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SPC manufacturing waiver enters final legislative stage in the EU, with possible extension to allow stockpiling

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The introduction of an SPC "manufacturing waiver" in the European Union, aimed at boosting the competitiveness of EU-based generics and biosimilar industry, gains momentum as the current EU legislative period draws to a close.

Under the EU's legislative procedure, the European Commission's initial proposal for a regulation amending Regulation (EC) 469/2009 on SPCs for medicinal products (COM(2018) 317 final), issued on 28 May 2018 (as previously reported on this blog), was submitted to the European Parliament where it has been scrutinized under the responsibility of the Committee on Legal Affairs (JURI).

The final report of the Committee on Legal Affairs was adopted on 23 January 2019 (PDF), and was tabled on 29 January 2019 for a future plenary first reading in the European Parliament. It has undergone significant revisions as compared to the preceding draft report issued by the Committee on Legal Affairs on 30 October 2018 (which was previously discussed on this blog).

The most notable legislative amendments finally endorsed by the Committee on Legal Affairs include:

- The manufacturing waiver is to be broadened to allow not only the making of the SPC-protected active ingredient(s) and the corresponding medicinal product for the exclusive purpose of export to third countries outside the EU, but also the making and storing of the protected product for "day-1 entry" to the EU market immediately after SPC expiry. Such stockpiling will be allowed "during the final 2 years of validity" of the respective SPC.
- A person intending to benefit from the manufacturing waiver must notify not only the national patent office that granted the SPC in question, but will also be required to directly inform the SPC holder in writing. This must be done no later than two months before the start date of the manufacturing (which is less than the three months foreseen in the draft report of the Committee on Legal Affairs, but is still longer than the mere 28 days envisaged in the original Commission proposal).
- A standard form (contained in a new annex) must be used for the notification to each competent national patent office.
- The protection of confidential and commercially sensitive information of generics

and biosimilar producers invoking the manufacturing waiver is further strengthened as compared to the draft report of the Committee on Legal Affairs. For example, such producers will no longer be required to indicate the precise address(es) of the premises where the making is to take place but must only indicate the corresponding EU member state. Moreover, the national patent office notified by the producer shall only publish the corresponding SPC number, while all further information provided by the producer shall neither be published nor made available for inspection by the public.

- A definition of the producer benefitting from the manufacturing waiver is to be added, which defines the "maker" as meaning "a legal person established in the Union on whose behalf the making of a product or a medicinal product containing that product, for the purpose of export to third countries or storing during the final 2 years of validity of the certificate is done".
- There will be a two-pronged transitional regime for the applicability of the manufacturing waiver: It will apply to all SPCs for which the underlying basic patent expires on or after 1 January 2021 (which is considerably earlier than the date of 1 January 2023 initially foreseen in the draft report of the Committee on Legal Affairs), and it will additionally apply to all SPCs that are applied for on or after the entry into force of the regulation introducing the manufacturing waiver (even if the underlying basic patent expires before 1 January 2021).
- The amendments establishing the manufacturing waiver are to be introduced into Article 5 ("Effects of the certificate") rather than Article 4 ("Subject matter of protection") of the SPC Regulation (EC) 469/2009. This clarifies that only the effects, not the scope, of the SPC right are modified.

The allowance of manufacturing and stockpiling of SPC-protected medicinal products for day-1 entry to the EU market goes far beyond the scope of the original Commission proposal and is certainly the most controversial amendment tabled by the European Parliament's Committee on Legal Affairs.

To allow such stockpiling specifically during the final two years of the SPC life time could create additional problems, particularly in connection with paediatric extensions which allow the SPC term to be extended by six months. Thus, it should be borne in mind that the paediatric extension is ancillary to the SPC itself, and does therefore not constitute a distinct IP right but merely alters the term of an SPC, as recently acknowledged by the CJEU in *Pfizer Ireland* (C-681/16). An application for the paediatric extension of an already granted SPC must be filed no later than two years before the expiry of the SPC, while the actual grant of the paediatric extension may take place considerably later. This could result in a prolonged period of legal uncertainty as to the allowance of manufacturing for the specific purpose of stockpiling in cases where an application for a paediatric extension is pending, but not yet granted, in the final two years of the basic (unextended) SPC term.

If the manufacturing waiver were indeed to be introduced in this form, how could such potential practical issues be resolved? It is noteworthy that the Committee on Legal Affairs also endorsed an amendment to recital 20 of the SPC Regulation, requiring the Commission to examine a possible further extension of the manufacturing waiver for stockpiling purposes. This objective could become relevant in combination with the proposed amendment to new Article 21a, according to which the Commission will be

required to carry out a reevaluation not only of the manufacturing waiver but also of "the SPC system" with regard to "the ability of generics to enter the Union market" every three years (rather than a reevaluation merely of the manufacturing waiver every five years, as set out in the original Commission proposal). It would seem that these amendments, if accepted, could facilitate the resolution of future issues with the manufacturing waiver by further curtailing the rights of SPC holders.

