Court of Appeal clarifies the standard for imminent infringement in the context of market access procedures

Follow-up on Boehringer Ingelheim vs Zentiva before the UPC

In *MAIinsight* Issue No. 3 (July 2025), we explored how the traditional German approach compares with the emerging UPC framework for marketing authorizations and the assessment of imminent patent infringement in the pharmaceutical sector, highlighting the first-instance UPC decision in *Boehringer Ingelheim v. Zentiva* (UPC_CFI_41/2025, 8 May 2025). The Court of Appeal has now overturned the decision of the Lisbon Local Division and granted Boehringer Ingelheim a preliminary injunction - providing important clarification of the UPC's approach to imminent patent infringement in the pharmaceutical sector (UPC_CoA_446/2025).

The decision clarifies how the UPC assesses imminent infringement in the pharmaceutical context. While confirming that the mere grant of a marketing authorization does not in itself establish imminent infringement, the Court of Appeal emphasized that the decisive question is whether the alleged infringer has already **»set the stage« for market entry**. The ruling therefore shifts the focus towards **»launch readiness«**, i.e., whether a generic manufacturer has completed the regulatory and commercial steps enabling immediate market entry.

Brief Summary of the Case

The UPC_CFI_41/2025 decision concerned Boehringer Ingelheim's request for a preliminary injunction against Zentiva based on the alleged imminent infringement of EP 1 830 843, which protects the use of nintedanib or nintedanib esylate to treat idiopathic pulmonary fibrosis (UPC_CFI_41/2025, recitals 1, 11, and 16-17).

Boehringer Ingelheim argued that Zentiva's imminent infringement was demonstrated by its acquisition of two marketing authorizations (MAs) and completion of a Prior Evaluation Procedure (PEP) (UPC_CFI_41/2025, recitals 2, 31, and 39-40). In Portugal, medicines containing nintedanib are restricted to prescription for hospital use only. While a marketing authorization allows supply to private hospitals, the supply of medicines to public hospitals and reimbursement under the National Health System (NHS) require completion of a PEP (UPC_CFI_41/2025, recitals 34-38, 61).

Once a PEP has been granted, the holder must follow pre-contractual procedures in order to supply medicines to the NHS, such as participation in framework agreements, prior consultation, or direct award procedures (UPC_CFI_41/2025, recitals 41-44). At the relevant time, Boehringer Ingelheim Portugal, Lda was the sole contractor listed in the framework agreement for the provision of nintedanib products (UPC_CFI_41/2025, recitals 44).

Following the grant of the Zentiva's PEP, INFARMED – the Portuguese National Authority of Medicines and Health Products, I.P. (»INFARMED«) issued a notification dated 12 December 2024 to the relevant health authorities. The notification stated that Zentiva's generic products had been approved on 06 December 2024 and could be purchased by public-sector entities for the approved indication, with marketing authorization holders having one year to begin commercialization (UPC_CFI_41/2025,recitals 39-40).

Recap of First-Instance Refusal of Preliminary Injunction

The Lisbon Local Division found that Zentiva's medicines contain nintedanib and are suitable for treating idiopathic pulmonary fibrosis, thus falling within the scope of EP'843 (UPC_CFI_41/2025, recital 53).

The Court emphasized that the pharmaceutical market is highly regulated and requires several administrative steps before a medicine can be marketed. Although the relevant procedures and legislation vary between Member States, this should not affect the assessment of the risk of infringement. According to the Court, imminent infringement must be assessed independently under the Agreement on a Unified Patent Court (UPCA), in particular in light of Articles 25 and 62 UPCA, rather than on the basis of national law (UPC_CFI_41/2025, recital 55).

The assessment of imminent infringement must therefore be made on a case-by-case basis. It requires conduct by the potential infringer indicating that it is more likely than not that the product will be offered or placed on the market before patent expiry. The burden of proof lies with the applicant to demonstrate, in light of the specific circumstances, that the defendant is highly likely to imminently enter the market (UPC_CFI_41/2025, recitals 56-58).

Against this background, the Court held that requesting an MA or initiating a PEP constitutes merely administrative steps and does not, in itself, establish a risk of infringement. This conclusion was supported by the common practice in Portugal for generic manufacturers to request a PEP before patent expiry (UPC_CFI_41/2025, recitals 62-63).

The Court was also not persuaded by Boehringer Ingelheim's argument that Zentiva requested the PEP more than a year before patent expiry to enable early market entry. Zentiva explained that it does not control the timing of the PEP and that the request followed its standard practice after obtaining the MAs. The Court therefore found no evidence that request for a PEP after the grant of the MAs indicated the timing of market entry or made it more likely that Zentiva would enter the market before expiry of EP'843 (UPC_CFI_41/2025, recital 64).

