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The European Commission presents its proposal for SPC Manufacturing Waiver proposal limited to exports

Proposal 2018/0161 (COD) for an amendment of Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products

An interesting proposal

The proposal of the so-called SPC Manufacturing Waiver presented by the European Commission will permit that while a Supplementary Protection Certificate (SPC) is in force, generics or biosimilars may be manufactured in the EU in order to be exported to countries where they can be marketed without breaching valid patents. According to the Commission, the purpose is to help European pharmaceutical companies to take advantage of the fast growing global markets, encourage employment and investments in the EU.

The proposal comes with safeguards aiming to provide transparency and avoiding that products that may infringe intellectual property rights are introduced in the European markets. In this regard, manufacturers willing to adhere to the SPC Manufacturing Waiver must notify their activity to a national authority and products manufactured under this system shall incorporate a label indicating that they are intended to be exported.

The SPC Manufacturing Waiver is expected to be applied only with regard to SPCs granted after the new regulation enters into force.

...but maybe insufficient

In the field of medicinal products, any debate about intellectual property raises emotional reactions that difficult a detailed analysis of the situation. This case is not an exception and our opinion is that the progress made with the SPC Manufacturing Waiver will be very limited without any real benefit for innovator companies.

The proposal is interesting, but insufficient. It is true that there is a risk of loss of investments in the EU because generics or biosimilars destined to be exported cannot be manufactured in the EU but also (and especially) because in the EU generics or biosimilar companies cannot manufacture and stock products in Europe in order to enter the EU market right after expiry of the corresponding SPC.

Because of this, European companies entrust manufacturers of third countries with the development and manufacture of generics and biosimilars that will still arrive to the EU the day after the SPC has expired. Innovators gain nothing since the generic or biosimilar reaches the market on day 1 after expiry of the SPC anyway. The real beneficiaries are the manufacturers of thirds countries, who have developed high level industrial and commercial abilities, operating under EU-GMPs, and who are benefiting from the transfer of technology that European manufacturers have carried out.

Consequently, we think that it makes little sense to legislate thinking only about the markets of countries outside of the EU. European manufacturers should be able to develop and manufacture, in the EU, the generics and biosimilars that could be marketed in the EU when intellectual property rights cease to be in force. Making this possible would benefit the European industrial network without harming the innovator companies.