Press Release

Court decision on Supplementary Protection Certificate (SPC) manufacturing waiver risks undermining its use

Brussels, 18 January 2024

Medicines for Europe and its members are strongly concerned by the first judgement on the Supplementary Protection Certificate (SPC) manufacturing waiver issued by the Munich District Court, Germany in October 2023.

The SPC manufacturing waiver is a legal tool enacted in 2019, aimed at enabling the manufacture of medicines, under certain conditions, during the up-to-5-year extension of the market protection of certain patented medicinal products in the EU, to preserve the competitiveness of the European generic and biosimilar medicines industry, stimulate investments in medicines manufacturing in Europe and avoid delocalisation in the medicines industry.

In this judgement, the Munich District Court adopted an inordinately restrictive interpretation of the SPC manufacturing waiver, which cannot be derived from the letter of the law, and which contradicts the purpose and spirit behind the amendments that were introduced during its prosecution until its final approval. This utterly frustrates the aims of the legislation and disincentivises investments in Europe.

The judgement purports that SPC manufacturing waiver for export would require notification of a marketing authorisation (MA) number - even if no MA number is publicly available - or the disclosure of confidential information about future country of submission, deducing those requirements from an alleged need to ensure that no intellectual property rights should exist in the foreign country of export.

Medicines for Europe and its members strongly disagree with this interpretation of the Munich District Court, as neither requirement is supported by the letter of the law and are in conflict with the objectives of the SPC manufacturing waiver, as evidenced by the legislative history and its explanatory memorandum.

The judgment further suggests that for manufacturing in the EU and export to a third country to be permissible, a granted marketing authorisation in such third country is required, a position which is fundamentally wrong and is a complete misunderstanding of which activities require a marketing authorisation under pharmaceutical regulatory laws. Only placing a medicinal product on the market requires an MA, not the manufacture , making or import.

Although it is a first-instance judgment in an expedited procedure, issued in a single – but, for the pharmaceutical industry, significant - EU country, it will certainly be used by SPC holders to further threaten existing and future users of the SPC Manufacturing Waiver with lawsuits, or to sue them, a practice already reported by users of SPC Manufacturing Waiver in the Medicines for Europe 2023 Industry Report and which distorts the use of the waiver, frustrating its goals. The judgement even maintains that "*the Regulation is not intended to put manufacturers within the Union on a completely equal footing with manufacturers in third countries*"[1], which clearly reflects a fundamental misunderstanding by the Court of the aims of the regulation.

[1] Unofficial translation.

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

Independent of the fact that the judgement errs on several aspects, it is today the first and only precedent on the SPC Waiver and therefore can be expected to be recognised as relevant in further proceedings, especially those expedited in which judges might not be familiar with this new legal tool and its legislative history and have to make decisions under time pressure. This judgement shows that the current SPC manufacturing waiver legislation is drafted in a way that allows SPC holders to misinterpret the language before Courts to the detriment of EU-based producers, and to the benefit of producers established out of Europe. This threatens planned and committed investments in manufacturing in Europe to the detriment of the fundamental goals of the legislation. This situation can only be aggravated by the current reform of the SPC regulation, whose recast proposed by the Commission to introduce a central granting procedure, lacks some of the original recitals of the SPC Waiver legislation, with further potential confusion.

It is imperative now to urgently simplify and clarify the SPC manufacturing waiver legislation to achieve the stated objective of the SPC Manufacturing Waiver legislation, namely to make the EU attractive for developers and manufacturers of pharmaceutical products, strengthen security of supply and address critical medicine shortages, and ensure timely entry of generics and biosimilars.

Medicines for Europe made the proposals for simplification and clarification in 2023, in the Medicines for Europe 2023 Industry Report, and urges the EU to include such proposals now in the general overhaul of SPC legislation.

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.