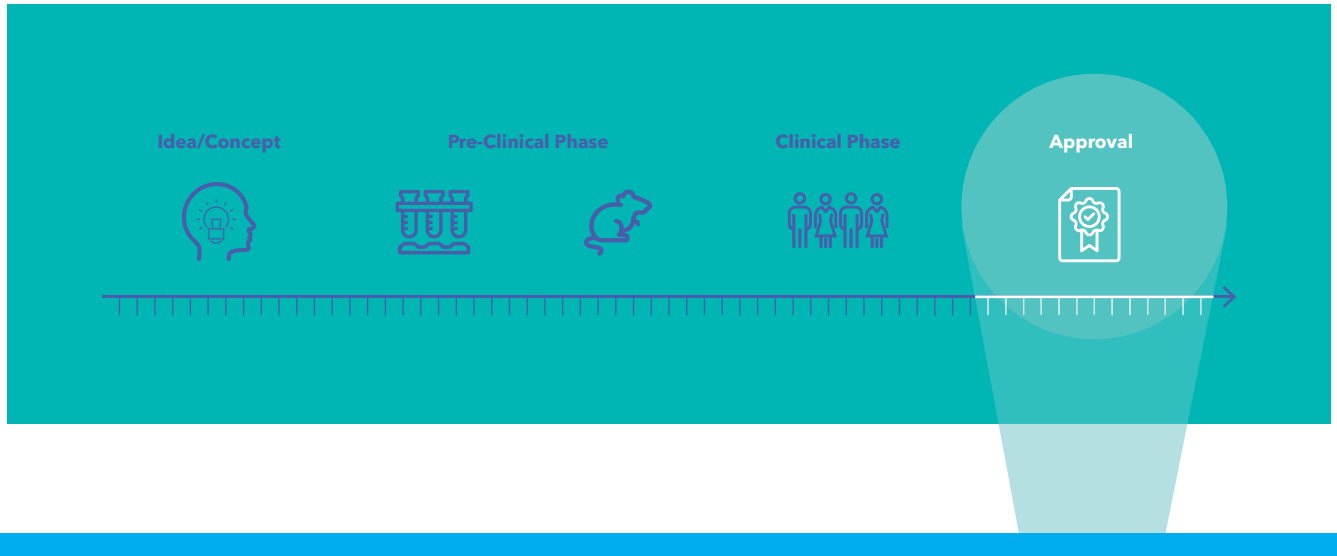
Similarly, the Court rejected Boehringer Ingelheim's argument that the INFARMED notice, stating that Zentiva had one year to commercialize its product, demonstrated imminent infringement. According to the Court, the risk that the PEP might expire as a result of non-commercialization lies with Zentiva itself. A written statement from Zentiva's head of scientific affairs confirmed that Zentiva is not obliged to commercialize within one year while conflicting patent rights remain in force, and that, in practice, a PEP had not lapsed due to non-commercialization caused by patent protection. The Court therefore held that Zentiva's awareness of this risk alone did not indicate the timing of market entry (UPC_CFI_41/2025, recital 65).

In the absence of further evidence indicating imminent market entry, the Court concluded that Zentiva's conduct did not make infringement more likely than not and therefore rejected the request for a preliminary injunction.

The Court of Appeal, however, took a different view and adopted a broader understanding of when regulatory steps may amount to imminent infringement.

UPC Court of Appeal Clarifies Approach to Imminent Infringement

Pursuant to Art. 62(1) and (4) UPCA, the Court may grant injunctions and order provisional measures to prevent any imminent or threatened infringement, provided that the applicant submits reasonable evidence satisfying the Court, with a sufficient degree of certainty, that infringement is occurring or is imminent (R. 206.2(c), R. 211.2, R. 213.2 RoP) (UPC_CoA_446/2025, recital 44-45).



The Court of Appeal held that imminent infringement may be characterized by circumstances showing that the infringement has not yet occurred but that the potential infringer has already **»set the stage«** for it, such that the infringement would occur simply by commencing the relevant activity. In other words, the decisive question is **whether the alleged infringer has completed the regulatory and commercial steps necessary to enter the market without further substantial preparations**. This assessment must be made on a case-by-case basis (UPC_CoA_446/2025, recital 46).

In the context of generic medicines, the Court of Appeal confirmed that the mere application for or grant of a marketing authorization does not in itself constitute imminent infringement (UPC_CoA_446/2025, recital 47). By contrast, **the completion of national procedures relating to health technology assessment, pricing and reimbursement may amount to imminent infringement if these steps enable the generic product to be offered on the market without further regulatory action**. In such cases, the assessment must take into account the national regulatory and legislative framework and the circumstances of the individual case (UPC_CoA_446/2025, recital 48).

