Kluwer Patent Blog

Is UPC hostile to pharmaceutical patents?

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Reading the title of this paper, perhaps you will smile, thinking about all the discussions that this issue has already ignited, even before the UPC came into force. Since the beginning, most patentees in the pharmaceutical field were suspicious concerning the new jurisdiction, especially regarding the same old question: pro-patentee or not? Hostile/not hostile to pharmaceutical patents? The results of the Court first year of operations does not seem very promising for the owners. But many questions remain, especially one of the most important: how will the UPC appreciate small molecule cases? As such, you don't have to read the rest of the paper if you are only looking for an answer to the title: we don't know yet. However, the fast development of the case law in this field gives us some clues on how the Court will deal with pharmaceutical patents in the future and how its activity could impact litigations in this field.

We have already reported here on the *NanoStrings vs. 10xGenomics* case, in which the Court of Appeal overturned the decision of the local Munich division granting a preliminary injunction to the patentee. We also reported on the PCSK9 case, in which Sanofi obtained the revocation of Amgen's patent.

Other recent cases have also caught our attention. **The UPC recently issued its first preliminary injunction ("PI") in a biosimilar case opposing Alexion to Amgen and Samsung Bioepsis**, two producers of eculizumab biosimilar. Alexion was relying on patent application EP 3,167,888, which was first opt-out in May 2023, before the carve-out was withdrawn in January 2024. This patent application relates to the treatment of patients with paroxysmal nocturnal haemoglobinuria using eculizumab. Eculizumab is marketed by the patentee under the name "Soliris". Alexion filed two PI applications with the Hamburg local division of the UPC on 19 March 2024. Both applications were dismissed, and the patentee was ordered to pay the costs. This case is part of a global litigation between the companies involved. In the US the PIs have also been rejected. In Germany, the Munich Higher Regional Court recently reversed a preliminary injunction based on Alexion's orphan drug exclusivity, which had been imposed by the Munich lower court in May 2023. Amgen also launched revocation proceedings in the UK against a Soliris patent in May 2023.

Shortly after the Alexion PI applications were filed, **on 9 April 2024, Novartis and Genentech applied for PIs against Celltrion, based on patent EP 3,805,248, which claims the anti-IgE antibody Xolair®(omalizumab) with a specific buffer formulation**. This patent has not been opt-out. It was also the subject of an EPO opposition procedure launched by Celltrion in October 2023. Celltrion filed a protective letter in December 2023 and the UPC set a deadline of 10 May

2024 for Celltrion's reply to the request. The dispute was heard by four UPC judges on 31 July 2024, with judgment due on 6 September 2024.

In addition, **on 13 May 2024, Sanofi launched four infringement actions against Dr. Reddy's Laboratories, Stada, Accord Healthcare and Zentiva**. **These actions relate to Jevtana® (cabazitaxel),which is intended for the treatment of metastatic castration-resistant prostate cancer (mCRPC).** This drug has been facing generic competition since the expiry of its regulatory exclusivity from Sanofi in March 2021. **Sanofi intends to counter this through a new medical use patent (EP 2,493,466). It should be noted that this patent has already been upheld in opposition by the EPO, but that this decision is currently the subject of an appeal**. **The Jevtana® case is not only one of the first traditional branded/generic disputes to be registered with UPC, but also one of the first small molecule cases to come before UPC**, whereas previous cases have involved biologics. If the UPC upholds the validity of the EP' 466 patent, generic manufacturers could become the target of injunction and damages claims in all UPC member countries. On the other hand, if the patent is revoked, generic manufacturers will avoid such sanctions. A hearing is expected to take place in March 2025, so decisions should be handed down in the second half of 2025.

The outcomes of these latest proceedings, brought by Novartis and Genentech as well as Sanofi, are eagerly awaited, as it may well foreshadow the future of pharmaceutical litigation before UPC. So, in answer to the question in the title of this paper, it is still too early to draw any conclusions about the UPC's position vis-à-vis the pharmaceutical industry. The fact remains that the first decisions have sent out unfavorable signals, and that the decisions to come will no doubt be decisive in determining the very future of pharma litigation before the UPC.

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