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A Christmas gift for the biosimilar industry: Landmark judgment in SPC Manufacturing Waiver case

Kristof Roox (Crowell & Moring) · Tuesday, December 31st, 2024

On December 23, the Brussels Enterprises Court issued a significant judgment confirming that Samsung Bioepis' notification complies with the legal requirements for relying on the SPC Manufacturing Waiver for export purposes, dismissing claims brought by Amgen on multiple fronts (Dutch language judgment here and English machine translation here).

It is the first judgment on the merits in Europe to interpret the SPC Manufacturing Waiver Regulation (the "Regulation"), a key development in European patent law. It allows manufacturers to produce generic and biosimilar medicines during the period of Supplementary Protection Certificate ("SPC") protection, for export to non-EU markets and stockpiling before SPC expiry.

Key takeaways from the judgment:

- The court agreed with Samsung Bioepis' interpretation of Article 5 of the Regulation by confirming that the notification does not need to include a marketing authorization number or list of countries where the product will be exported.
- The court rejected Amgen's argument that countries receiving exported products must be patent-free to rely on the SPC manufacturing waiver. The court stated that such a requirement would be contrary to the Regulation's objective of creating a level playing field between EU and non-EU manufacturers.
- The court also rejected Amgen's argument that stockpiling under the SPC manufacturing waiver is only permitted if strictly necessary for immediate export. Instead, the court noted that the waiver allows stockpiling for a period of time customary in the normal course of business.
- The court sided with Samsung Bioepis' analysis of previous decisions from courts in other countries. It specifically disagreed with the German Preliminary Injunction (PI) judgment and agreed with the PI judgment from the Netherlands.
- Finally, the court dismissed Amgen's claim that Samsung Bioepis' notification to eventually manufacture the denosumab biosimilar for export purposes constituted an unfair trade practice, as Amgen failed to prove a serious risk of infringement.

This judgment is important given the divergence in decisions across Europe. While Germany had a more restrictive approach, requiring additional details in notifications, the Belgian court followed the more flexible interpretation seen in the Netherlands. This is a major victory and important precedent for the biosimilar and generic industry. The judgment also demonstrates that Belgian courts are capable of handling complex patent law issues and that these matters should not be

exclusively decided by the more established patent courts in Europe.

The author acted as counsel for Samsung Bioepis in this case.

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