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UPC COURT OF APPEAL CLARIFIES STANDARDS FOR IMMINENT INFRINGEMENT IN PHARMACEUTICAL PATENT DISPUTES

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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**"). August Debouzy's related article and more details on the case can be found here.

Boehringer filed an appeal, and on 13 August 2025, the UPC Court of Appeal reversed the order (*Boehringer Ingelheim International GmbH v. Zentiva Portugal LDA*, UPC CoA, 13 August 2025, UPC_CoA_446/2025).

First, the Court adopted the CFI's reasoning according to which there is no basis for dismissing the motion for PI on the ground of lack of necessity, even if an injunction based on an SPC was already issued by the Portuguese Intellectual Property Court.[1]

The Court then rejected Zentiva's argument regarding the Bolar exemption which was in a nutshell based on the "Proposal for a Directive of the European Parliament and of the Council on the Union Code concerning medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC"[2], ruling that the draft cited by Zentiva was not in force and that the Court of Appeal only rules on the basis of "*existing legislation*."

Clarification of the Legal Standard for Assessing Imminent Infringement in Pharmaceutical Cases

The Court aimed to clarify the concept of imminent infringement and recalled legal standards in that respect. According to it: "*imminent infringement may be characterised by certain circumstances which suggest 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.*"

Most importantly, the Court also indicated that the mere filing and obtention of a marketing authorisation ("**MA**") does not amount to imminent infringement. However, it underlined that the completion of national procedures such as the assessment and grant of pricing and reimbursement for a generic medicine may, depending on the circumstances of the case and the relevant national regulatory and legislative context, amount to imminent infringement.

The Court stated that determining imminent infringement involves assessing whether circumstances show that the potential infringer has established conditions for it to occur. It noted that Zentiva's process for obtaining a legally required Prior Evaluation Procedure ("**PEP**")[3] was completed earlier than usual, *i.e.*, more than one year before the expiry of the patent-in-suit, and that the implications of this early PEP obtention were not further considered by the CFI.

To evaluate whether such an early PEP application represents imminent infringement, the Court has examined four specific questions.

The first one relates to the question of whether the potential infringer must take further administrative steps to commercialize the generics. In that respect, the Court found that the mere fact that a required pre-notification to Infarmed[4] had not yet been made does not prevent the qualification of imminent infringement since such pre-notification "*can be fulfilled with by the supplier with relative ease and at short notice*".

The second question addresses whether, under Portuguese law, the procedures for acquiring pharmaceuticals are considered precontractual. In that regard, the Court ruled that the mere fact to take part in public procurement procedure generally amounts as an offering within the meaning of article 25 UPCA. The Court further indicated that to assess imminent infringement "*the relevant question to answer in the first place is whether there are further administrative procedures required that prevent Zentiva from offering the generics in Portugal after it has obtained a market authorisation and PEP*".

The third one concerns the question of whether nintedanib products can only be acquired through public procurement procedures. In this regard, the Court pointed out that, according to the Portuguese Public Procurement Code, public hospitals are not bound by any framework agreement in force if that agreement results in the payment of a price that is at least 10% higher than that of an item with the same characteristics and the same level of quality. Consequently, the Court ruled that it is more likely than not that the PEP granted to Zentiva can allow it to offer the generics to Portuguese public entities, thereby rejecting Zentiva's arguments that only Boehringer was allowed to sell its nintedanib product to national health services in Portugal.

The fourth and ultimate question is whether Zentiva is effectively hindered from taking part in any proceedings for the acquisition of the generics. In that regard, the Court found that no evidence has been put forward by Zentiva demonstrating that it would be excluded from public procurement procedures due to duty of public entities to assess compliance with patent rights when acquiring medicines. In the absence of such a demonstration, the Court considers that "*self-retaining*" is the real mechanism for preventing infringement.