A significant improvement of the safeguards for SPC holders, however, is provided by obliging generics and biosimilar producers to directly inform the SPC holder of the intended manufacture, rather than encumbering the latter with the burden to actively monitor the relevant publications of the national patent offices of all EU member states. This rectifies one of the most apparent shortcomings of the original Commission proposal.

Finally, the new two-pronged transitional regime will cast a tight net which will, simply put, apply to all SPCs except for those that cumulatively fulfill the conditions of (i) coming into force by the end of December 2020 and (ii) having been filed before the entry into force of the regulation establishing the manufacturing waiver (which could mean by mid-2019). While these rules, if enacted, would leave very little time to adapt to originator companies having made considerable investments in pharmaceutical research in the expectation of being able to rely on the existing SPC regime, they still seem preferable over the original Commission proposal. The latter intended to couple the applicability of the manufacturing waiver to the SPC grant date, which would have resulted in an unnecessary and complex legal fragmentation caused by the different durations of the SPC grant procedures before the various national patent offices (which could lead to differences in the applicability of the manufacturing waiver even between parallel SPCs that are simultaneously filed in different EU member states on the basis of the same European patent and the same centralized marketing authorization).

As an aside, what is surprising, if not alarming, about the final report of the European Parliament's Committee on Legal Affairs is the unusual extent of (presumed) legislative drafting errors. For example, the proposed amendments to Article 5 of the SPC Regulation establish, in new paragraph 2, that "*the certificate shall not confer protection against certain acts … if the following conditions are met: [(a)-(c)…;] (d) the notification to the certificate holder does not contain any confidential or commercially sensitive information; (e) the information provided by the maker to the certificate holder is treated as strictly confidential by the certificate holder and is not published; …*". On a literal reading, new Article 5(2) would seem to make the right of a generics or biosimilar producer to rely on the manufacturing waiver dependent on the condition that they do not notify confidential information to the SPC holder and the further condition that the SPC holder treats the information actually provided by the manufacturer as strictly confidential. This would allow the SPC holder to prevent a generics or biosimilar producer from making use of the manufacturing waiver simply by not treating the information received as confidential, which does obviously not make sense. Similarly, it is confusing to see that the Committee on Legal Affairs has deleted the requirement for generics and biosimilar producers to indicate the address(es) of the premises where the making is to take place (see new Article 5(3)(b) and the deletion of Article 4(3)(b)) and the requirement to identify the product in

question (see new Article 5(3) and the deletion of Article 4(3)(c)) but has retained the corresponding fields in the standard form to be used for notifying the competent national patent offices (see Annex-I, points b and c). Not only pessimists may be tempted to imagine that the provision of this information might be considered as voluntary by some national patent offices and as obligatory by others. These drafting issues are compounded by clerical mistakes, such as wrong back-references (e.g., the reference in new Article 5(2)(b) to the non-existent point (f) of Article 5(3), the reference to the deleted Articles 4(2) to (4) in new Article 21a, and the reference to deleted Article 4(2) in Annex-I), as well as stylistic nadirs like "*The the competent industrial property office … the office shall provided that information*" in new Article 11(4). All this gives reason to worry that maintaining the EU's usual legislative quality under the pressure of finalizing the regulation introducing the SPC manufacturing waiver before the European elections in May 2019 will be challenging.

With the final report of the European Parliament's Committee on Legal Affairs having been adopted, the Committee decided to open inter-institutional negotiations with the Council and the Commission.

In the meantime, the Council of the EU has produced several successive compromise proposals based on discussions in the Council Working Party on IP (the compromise proposal of 22 November 2018 with detailed explanations of the proposed changes has been made available by Politico), and finally agreed on a mandate for negotiations with the European Parliament on 16 January 2019 which includes the text endorsed by the Council. In substance, it is rather close to the amendments proposed in the earlier draft report of the European Parliament's Committee on Legal Affairs, and contains further sensible amendments such as the requirement to affix the "EU export" logo to both the outer packaging and, where feasible, the immediate packaging. Unsurprisingly, however, the text endorsed by the Council does not cover stockpiling which, as the Council Presidency noted in November 2018, would go substantially beyond the scope of the original Commission proposal and would not result in agreement in Council. Yet, it remains to be seen which position will eventually prevail in the further EU legislative procedure as the trilogue negotiations between Parliament, Council and Commission begin.

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