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EU introduces new SPC manufacturing waiver

Cristina Biggi of **Bugnion** examines the introduction of the new SPC manufacturing waiver, including the process that led to its creation and the amendments it makes to the SPC regulation

What is a supplementary protection certificate?

Supplementary protection for patented medicinal products was created in the European Union (EU) in 1992 with Council Regulation No. 1768/92 of June 18 1992 – repealed by Regulation (EC) No. 469/2009 of May 6 2009 which is an updated version of the 1992 regulation – with the purpose of fostering investments in the development of new medicinal products within the European Union. It aimed to do this by offering adequate prolonged patent protection that could compensate for the time necessary to obtain a marketing authorisation for placing a drug on the market, similar to legislation already adopted by other developed countries. Efforts from the European Union to provide a uniform supplementary protection regulation for the member states came from a desire to prevent the heterogeneous development of national laws leading to disparities which would likely create obstacles to the free movement of medicinal products within the union, thereby directly affecting the functioning of the internal market.

According to Article 13 of Regulation (EC) No. 469/2009 (the SPC regulation) the duration of supplementary protection is equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the union, reduced by a period of five years. The maximum duration cannot exceed five years from the date on which it takes effect.

Articles 4 and 5 of the SPC regulation state that the supplementary protection certificate, as far as the product covered by the authorisation to place the medicinal product on the market and any

use of that product as a medicinal product that has been authorised before the expiry of the certificate are concerned, provides the same rights as conferred by the basic patent and is subject to the same limitations and obligations. This means that a valid supplementary protection certificate prevents third parties from manufacturing, selling, importing and offering for sale a generic or biosimilar version of the medicine that is the subject of the marketing authorisation. This includes manufacturing for the purpose of exporting the medicine to third countries outside the EU where supplementary protection has already expired or does not exist, or for the purpose of stockpiling for entry into the EU market immediately after the expiry of the supplementary protection certificate (SPC).

Indeed, during both the patent and the SPC protection period, the patent and SPC owners have the manufacturing and marketing monopoly for the active ingredient of a given drug.

Single market strategy report and Inception Impact Assessment

On October 28 2015, the European Commission issued a new single market strategy which included a focus on the problem of loss of competitiveness of EU-based manufacturers of generic and biosimilar drugs with respect to companies operating in non-EU countries where SPC protection does not exist (e.g. Brazil, Russia, India and China). According to the single market strategy report, non-EU generic and biosimilar manufacturers enter markets in which patent protection has expired up to five years earlier than EU based manufacturers, due to the fact that EU-based companies are not allowed to produce in the EU member states during the period of the SPC protection, while manufacturers based in non-EU countries where SPC protection does not exist can start production as soon as the relevant patent has expired. This situation, according to the single market strategy report, could have the effect of encouraging European manufacturers of generics and biosimilars to move their production outside the EU – either via delocalisation or long-term outsourcing contracts – with the consequence of a loss of jobs and investments within the EU.

Cristina Biggi

Cristina Biggi graduated in chemistry (master's degree) from the University of Pavia (Italy) in 1999 and then completed her PhD studies at the University of Milan in 2002, including one year spent as a visiting student to the University of Southampton (UK). During her PhD she worked on the synthesis of novel organic compounds with pesticide activity and, in Southampton, on the solid phase synthesis of antiparasitic peptides.

Prior to joining Bugnion in 2008, she was a trainee in patent law at a major intellectual property law firm in Milan for almost five years.

She is a qualified European and Italian patent and design attorney and a qualified litigator for the upcoming Unified Patent Court. In 15+ years of practice, she has drafted, filed and prosecuted hundreds of patent cases before the EPO, WIPO and the Italian PTO; she also deals with freedom to operate, infringement and patentability opinions, opposition and appeal proceedings at the EPO and national litigations.

Her technical expertise is chemistry, with extensive experience in technological areas such as organic compounds, processes, compositions, formulations, polymer fibres for woven-non-woven fabrics, kits for analysis, natural extracts, medical uses and methods, non-medical uses and methods, polymers, cosmetics, paintings, coatings, nanotechnology, fertilisers, bio-stimulants, crystallography, catalysts, pharmaceutical compounds and their use, cosmetic and pharmaceutical formulations, biomaterials for medical use, diagnostic and therapeutic methods, electrochemical cells, food chemistry, microorganisms, peptides, probiotics. She has also filed and prosecuted plant variety applications.

She has been leading the chemistry and life sciences patent group at Bugnion since 2011. She is a partner at Bugnion.

In addition, the European Commission expressed concerned about the impact of delayed entry of generic and biosimilar drugs after the expiry of SPC protection on national health budgets, also caused by the prohibition on manufacturing such medicines during the SPC period.

Accordingly, the report stated that, following stakeholder consultation, a reconsideration of the SPC regulatory framework of the EU will be conducted with a particular focus on the implementation of a SPC manufacturing waiver for export purposes that could allow manufacturers of generic and biosimilar medicines to compete on an equal footing with competitors from non-EU countries.

