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# Brussels Court Clarifies Requirements In Samsung Patent Win

By **Alex Baldwin**

Law360, London (January 3, 2025, 2:55 PM GMT) -- The Brussels Enterprise Court has held that Samsung Bioepis complied with requirements to waive supplementary patent protection for a biosimilar version of Amgen's osteoporosis treatment Denosumab, rebuffing Amgen's bid to halt its competitor's product.

Samsung's biotechnology division did not need to include a specific marketing authorization number in a notification sent to Amgen, a biopharmaceutical multinational, the court held. Nor was it required to provide a list of countries where its biosimilar treatment will be marketed.

This is the first time that European courts have weighed in on regulations that allow competitors to make generics or biosimilars of drugs currently protected by a supplementary protection certificate. The ruling is also a significant detour from established case law on waiver requirements.

"While Germany had a more restrictive approach, requiring additional details in notifications, the Belgian court followed the more flexible interpretation seen in the Netherlands," Jurgen Figys, counsel at Crowell & Moring LLP, which acted for Samsung Bioepis, said. "This is a major victory and important precedent for the biosimilar and generics industry."

Amgen initiated proceedings, arguing that the Samsung Bioepis notification did not meet requirements for a "formal notification" outlined in Article 5 of the European Union SPC Regulation.

Amgen specifically argued that Samsung should have included a marketing authorization number — a form of permission offered through the European Medicines Agency — or any equivalents.

But the court said in a Dec. 23 judgment that the wording of the SPC regulation was clear: a company sending the notification does not need to have secured the marketing authorization to obtain a valid waiver. Nor does it have to list the countries to which it plans to export the biosimilar product.

The court also dismissed Amgen's allegations that the waiver allowing Samsung to export its biosimilar to "third countries" outside the European would apply only if Amgen did not have any active IP protection for the drug in those countries.

As a result, Samsung did not breach provisions of regulations outlining protection for supplementary patent certificate waivers.

Representatives for Amgen did not immediately respond to requests for comment.

Amgen Inc. was represented by Christophe Ronse, Kirian Claeys and Julie Peeters of Altius LLP.

Samsung Bioepis NL BV was represented by Kristof Roos, Jurgen Figys and Christopher Dumont of Crowell & Moring LLP.

The case is Amgen Inc. v. Samsung Bioepis NL BV, case number A/24/02113, in the Brussels Enterprise Court.

--Editing by Ed Harris.

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