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EU adopts SPC manufacturing waiver under protest from several member states

Oswin Ridderbusch, Alexa von Uexküll (Vossius & Partner) · Tuesday, May 14th, 2019

After the European Parliament adopted a controversial new regulation introducing an SPC manufacturing waiver for export and stockpiling in its last plenary session on 17 April 2019, as previously reported on this blog, the corresponding legislative act has now also been adopted by the Council of the European Union in its meeting today on 14 May 2019.

While it had been widely expected that the Council would approve the European Parliament's position and adopt the SPC manufacturing waiver legislation, this came under vehement protest from several member states in light of the extension of the waiver to allow not only manufacturing for export but also stockpiling for "day-1 entry" to the EU market immediately after SPC expiry.

Thus, Denmark recorded in a [written statement](#) that it does not believe that a balanced approach has been achieved, and that the compromise now reached may generate significant damage for the innovative pharmaceutical industry. "*By allowing storing of medicinal products and affecting acquired rights of the SPC holders, Denmark believes that the result is disproportionate and goes far beyond what is necessary in order to achieve with the objective of the proposal. The absence of meaningful safeguards for storing will undermine legal certainty for the generic, biosimilar and innovative industry. It will also further deteriorate market conditions for investments in research and innovation, which are, by far, higher than any benefit that the SPC waiver proposal can generate.*" Czechia and Malta similarly voiced serious concerns, with Czechia denouncing the limitation of the rights of SPC holders and the weakening of intellectual property protection in Europe.

Yet, under the qualified majority voting rules which have only recently been extended to the field of intellectual property by the Lisbon Treaty, the Council approved the SPC manufacturing waiver legislation with the votes of 22 member states in favor, representing 80.14% of the EU population, whereby the required qualified majority (at least 55% of the member states, i.e. 16 states, which must account for at least 65% of the population) was comfortably surpassed. Denmark, Malta, Sweden and the United Kingdom notably voted against this legislation, with Austria and Czechia abstaining.

Following the adoption of the new EU regulation introducing the SPC manufacturing waiver by both the European Parliament and the Council, it must now be signed by the two institutions' respective presidents and published in the Official Journal in order to come into force. A [summary of the key features of the SPC manufacturing waiver](#) as now adopted has been provided in an

earlier post on this blog. The legal text of the new regulation is available [here](#).

UPDATE: The new regulation introducing the SPC manufacturing waiver was signed by the President of the European Parliament and the President of the Council on 20 May 2019 (see here for the [updated text of the new regulation](#)). It will come into force on the 20th day after its publication in the Official Journal of the EU, which should happen anytime soon.

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.

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