SPC manufacturing waiver enters into force in July 2019

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The legislative procedure introducing an SPC manufacturing waiver in the European Union has been completed today on 11 June 2019 with the publication of the corresponding new Regulation (EU) 2019/933 of 20 May 2019 (PDF) in the Official Journal of the EU. The manufacturing waiver provisions will enter into force on the 20th day after publication, i.e. on 1 July 2019.
In consequence, SPCs that are applied for in the EU member states on or after 1 July 2019 will no longer confer protection against the manufacture of active ingredients and corresponding medicinal products for the purpose of export to third countries outside of the EU, nor against the manufacturing and stockpiling for day-1 entry to the EU market immediately after SPC expiry. The export exemption will apply throughout the entire SPC term while stockpiling will only be allowed during the last 6 months before SPC expiry.

The introduction of an SPC manufacturing waiver had been endorsed in the EU's single market strategy adopted in 2015 with the aim of boosting the competitiveness of Europe's generics and biosimilar industry, and a corresponding legislative proposal limited to exempting manufacture for export alone was put forward by the European Commission on 28 May 2018. The exemption of stockpiling was only belatedly added by the European Parliament's Committee on Legal Affairs (as previously reported here and here on this blog) against the initial resistance of the Committee's rapporteur and the Council of the EU, and met fierce criticism up until the formal adoption of the corresponding legislation last month (as reported here). On the other hand, the European Parliament deserves credit for having substantially improved the safeguards for SPC holders against abuses of the manufacturing waiver, most notably by requiring generics and biosimilar producers wishing to rely on the manufacturing waiver to notify not only the national patent offices of those member states where production and any first related acts should take place but also to directly inform the SPC holder (as reported here and here). The further features of the SPC manufacturing waiver have been previously summarized on this blog.

Under the applicable transitional regime, the manufacturing waiver will not affect SPCs that are already in effect on 1 July 2019. For SPCs that are filed before this date but come into effect only afterwards, the manufacturing waiver will become applicable only after 3 years, i.e. from 2 July 2022 onwards. Where possible, it is thus advisable to file new SPC applications by 30 June 2019 in order to benefit from this 3-year transitional period.

The new Regulation (EU) 2019/933 also requires the European Commission to carry out an evaluation of the manufacturing waiver provisions by 1 July 2024 at the latest, and then again every 5 years, in order to assess their impact and particularly to determine whether the 6-month period for stockpiling is sufficient to achieve the objective of day-1 launch of generics and biosimilars in the EU. It remains to be seen whether any attempts to readjust the scope of the SPC manufacturing waiver will be made on this occasion.

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 2018.*