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The European Commission proposes an 'export manufacturing waiver' for Supplementary Protection Certificates

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On 28 May 2018 the European Commission presented a proposal for a Regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products¹, introducing a manufacturing exemption for export purposes (so-called 'export manufacturing waiver') during the term of a Supplementary Protection Certificate (SPC).

SPCs are intellectual property rights that extend by up to five years² the patent monopoly for a medicinal product authorised by national or EU regulatory authorities, and are governed by Regulation (EC) No 469/2009³. They aim at compensating the patentee for the 'loss' of effective patent protection caused by the lengthy compulsory testing and clinical trials required before a medicine is authorised to be placed on the EU market, and at the same time reward investment in innovation, protect intellectual property and prevent the relocation of cutting-edge pharmaceutical research outside of the EU.

The proposal was announced within the Single Market Strategy⁴, in whose context the European Commission has affirmed its intention to '*... improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations...*' and recalibrate certain aspects of patent and SPC (Supplementary Protection Certificate) protection. Also the European Parliament, in its 2016 Resolution on the Single Market Strategy⁵, stressed the importance of revisiting the European SPC regime, urging the Commission '*... to introduce and implement before 2019 an SPC manufacturing waiver to boost the competitiveness of the European Generics and Biosimilar Industry in a global environment, as well as to maintain and create additional jobs and growth in the EU, without undermining the market exclusivity granted under the SPC regime in protected markets...*'.

Following the adoption of the Single Market Strategy, a number of studies on the EU SPC framework were conducted⁶. Among the issues having emerged, the Commission noted a trend to lose export markets (including new business opportunities), and a lack of timely (namely 'day-1') entry onto Member State markets following expiry of the SPC, for EU-based manufacturers of generics and biosimilars, due to unintended effects stemming from the current EU SPC regime, first introduced in 1992, and in view of changes in the pharmaceutical sector (e.g. the increasing importance of biosimilars).

¹ COM(2018) 317 final, available at the following [LINK](#).

² The so-called Paediatric Regulation [Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, OJEU L 378, 27.12.2006] provides for SPCs for a medicinal product to be extended by a further six months if the authorised medicine has been part of a 'paediatric investigation plan'.

³ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products. OJEU L 152, 16.06.2009.

⁴ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 28.10.2015, *Upgrading the Single Market: more opportunities for people and business*, COM(2015) 550 final, available at the following [LINK](#).

⁵ European Parliament Resolution of 26.5.2016 on the Single Market Strategy, 2015/2354(INI). Available at the following [LINK](#).

⁶ See the following [LINK](#)

While accomplishing the objective of extending originators' market exclusivity to recoup the research and development investments made and past loss of "regulatory time", SPCs may put EU based manufacturers of generics and biosimilars at a disadvantage towards the non-EU based industry, since, 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 competitive disadvantage entails a risk of delocalisation of manufacturing and loss of investment and jobs in Europe. Moreover, SPCs make it more difficult for EU generic manufacturers to enter the EU market immediately after expiry, since that they are not in a position to build up production capacity protection has lapsed⁷. Many SPCs will start to lapse from around 2020, with a significant number of medicinal products entering the public domain. This will generate new opportunities in the fast-growing generic and biosimilar market.

The proposed 'export manufacturing waiver' aims at addressing this issue by allowing EU manufacturers of generics and biosimilars to lawfully engage in manufacturing in the territory of a Member State, during the life of the SPC, for the exclusive purpose of exporting their products to non-EU markets where protection does not exist or has expired. The waiver will also address the 'day-1' issue, since a manufacturer that has set up a manufacturing line for export purposes will easily be able, after the SPC expiry, to use the same to manufacture generics or biosimilars for the EU market⁸.

The proposal is expected to contribute to Europe's competitiveness as a hub for pharmaceutical R&D and manufacturing and help new pharmaceutical companies start up and scale up in high growth areas, boosting investment and job creation in the Union. As the manufacturing capacity established for export purposes could, prior to the expiry of the certificate, be used with a view to supplying the EU market from day-1, it is also expected to boost, to some extent, access to medicines in the Union by enabling generic and biosimilar medicines to enter the market more quickly, thereby ensuring the availability of a wider choice of affordable medicines once the period of patent and SPC protection is over.

The proposal is not intended to affect SPC holders' rights during the full SPC term. This will be achieved by providing a series of safeguards to ensure transparency and avoid the diversion onto the Union market of generics and biosimilars that are produced for export and in respect of which the originator product is protected. In particular, businesses intending to start manufacturing for export purposes will be under an obligation to notify the competent authorities, and the information contained in that notification will be made public. Moreover, they will have to inform their supply chains that the products in

⁷ The same is not true of manufacturers located in non-EU countries where protection does not exist or has expired.

⁸ These manufacturers should comply fully with the applicable pharmaceutical legislation and, to exemplify, possess a valid marketing authorisation at the time the products are placed on the EU market.

question are only for export. Finally, any export of SPC-protected products outside the Union will be subject to compliance with specific labelling requirements. These measures are expected to prevent IP-infringing products from re-entering Member State markets and interweave with the Commission's 2017 package to reinforce IP rights that focused, in particular, on IP rights enforcement⁹.

In relation to IP rights protection in a broader perspective, it is worthwhile noting that the proposal concerns SPCs, not their basic patents during their regular life. The exclusive rights conferred by a patent, also, inasmuch as they cover manufacturing for export purposes, would remain unaffected. In particular, Article 28 of the TRIPs Agreement¹⁰ will still include the making of the product which is the subject matter of a patent, in the list of acts forbidden to third parties without the patent owner's consent, notwithstanding any manufacturing waiver.

Under Italian law, even a more comprehensive rule applies, whereby (within the limits and at the conditions established by the Italian Industrial Property Code, IPC) '*... [T]he patent rights for an industrial invention consist of the exclusive right to implement the invention and profit from the same in the territory of the Country...*'¹¹. In this regard, the Italian Supreme Court clarified that '*... [T]he profit to which the law alludes is not only the one implied ... by the sale of the product to the market, but any benefit that could be drawn from the patented invention...*'¹². According to the case-law, manufacturing the patented product within national territory currently amounts to an infringement even if the product is only destined to export¹³.

Therefore, as a consequence of the proposed amendment, the overlap between patent protection and SPC protection may become imperfect and such asymmetry should be taken into account by patent/SPC owners as well as generic "early" manufacturers, unless a change in the domestic legislation to coordinate Article 66 of the IPC with the new Regulation is introduced.

⁹ In November 2017, as a deliverable from the Single Market Strategy, the Commission presented a package of measures to further reinforce enforcement, including providing guidance on implementing the EU Directive on the enforcement of intellectual property rights. The package was endorsed by the Council on 12.03.2018. See the following [LINK](#).

¹⁰ WTO, Agreement on Trade Related Aspects of Intellectual Property Rights, Article 28: '*... 1. A patent shall confer on its owner the following exclusive rights:*

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing ⁽⁶⁾ for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts...'.

¹¹ Article 66, para. 1, IPC.

¹² Civil Cassation, Sect. I, 03.04.2003, no. 5112.

¹³ See, among others, Court of Milan, 10.02.1997, in *GADI*, 1997, 3650; Court of Milan, 22.03.1997, published in *GADI*, 1997, 3654; Court of Alba, 26.02.2001, published in *GADI*, 2001, 4264.