Based on the foregoing, the Court concluded that it is more likely that not that Zentiva can offer the generics products to public hospitals in Portugal, without the need of any further administrative steps or procedures. Additionally, the Court pointed out that, from the date of issue of the PEP, MA holders have "*one year to start commercializing*" their generic products, emphasizing on the fact that Zentiva had not provided explanations on why it would be useful for it to obtain a PEP more than one year before the patent expires.

With regard to the necessity of the injunction, the Court considered that the marketing of Zentiva's generic product would be at least 30% lower than Boehringer's which would also lead to permanent price reduction. Additionally, the Court found that the absence of strong mechanisms to bar Zentiva from offering its products, the premature PEP application and notification of the PEP approval by the national authorities can qualify an imminent infringement since public hospitals can expect that the generic will be offered before the patent expires.

With regard to the urgency criterion, the Court found that the relevant point in time for Boehringer was on 12 December 2024, when Infarmed made public the issue of the PEP for the Zentiva Generics. The application for provisional measures, submitted on 23 January 2025, satisfied the established urgency criterion.

Consequently, the Court of Appeal overturned the first instance order and issued provisional measures applicable in all Contracting Member States in which the patent is effective.

Should the case considered by the Court had taken place in France and thus decided by French courts, the outcome would likely have been similar. As ruled by the UPC Court of Appeal, in France, granting a marketing authorization is neither an act of infringement nor an imminent threat.[5] However, it may contribute to evidence of imminent threat of infringement when combined with actions like early applications for price and reimbursement at CEPS, or advertising before patent expiry.

In France, the application for price and reimbursement of a generic product should not constitute an infringing act nor a threat of imminent infringement if it takes place less than 6 months prior to patent expiry[6]. If the application for price & reimbursement takes place more than 6 months prior to patent expiration, the generic company will be requested to provide a non-infringement statement.[7] This statement will be forwarded by the CEPS to the IP rights holder and may serve (depending on how it is phrased) to initiate a PI based on an imminent threat of infringement.[8]

In conclusion, the UPC Court of Appeal has provided welcomed clarifications for the assessment of imminent infringement for pharmaceutical cases which seems to be aligned with the case law from national courts of other European jurisdictions and notably France as highlighted above.

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[1] Of note, the Court has also examined procedural issues that will not be further developed in this article.

[2] Of note the current draft of article 85 of said Proposal for a Directive indeed proposes to extend the Bolar exemption to the obtention of price and reimbursement approvals.

[3] Which is in a nutshell the price and reimbursement procedure in Portugal.

[4] Infarmed ("*Autoridade Nacional do Medicamento e Produtos de Saúde*") is the Portuguese national authority responsible for regulating medicines, medical devices, cosmetics and other health products.

[5] See TGI Paris, 19.08.2010, *Sanofi v. Teva*, RG No 10/56889, Taxotere; TGI Paris 05.04.2011, *Novartis v. EG Labo*, RG No 11/52706; CA Paris, 21.03.2012, *Novartis v. Mylan*, RG n° 11/12942, rivastigmine; CA Paris 23.05.2013, Sanofi v. Arrow, RG No 12/16016, irbesartan/hydrochlorothiazide.

[6] This is summarized in TGI Paris, 19.08.2010, *Sanofi v. Teva*, RG No 10/56889, taxotere: "*the law authorised pharmaceutical companies to submit applications for marketing authorisation for generic products and to obtain registration on the list of reimbursable medicines and on the repertoire of generics despite the existence of intellectual property rights and during the preparatory work on the Law of 29 October 2009, the legislator did not retain the qualification of imminent infringement for price applications to the Economic Committee for Health Products*". The 6 months period derives from the Framework Agreement between CEPS and LEEM, art. 3, paras 3 and 4.

[7] Art. 3 of the Framework Agreement between CEPS and LEEM.

[8] CA Paris, 21.03.2012, *Novartis v. Mylan*, RG n° 11/12942, rivastigmine; CA Paris 23.05.2013, *Sanofi v. Arrow*, RG No 12/16016, irbesartan/hydrochlorothiazide.