EIP

Provisional Injunction Denied for Small Molecule Kinase Inhibitor

Zentiva Portugal, LDA v. Boehringer Ingelheim International GMBH (UPC_CFI_41/2025 relating to EP1830843)

Court of First Instance Order dated 8 May 2025 ORD_18599/2025 [1]

Summary

The Application for a PI by the Applicant, Boehringer, against the Defendant, Zentiva, was denied by the Court of First Instance. The Court did not find evidence to suggest a risk of imminent infringement of the Patent, relating to products containing nintedanib, based on Articles 25 and 62 UPCA. Boehringer was ordered to pay Zentiva EUR 92,944.15 in recoverable costs.

Background

The Applicant Boehringer Ingelheim International GMBH (hereinafter "Boehringer") is the co-proprietor of European patent number EP1830843 (hereinafter "the Patent"), entitled "Indolidone derivatives for the treatment or prevention of fibrotic diseases". The Patent relates to products containing nintedanib or nintedanib esylate, a small molecule tyrosine kinase inhibitor, for use in the prevention or treatment of idiopathic pulmonary fibrosis.

The Defendant Zentiva Portugal, LDA (hereinafter "Zentiva") is a Portuguese pharmaceutical company holding two Marketing Authorisations (hereinafter "MA") in Portugal for generic medicines comprising nintedanib (hereinafter "Zentiva Generics").

In January 2025, Applicant Boehringer applied for a provisional injunction (hereinafter "PI") against Defendant Zentiva before the Lisbon Local Division of the UPC. The

Applicant alleged that the Patent was at risk of imminent infringement since 12 December 2024, which marked the announcement by INFARMED – National Authority of
p2 Medicines and Health Products, I.P. (hereinafter "Infarmed") that Zentiva Generics could be purchased.

In March 2025, the Defendant denied the risk of imminent infringement and raised an objection to the competence of the UPC. The Defendant also requested a stay of proceedings due to a parallel application before the Lisbon Intellectual Property Court. Following the grant for a PI in the parallel application before the Portuguese Intellectual Property Court, the Defendant withdrew their request for a stay of the proceedings.

Order Sought by the Parties

The Applicant requested that the Court order the Defendant to refrain from making, offering, placing on the market or using, or importing or storing for those purposes any product comprising nintedanib or nintedanib esylate for use in the prevention or treatment of idiopathic pulmonary fibrosis, where the patent is in force: Austria; Belgium; Bulgaria; Denmark; Estonia; Finland; France; Germany; Italy; Latvia; Lithuania; Luxembourg; Netherlands; Portugal; Romania; Slovenia; and Sweden. They also requested documentation relating to the quantities of Zentiva Generics ordered, imported, stored and supplied. The Applicant sought for the Defendant to pay a penalty payment of EUR 250,000 for any violation of the order, as well as paying the interim costs of the proceedings.

The Defendant requested that the Court decline jurisdiction over the Application and dismiss it as inadmissible, or dismiss the Application and impose the costs of proceedings on the Applicant.

Grounds for the Order

1. Jurisdiction and Competence

The Defendant objected to the jurisdiction of the UPC, arguing that only a Portuguese administrative court is competent to hear the case due to the allegation of imminent infringement arising from an act carried out by a public administrative body (Infarmed). However, this objection was deemed to be unfounded due to the UPC having jurisdiction and competence under Articles 31 and 32 (UPCA).

Article 31 establishes the international jurisdiction of the UPC in accordance with Regulation (EU) No 1215/2012. Article 32(1) outlines the competence of the court, including in respect of actions for: actual or threatened infringements of patents (a); and provisional measures/injunctions (c). Overall, the assertion of imminent infringement of

the Patent is sufficient to establish the jurisdiction and competence of the UPC.

