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SPC manufacturing waiver adopted by European Parliament

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The European Parliament has finally adopted the legislation introducing an SPC manufacturing waiver in its last plenary session before the upcoming European elections. The corresponding legislation was endorsed today on 17 April 2019, with 572 votes in favor, 36 votes against, and 22 abstentions. The vote was preceded by a discussion in plenum yesterday late in the evening (see here for a video recording, and here for the minutes of the debate).

The final text of the new regulation amending Regulation (EC) 469/2009 on SPCs for medicinal products is based on the provisional agreement reached in the inter-institutional trilogue negotiations between Parliament, Council and Commission in February 2019 (as previously reported on this blog), which has merely undergone formal and linguistic revisions by the European Union's jurists-linguists.

The key features of the SPC manufacturing waiver as now adopted by the European Parliament can be summarized as follows:

- The effects of supplementary protection certificates will be curtailed to no longer confer protection against 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-1 entry to the EU market immediately after SPC expiry.
- The manufacture for export will be allowed throughout the entire SPC lifetime whereas the manufacturing and stockpiling for day-1 marketing in the EU will be permitted only during the last six months before SPC expiry.
- A generics or biosimilar producer intending to benefit from the manufacturing waiver has to notify not only the national patent office that granted the SPC in question, using a standardized form, but must also directly inform the SPC holder no later than three months before the intended start of manufacture (or the first related act). The competent national patent office will be required to publish the notified information together with the date of notification as soon as possible. Moreover, the national patent offices will be allowed to charge a fee of such notifications.
- The information to be notified to the competent national patent office includes the name and address of the manufacturer; an indication 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 authorization 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 outer packaging and, where feasible, the immediate packaging of products made for the purpose of export to third countries outside the EU.
- Under the agreed transitional regime, the applicability of the manufacturing waiver will depend on the filing date of an SPC and the date when the SPC takes effect:
    - The SPC manufacturing waiver will apply to all new SPCs filed on or after the day of entry into force of the corresponding legislation.
    - Conversely, the manufacturing waiver will not affect any SPCs that are already in effect when the corresponding legislation enters into force.
    - 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 legislation – the manufacturing waiver will initially not apply but will become applicable after three years from the entry into force of the corresponding legislation.

Following the adoption of the new regulation introducing the SPC manufacturing waiver by the European Parliament, it must still be adopted by the Council of the EU, which has already signaled its willingness to approve the European Parliament's position and adopt the regulation as agreed in the preceding trilogue negotiations.

The new regulation will then enter into force on the 20th day after its publication in the Official Journal of the EU, which can be expected to occur approximately in June or July 2019.

Dr. Alexa von Uexküll *and* ***Oswin Ridderbusch****, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the handbook* ***European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe*** *published by Wolters Kluwer in November 2018.*

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