In February 2017, the European Commission published an Inception Impact Assessment on the adoption of an SPC manufacturing waiver aiming to inform stakeholders on the initiative and invite them to provide feedback on the commission's understanding of the problem and provide different opinions. This was followed by a public consultation held between October 2017 and January 2018. In addition, a number of studies relating to the EU SPC framework were conducted between 2015 and 2018 and, finally, a legislative proposal of the European Commission amending Regulation (EC) No. 469/2009 was issued on May 28 2018. The legislative proposal was limited to exempting manufacture of generic or biosimilar drugs for export. The exemption of stockpiling for day-one commercialisation after expiry of the relevant SPC was added later, after an initial proposal from the European Parliament's Committee on Legal Affairs to allow storing of generics or biosimilars two years before the expiry of the relevant SPC.

After fierce discussion and criticism relating to the introduction of a manufacturing waiver not only for export but also for stockpiling by some of the member states such as the UK, Sweden, Denmark and Malta, the European Council adopted a hydrid position, allowing the manufacturing waiver for the purpose of stockpiling only within the last six months of SPC protection, rather than the final two years of validity of the certificate.

The proposal was approved with a large majority and Regulation (EU) 2019/933 (SPC manufacturing waiver regulation) was adopted by the European Union's Parliament on May 20 2019 and entered into force on July 1 2019.

Amendments

The SPC manufacturing waiver regulation represents an amendment to the SPC regulation No. 469/2009.

In particular, Article 5 of the SPC regulation, relating to the effects of an SPC certificate, has been re-written to provide for a derogation to the original formulation that a certificate confers the same rights as the basic patent. The derogation can be summarised as follows:

- The manufacturing of SPC-protected active ingredients and corresponding medicinal products for the purpose of (i) export to third countries outside the EU as well as (ii) stockpiling for day-one entry to the EU market immediately after SPC expiry is no longer prohibited.

- The manufacture for export will be allowed throughout the entire SPC lifetime whereas the manufacturing and stockpiling for day-one marketing in the EU will be permitted only during the last six months before SPC expiry.

- A generic or biosimilar manufacturer intending to benefit from the manufacturing waiver has to notify not only the national patent office that granted the SPC in question, but also the SPC holder no later than three months before commencing the production. The competent national patent office will be required to publish the notified information together with the date of notification as soon as possible. Moreover, national patent offices will be allowed to charge a fee for such notifications.

- The information to be notified to the competent national patent office includes the name and address of the manufacturer; an indication of whether the intended manufacture is for the purpose of export, storing, or both export and storing; the EU member state where the manufacture is to take place (and, if applicable, the member state where the first related act prior to manufacture is to take place); the number of the SPC in question; and, in the case of export to third countries, the reference number of the marketing authorisation in each third country of export. Any subsequent changes to this information must also be notified.

- The new "EU export" logo must be affixed to the outside of products made for the purpose of export to third countries outside the EU.

The provisions relating to the information that the manufacturer must notify to both the patent office and the certificate holder have been inserted for transparency reasons and to safeguard the rights of the certificate holder to enforce protection in the union and check compliance with the conditions set out in the SPC manufacturing waiver regulation (as stated in preamble (13) of the regulation and in paragraph (4) of Article 5(2)).

"The manufacturing of SPC-protected active ingredients and corresponding medicinal products for the purpose of (i) export to third countries outside the EU as well as (ii) stockpiling for day-one entry to the EU market immediately after SPC expiry is no longer prohibited."

Other provisions in favour of the certificate holder have been inserted in paragraphs (3) and (9) of Article 5 of the regulation: paragraph (3) forbids importation of the medicinal product or the active ingredient into the union for the purpose of repackaging, re-exporting or storing; paragraph (9) obliges the manufacturer to inform any person in a contractual relationship with it (who is engaged in acts that are the subject of the manufacturing waiver) that to place on the market, import or re-import the medicinal product or the active ingredient into the EU may constitute infringement of the SPC certificate.

A new Article 21a is inserted in the SPC regulation, which provides for an evaluation every five years in order to asses whether the objectives of the new derogations have been achieved and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee. In addition to evaluating the impact of the exception of manufacture for the purpose of export, special account will be taken of the effects of manufacturing for the purpose of stockpiling for day-one commercialisation on public health expenditure, and of whether the waiver and, in particular the period of six months prior to the expiry of the certificate, is sufficient to achieve the objectives referred to in Article 5, including public health.

This provision leaves the door open to further developments in the sector including a possible extension of the six month period for manufacturing and storing the medicinal product and the active ingredient in view of day-one commercialisation or, conversely, for a shortening of the period.

Finally, transitional provisions safeguard the rights conferred by SPC certificates granted before July 1 2019 to which the manufacturing waiver is not applicable.

The SPC manufacturing waiver will apply to all new SPCs filed on or after the day of entry into force of the SPC manufacturing waiver regulation, i.e. on or after July 1 2019.

For all other SPCs – i.e. SPCs that are filed before, but take effect only after, the entry into force of the SPC manufacturing waiver regulation – the manufacturing waiver will initially not apply but will become applicable after three years from its entry into force.

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