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Biosimilars: new rejection of an application for preliminary injunction by a UPC German local division (omalizumab)

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Is Germany no longer the Eldorado for preliminary injunctions ("PI") applicants? Whatever the answer to this question, the UPC local division of the most famous German patent forum (i.e., Düsseldorf) has rejected Novartis and Genentech's application for a PI against Celltrion relating to the anti-IgE antibody marketed under the name Xolair® (omalizumab), ruling that there was no imminent threat of infringement.

As a reminder (see here), on 9 April 2024, Novartis and Genentech applied for PI against Celltrion, based on patent EP 3 805 248, which claims the anti-IgE antibody marketed under the name Xolair® (omalizumab) with a specific buffer formulation. This patent has not been *opt-out*. Besides, Celltrion launched an EPO opposition procedure against it in October 2023. Celltrion also filed a protective letter in December 2023. The case was finally heard on 31 July 2024 and judgment was rendered on 6 September 2024.

The two patentees accused Celltrion of preparing to market a biosimilar of Xolair®. To this end, they claimed to prove imminent infringement through Celltrion's application for marketing authorization ("MA") in the European Union for a biosimilar (marketed under the name "Omlyclo") reproducing the formula protected by EP'248. Celltrion argued that it was merely preparing for market entry after the expiry of EP'248.

The Court found that there was insufficient evidence of imminent infringement. More specifically, the Judges stated that in this case the infringement could not be deemed imminent because all the pre-launch preparations had not yet been completed. Furthermore, although an application for MA had been filed, there was no precise timetable for marketing nor had negotiations been launched on price or claims for reimbursement. In addition, no samples had been presented to potential customers.

This is the second rejection of a PI application in relation with biosimilars by UPC local division, following that of the Hamburg one in March 2024 in the case opposing Alexion to Amgen and Samsung Bioepsis (eculizumab, Soliris®, see here). However, whatever one may think of these judgements, they are gradually giving an indication of UPC's requirements regarding PIs, most especially in the pharmaceutical sector. In the commented case, all the elements mentioned above can, *a contrario*, be understood as indications of imminence (e.g., the presentation of a sample to a potential customer). In addition, the Court confirmed its jurisdiction over a company (i.e.,

Celltrion) whose previous activities did not concern UPC's territory.

In this way, UPC's case law is being built up from one decision to the next. But when we say that, shouldn't we also say that the case law of German local divisions is being built up in the pharmaceutical sector? It is true that German national Courts are known for their PIs. But it seems that the same will not be true of UPC's German local divisions, which are decidedly not the Eldorado of patentees seeking PIs. Would, for instance, the Paris local division issue identical decisions? Only experience will tell…

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