Getting The Deal Through

European Commission proposes SPC exemptions for generics selling outside the EU

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The European Commission has proposed amendments to the EU's supplementary protection certificate (SPC) regime to allow manufacturers based in the EU to develop and sell generic versions of patented treatments outside of the bloc.

The 28 May proposal introduces the idea of an "export manufacturing waiver" for generics, allowing them to get around the restrictions imposed by SPCs – which allow innovative drug

companies a five-year extension on the patent exclusivity for medicinal products within the EU.

SPCs were introduced in the EU in 1992 and sought to offset the losses to patent life, and profits, incurred by innovators whose products undergo lengthy compulsory testing and clinical trials before they gain marketing approval.

In its announcement of the proposed waiver, however, the EC noted that SPCs can have the unintended consequence of putting EU manufacturers at a disadvantage by preventing them from creating generic or biosimilar variants on protected products during the SPC period, even if they intend to sell them outside of the certificate's jurisdiction.

"This major competitive disadvantage entails a risk of delocalisation of manufacturing and loss of investment in Europe," the EC said, adding that SPCs also make it harder for generics to build up production capacity to a sufficient level to enter the EU market, as they must wait until the protections have lapsed to set up shop.

Elżbieta Bieńkowska, the commissioner for the internal market, industry, entrepreneurship and SMEs, said in a statement that the waiver "strikes a balance between the imperative to ensure the attractiveness of Europe for innovative pharmaceutical companies and the urgency to allow EUbased generics and biosimilar to compete on the global markets." Greater market access for generic manufacturers could generate an estimated €1 billion a year in sales she said, adding that increased competition in the sector would have positive effects on patient access to a wider choice of medicines.

The European Federation of Pharmaceutical Industries and Associations (EFPIA), however, was quick to criticise the proposal, which it said "reduces IP rights and thereby jeopardises patient access to innovative treatments."

"Approximately half the patent life of a new treatment is lost during the research, development and regulatory processes and the SPC went some way to restoring some of that patent life," EFPIA general counsel Kristine Peers added: "Granting an SPC manufacturing waiver erodes the foundations of medical research, putting the future of medical research in Europe at risk."

Hein van den Bos of Hogan Lovells in Amsterdam told *PLN* that he expected generics to welcome the proposal but that innovators would have a harder time accepting the changes. "Having the SPC regime changed, even in this narrow sense, is a limit to exclusivity rights that have been carefully crafted to strike a balance between stimulating innovation and keeping healthcare cost containable in Europe," he said. "The EC is careful in its proposal to say the changes only address manufacturing within the EU, and have not changed IP rights more generally, but innovators might see it as a loss of rewards for innovation."

Laura Opilio and Maria Letizia Patania of CMS Adonnino Ascoli & Cavasola Scamoni in Rome told *PLN* that the proposal would have the effect of allowing more generics to set up facilities inside the EU and not be forced to relocate to other jurisdictions and that this in turn would boost consumer trust in their products, which would be shown to have met the bloc's drug manufacturing standards.

"From another perspective the originators should not be penalised by the proposal because, although at first glance it certainly represents a limitation of the rights deriving from the SPC, it must be considered that the fact that the production centres of the generic competitors are located inside or outside the EU should not cause any harm from an economic perspective," they suggested.

In a memo (https://www.out-law.com/en/articles/2018/may/manufacturing-waiver-supplementary-protection-certificates/) published on Pinsent Masons' Out-Law blog, Dublin-based life sciences specialist Karen Gallagher says innovators "might take comfort from the fact that the proposal does contain a number of safeguards aimed at

ensuring that products are not diverted on to the EU market". These include requirements for manufacturers to publish details of their operations and follow specific labelling requirements for any SPC-protected export products.

Such measures "will make it easier for both SPC holders and public authorities to detect and fight such infringements, via the existing means of judicial redress offered under existing Intellectual Property Rights (IPR) enforcement legislation," the commission says.

Pinsent Masons' UK life sciences regulatory lawyers Catherine Drew and Charlotte Weekes add that the proposal would also prevent generic and biosimilar manufacturers from stockpiling drugs ahead of a particular SPC's expiry date for sale within the EU. They also point out that the new notification and labelling requirements could prove expensive and onerous for generics: "With this in mind it is unclear if the proposal represents a 'win' for those manufacturers that it is presented as".

"As far as costs are concerned, in addition to considering those related to the export process, the ones connected to the actual production process will be probably higher due to the higher cost of the workforce in Europe compared to other countries," Opilio and Maria Letizia Patania said. "It is in fact to be considered that the choice to relocate production sites outside the EU is often related to lower costs and is not linked to the presence of regulatory obstacles such as the SPC."