European Commission proposes manufacturing waiver for SPCs

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The European Commission has proposed to introduce an 'export manufacturing waiver' to Supplementary Protection Certificates (SPCs) to 'help Europe's pharmaceutical companies tap into fast-growing global markets and foster jobs, growth and investments in the EU'.

According to a press release of 28 May 2018, 'Supplementary Protection Certificates extend patent protection for medicinal products which must undergo lengthy testing and clinical trials prior to obtaining regulatory marketing approval. Thanks to the waiver, in the future EU-based companies will be entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the certificate, if done exclusively for the purpose of exporting to a non-EU market where protection has expired or never existed.'

Elżbieta Bieńkowska, Commissioner for Internal Market, Industry, Entrepreneurship and SMEs, states in the press release: 'Today's proposal strikes a balance between the imperative to ensure the attractiveness of Europe for innovative pharmaceutical companies and the urgency to allow EU based generics and biosimilar to compete on the global markets. This will help create growth and high-skilled jobs in the EU. It could generate €1 billion net additional sales per year and up to 25.000 new jobs over 10 years.'

The proposal amends Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

According to the explanatory memorandum, 'the EU has been a hub for pharmaceutical research and development (R&D) and production. Biosimilar production, for instance, started in 2006 in the EU, in other words much earlier than elsewhere, and given its excellent ecosystem for this type of production, the EU became a world leader in biosimilar development.

However, its competitive position is under threat today. While Europe's trading partners are increasingly involved in the manufacturing of generics and biosimilars, EU-based manufacturers of generics and/or biosimilars face a significant problem: during the SPC period of protection of the product in the EU, they cannot manufacture for any purpose, including export outside the EU to countries where SPC protection has expired or does not exist, while manufacturers based in those non-EU countries can do so.

This problem puts EU-based industry at a disadvantage vis-à-vis manufacturers located outside the EU, not only in global markets, but also in day-1 EU markets. This is because the certificate makes it more difficult for EU manufacturers to enter the EU market immediately after its expiry, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed. The same is not true of manufacturers located in non-EU countries where protection does not exist or has expired.

The problem is aggravated by the dynamics of the generics/biosimilars markets whereby, after expiry of patent/SPC protection of the reference medicine, only the first few generics/biosimilars to enter the market capture a significant market share and are financially viable. There is an urgent need to tackle this specific twofold problem, as the markets for generics and biosimilars are highly competitive and steadily growing, with a significant number of medicinal products entering the public domain – i.e. with the patents or the SPC coming to the end of their term – in the coming years.

This development will generate significant new market opportunities for generics, and for biosimilars in particular. Unless action is taken now, Europe risks missing the opportunities offered by this upcoming 'patent cliff', as the above unintended aspects of the current SPC regime act as a disincentive for companies willing to invest in the new generics and biosimilars opportunities. If the current legal barrier in Europe is maintained, companies wanting to produce generics or biosimilars might start to manufacture outside the Union.'

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