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UPC Refuses Provisional Injunction finding imminent infringement not substantiated

Novartis AG and Genentech, Inc. v Celltrion Inc. UPC_CFI_166/2024

Novartis AG and Genentech, Inc. v Celltrion Healthcare Hungary Kft., Celltrion Healthcare Deutschland GmbH, Celltrion Healthcare Belgium SPRL, Celltrion Healthcare France SAS, Celltrion Healthcare Finland Oy, Celltrion Healthcare Italy S.R.L., Celltrion Healthcare Netherlands B.V. UPC_CFI_165/2024

Decisions of 6 September 2024 ORD_50565/2024[1] and ORD_50564/2024[2]

Novartis and Genentech brought two actions at the Düsseldorf local division alleging imminent infringement of EP 3805248, which is owned by the two claimants. The first action (UPC_CFI_166/2024, “the ‘166 case”) sought a provisional injunction against Celltrion Inc. (based in Korea), whilst the second action (UPC_CFI_165/2024, “the ‘165 case”) was against a number of European Celltrion entities. The patent relates to omalizumab, which is used for treatment of asthma and other conditions.

There were already pending in the Netherlands accelerated proceedings brought by Celltrion Healthcare Netherlands B.V. seeking revocation of the Dutch part of the patent and a declaration of non-infringement; to which the defendants (in that action) filed a counterclaim for infringement. An opposition was also pending at the European Patent Office in which Celltrion Inc. was an opponent. In the UPC action naming Celltrion Healthcare Netherlands B.V. as a defendant, the Netherlands was specifically excluded.

Competence of the UPC and the Düsseldorf local division

The court held that where one of the defendants has its residence within the territory of the UPC, the UPC has competence with respect to the other defendants if the multiple defendants have a commercial relationship, and the action relates to the same alleged infringement, as provided by Article 33(1)(b) UPCA. In this respect, it followed the reasoning of the Paris local division in an earlier case.^[3] The court considered that the defendants in the '165 case had the necessary quality and intensity of a commercial relationship.

In respect of the '166 case, the court considered that it had jurisdiction under Article 33(1)(a) UPCA (place of alleged imminent infringement), and that the defendant was the parent company of the group including Celltrion Healthcare Deutschland GmbH. The court stated that the defendant was the "spider in the web", and therefore responsible for the distribution of the German company.

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In both actions, the court held that Article 29 of Regulation 1215/2012 (mandatory stay if proceedings involve the same cause of action and the same parties) did not apply to either UPC action: in the '166 case the parties were not the same; whilst in the '165 case the Netherlands was excluded, and also the cause of action was not the same because the Dutch case was a proceeding on the merits while the UPC action was for provisional measures. Article 31 was inapplicable for similar reasons.

Instead, the Court held that the situation fell under Article 30 of Regulation 1215/2012, where a stay is discretionary for related actions. The court considered that a stay of its proceedings would be incompatible with the urgent nature of the provisional measures. Moreover, it stated that Rule 295 RoP providing various possibilities for a stay only applies to actions on the merits and not to provisional proceedings.

No imminent infringement

The court found that the defendants' product would infringe the patent. However, it was not prepared to find that the defendants' conduct amounted to imminent infringement of the patent. The court stated:

A situation of imminent infringement must be characterised by certain circumstances which indicate that the infringement has not yet occurred but that the potential infringer has already set the stage for it to occur. The infringement is only a matter of starting the action. The preparations for it have been fully completed. These circumstances must be assessed on a case-by-case basis. The burden of presentation and proof in this regard lies with the Applicants.

Celltrion had obtained a marketing authorisation and had promoted its product at an international conference. However, this did not show any specific timeline and there were no other indications that any price negotiations or reimbursement applications by the defendants had already started or were ongoing. Nor was any specific situation shown to the court in which samples were actually presented to potential customers. The defendants' evidence was that no Celltrion entity was actively negotiating prices for their product with the competent authorities in any UPC member state and their position was that they would not commercialise their product as long as the patents were valid. While there were contradictory statements from both sides about statements and actions alleged against Celltrion employees, ultimately the court felt that it could not conclude that Celltrion had announced the availability of samples in the near future.

Therefore the court rejected the application for provisional measures. In view of its finding of no imminent infringement, the validity of the patent was not considered. The applicants were ordered to pay interim costs of the proceedings.

This judgment follows the German approach to provisional injunctions in respect of medicinal products, by requiring more than the granting of a marketing authorisation to enable provisional relief. This is perhaps not so surprising given the case was brought before the Düsseldorf local division, and it remains to be seen how other divisions, and importantly the appeal court, view this. Nevertheless, this potentially sets a high evidentiary bar for patentees seeking a provisional injunction before an alleged infringer has actually entered the market.

[1] <https://www.unified-patent-court.org/en/node/1061>

[2] <https://www.unified-patent-court.org/en/node/1060>

[3] <https://www.unified-patent-court.org/en/node/659>