launched on the market may be the subject of a supplementary protection certificate. The terms and conditions for obtaining such a certificate are described in Article 3: the product must be protected by a basic patent remaining in force, admitted to be traded on the basis of a valid permit, which must be the first authorisation for the product to be placed on the market as a medicinal product, and additionally the product could not be the subject of a certificate in the past. Under Article 5 of this Regulation, the certificate confers the same rights as are granted under the basic patent. The design thereof is such that the supplementary protection certificate is in a sense an extension of the patent.

SPC prevents the production of generic and biosimilar drugs even for the markets of countries outside the European Union. We remain worried about the long term loss of competitiveness of the European pharmaceutical industry, that will result in expenditures cut on innovation, research and development, hence less possible remedies needed in facing the challenge of ageing European population, smaller growth and limited new jobs across the EU.

We propose for your consideration a new legislative proposal, that would protect the values resulting from the current supplementary protection certificate for product, while allowing European entities to compete with other companies on the markets of third party countries. SPC Manufacturing Waiver Mechanism introduction (SPC MW) would enable production of medicines in Europe (while SPC protection is in force) for export only to third party markets where protection under SPC does not apply. the mechanism will not infringe intellectual property rights or the essence of SPC regulations, at the same time allowing smaller European entities to produce medicines for third party markets, while protecting them with additional certificates.

ZPP

Introducing the postulate into the legal order would require the European Commission to take a legislative initiative and submit a draft of an amendment to the regulations both to the Council of the European Union and the European Parliament. We hope that our arguments will be taken into due consideration and a project will be put forward to the above-mentioned EU Institutions.

Cezary Kaźmierczak
President

Marcin Nowacki
Vice-President