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2. Relevance of the Portuguese Court Order to this PI

The Defendant alleged that the Application for a PI has no legal basis, arguing that they are already prevented from carrying out activities relating to the Patent due to a PI being granted in a Portuguese Court Order, relating to SPC No.679, which expires later than the Patent. However, the Court found no basis for this request for at least the following reasons. Firstly, the present PI applies to all Contracting Member States of the UPC whilst the Portuguese PI is restricted to Portugal. Secondly, the Portuguese Court Order has potential to be appealed, as well as being granted on a prima facie basis. Also, the IP right itself has potential to be judicially amended or revoked.

3. Imminent Infringement

The Applicant argued that there is an imminent risk of infringement due to an alleged risk of the Defendant offering/placing Zentiva Generics on the market. Article 25 UPCA states that such acts would be acts of infringement and Article 62 UPCA states that the Court can grant injunctions to prevent imminent infringement.

Although it is undisputed among the parties that the Zentiva Generics medicine falls within the scope of the Patent, the Court states that administrative procedures and legislation associated with gaining market access for a medicine, which vary within each Contracting Member State, are not the basis on which the Court's assessment of imminent infringement should be made. Rather, the Court must assess the risk based on Articles 25 and 62 UPCA.

It must be established, under Article 25 UPCA, that the acts of the potential infringer are more likely than not to intend to offer/place the product on the market prior to the expiration of the patent in question.[2] The Applicant bears the burden of proof that the Defendant is highly likely to enter the market.

Specifically, the Applicant alleged that the risk of infringement stems from the Defendant obtaining two marketing authorisations (hereinafter "MA"), and then pursuing and obtaining a Prior Evaluation Procedure (hereinafter "PEP"), whose grant represents the final administrative step necessary for the Defendant to offer and sell its product to the public hospitals.

The Court held that in this situation the issuance of the PEP in itself does not create a risk of infringement. Rather, Articles 25 and 62 UPCA require the risk to stem from the Defendant's actions. Furthermore, the timing of the PEP was not considered by the Court to increase the risk of infringement. The Applicant further argued that there was

evidence of imminent infringement in the Notice of 12 December 2024 by Infarmed announcing that the PEP had been completed, which set a one-year time limit to commercialise Zentiva Generics. However, the Defendant contested the relevance of the timing and the Court agreed that this did not indicate imminent infringement.

The Court also rejected allegations of imminent infringement in respect of possible sales to private hospitals, which would have been possible since the granting of the MAs on 30 August 2024. The Court considered that the Applicant had not demonstrated any conduct by the Defendant in that time making imminent infringement likely.

Overall, the request for a PI was dismissed because no imminent infringement could be demonstrated by the Applicant.

Value of the Case

The value of the case was set to EUR 1,000,000, in accordance with the Guidelines for the Determination of the Court Fees and the Ceiling for Recoverable Costs.[3] The Court also stated that due to the Application relating to provisional measures, the value of the case only relates to recoverable costs whilst Court fees are fixed.

Costs

Although the Defendant requested that provisional costs be set at EUR 250,000, only EUR 92,944.15 was substantiated. Therefore, the Court ordered the Applicant to pay the Defendant EUR 92,944.15 in costs, which falls within the recoverable costs ceiling as set by the Administrative Committee (which is EUR 112,000 for a value of proceedings being EUR 1,000,000).[4]

This decision falls in line with Article 69 UPCA, which provides that the losing party must bear the successful party's costs, including reasonable and proportionate legal costs, in the absence of exceptional circumstances.

[1] The Order: https://www.unified-patent-court.org/en/node/118300

[2] Novartis/Genentech v. Celltrion, UPC_CFI_166/2024: https://www.unified-patent-court.org/en/node/1061

[3] https://www.unified-patent-court.org/sites/default/files/upc_documents/d-ac_09_24042023_guidelines_e_for-publication.pdf

[4] https://www.unified-patent-court.org/sites/default/files/upc_documents/d-ac_10_24042023_ceiling_e_for-publication.pdf