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THE LD LISBON OFFERS SOME LIMITED INSIGHT ON IMMINENT THREAT OF INFRINGEMENT

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LIFE SCIENCES & HEALTHCARE

On 8 May 2025, the Lisbon Local Division of the Unified Patent Court (“UPC”) issued an order (*Boehringer Ingelheim International GmbH v. Zentiva Portugal LDA, Lisbon LD*, 8 May 2025, UPC_CFI_41/2025) denying a preliminary injunction application filed by *Boehringer Ingelheim International GmbH* (“Boehringer”) against *Zentiva Portugal LDA* (“Zentiva”).

The preliminary injunction application was based on patent No EP 1 830 843 B1 (“EP’843”) titled “*Indolidone derivatives for the treatment or prevention of fibrotic diseases*”, which expires on 21 December 2025. It is part of Boehringer’s broader strategy to prevent Zentiva from marketing generic versions of its medicine OFEV®, covered by EP’843 and Supplementary Protection Certificate (“SPC”) No 679, which is based on patent No EP 1 224 170 (SPC No 679 expires on 9 April 2026, hence after the expiration of EP’843).

It is important to note that *Boehringer Pharma Ingelheim GmbH & CO. KG*, another Boehringer subsidiary, previously obtained a preliminary injunction in Portugal against Zentiva, based on SPC No 679. This injunction, issued by default since Zentiva did not challenge the request, was rendered on 25 March 2025 by the Portuguese Intellectual Property Court.

Boehringer submitted its request to the UPC after Zentiva received a national Marketing Authorization (“MA”) and a Prior Evaluation Procedure (“PEP”) in Portugal, which permitted pre-marketing activities. The Lisbon LD recalled that imminent infringement should be evaluated based on the concrete likelihood that, considering the case’s circumstances, the Defendant is more likely than not to commit an act of infringement. This reasoning is consistent with the decision of the Düsseldorf Local Division (*Novartis AG/Genentech, Inc. v. Celltrion Inc.*, LD Düsseldorf, 6 September 2024, UPC_CFI_166/2024).

Before the UPC, it is worth noting that Zentiva did not submit any arguments regarding validity of EP’843 (contrary to what was observed in other cases – and as usual in preliminary injunctions cases[1]). Indeed, Zentiva chose to focus its arguments on the absence of evidence of imminent threat of infringement.

In this case, the Court adopted Zentiva’s approach and ruled that Boehringer failed to adequately demonstrate an imminent threat of infringement.

Firstly, the Court indicated that the administrative steps undertaken by a defendant – namely obtaining a Marketing Authorization and a PEP – are insufficient to demonstrate an imminent threat of infringement. The Court stated that these are purely administrative actions and do not, in themselves, indicate a risk that the defendant would enter the market without further steps demonstrating such intent.

Secondly, the Court observed that although Zentiva was administratively authorized to market its medicine to private hospitals as only an MA is required, there is no established imminent threat of infringement. Indeed, the MA was granted to Zentiva on 30 August 2024, and no subsequent activities indicating market engagement have been observed. Furthermore, the Court emphasized that private hospitals constitute only 2% of the overall market.

All of the foregoing led the Court to dismiss Boehringer’s preliminary injunction application.

Hence, urgency is a key factor before the UPC for preliminary injunctions, and its assessment is always carried out on a case-by-case basis.

It is worth noting that SPC No 679 (and which led to a PI not defended by Zentiva) is due to expire after EP’843, the patent on which Boehringer had based its application for a preliminary injunction before the UPC. The outcome of the present UPC preliminary injunction order has thus limited effect in practice. More case law on this issue will be necessary to draw clear rules on the question of imminent threat in pharmaceutical cases notably considering the various different “trigger points” for preliminary injunctions across national EU jurisdictions.

The order can be found here.

[1] For instance, please see : *Telefonaktiebolaget LM Ericsson v. Asustek Computer Inc/Arvato Netherlands B.V./Digital River Ireland Ltd*, LD Lisbon, 15 October 2024, UPC_CFI_317/2024 ; *NanoString Technologies v. 10x Genomics, Inc./P resident and Fellows of Harvard College*, UPC CoA, 26 February 2025, UPC_COA_335/2023; and *Insulet Corporation v. EOFlow Co., Ltd.*, UPC CoA, 30 April 2025, UPC_COA_768/2024