The Court of Appeal further clarified that, although national law forms part of the applicable legal framework under Art. 24 UPCA, it is for the parties to present the relevant facts and evidence concerning the content and application of that national law (UPC_CoA_446/2025, recital 72).

Since the case concerned solely the allegation of imminent infringement, the applicable standard of proof required a sufficient degree of certainty. On the balance of probabilities, it must be more likely than not that infringement is imminent. Accordingly, Boehringer Ingelheim bore the burden of presenting and proving the facts establishing imminent infringement and the circumstances supporting its request (UPC_CoA_446/2025, recital 52).

The Court of Appeal Reverses First Instance Decision granting Boehringer Ingelheim preliminary injunction

Applying the above principles, the Court of Appeal examined whether Zentiva had already completed the regulatory and commercial steps necessary to enable market entry. In particular, the Court of Appeal considered the significance of Zentiva having obtained a PEP more than one year before the expiry of EP 1 830 843. Since a PEP establishes the conditions for the acquisition of medicines by public entities, such as price, reimbursement, and therapeutic indications, the Court of Appeal held that the implications of this step had not been sufficiently assessed by the first instance decision (UPC_CoA_446/2025, recitals 56-57).

Whether the early completion of a PEP constitutes imminent infringement, according to the Court of Appeal, must be assessed in light of the specific regulatory framework. **Relevant factors include whether additional administrative steps are required before market entry, the structure of public procurement procedures, and whether the generic manufacturer is effectively prevented from offering the product on the market** (UPC_CoA_446/2025, recital 58).

The Court then addressed several arguments raised by Zentiva.

- **First,** Zentiva argued that the interpretation of imminent infringement should take into account the draft Art. 85 of the proposed EU pharmaceutical legislation, which would extend the Bolar exemption to certain pricing and reimbursement activities. The Court of Appeal rejected this argument, noting that the draft provisions are not yet in force and that Zentiva had not claimed that its conduct falls within the existing Bolar exemption (UPC_CoA_446/2025, recital 53).
- **Second,** the Court of Appeal considered the parties' dispute regarding the listing of products in INFARMED's database. Zentiva argued that a product is only listed as »available« after a pre-notification step. Boehringer Ingelheim argued that this step is merely a formality and that the products may be offered for sale once the listing becomes visible in the database. The Court of Appeal found that pre-notification is a straightforward formality that can be completed rapidly, making it difficult for the patent holder to determine whether generics have already entered the market or are about to do so (UPC_CoA_446/2025, recital 59-62).
- **Third,** the Court of Appeal addressed the role of public procurement procedures in Portugal. Zentiva argued that such procedures are merely pre-contractual and therefore cannot constitute an act of infringement. The Court of Appeal rejected this argument, emphasizing that **participation in procurement procedures during the term of the patent may constitute an act of offering, irrespective of their pre-contractual character** (UPC_CoA_446/2025, recitals 63-65).

Furthermore, the Court of Appeal examined whether public hospitals are limited to acquiring medicines through framework agreements. Boehringer Ingelheim demonstrated that Portuguese procurement laws allow alternative acquisition methods, including direct awards for smaller purchases and prior consultation procedures. In light of these mechanisms, the Court of Appeal considered it more likely than not that Zentiva could offer its generic products to public entities once the PEP had been granted (UPC_CoA_446/2025, recitals 66-68).

Finally, the Court of Appeal rejected Zentiva's argument that legal barriers prevented it from participating in procurement proceedings. Zentiva relied primarily on its own intention to refrain from infringing EP 1 830 843. However, the Court of Appeal found no evidence of a legal mechanism preventing Zentiva from offering the generic products on the Portuguese market (UPC_CoA_446/2025, recitals 71-76).

Against this background, the Court of Appeal concluded that, following completion of a PEP, Zentiva had effectively »set the stage« for offering the generics to public hospitals in Portugal. Since no further administrative steps were required and no legal obstacles prevented market entry, it was more likely than not that infringement would occur once Zentiva decided to proceed with commercial activities (UPC_CoA_446/2025, recital 77-81).

The Court of Appeal therefore held that Boehringer Ingelheim had demonstrated a risk of imminent infringement, justifying the grant of provisional measures.

The Court of Appeal finds both necessity and urgency established

The Court of Appeal found that urgency and necessity were satisfied. It accepted Boehringer Ingelheim's argument that Zentiva's generics, being at least 30% cheaper than Ofev®, Boehringer Ingelheim's originator product, could trigger a near-complete market switch and lead to irreversible price erosion, thereby justifying the grant of provisional measures (UPC_CoA_446/2025, recitals 82-85).

As regards urgency, the Court of Appeal found that Boehringer Ingelheim had not acted with undue delay. Boehringer Ingelheim became aware of the potential infringement when INFARMED published the PEP approval on 12 December 2024, and the application for provisional measures filed on 23 January 2025 was therefore considered timely (UPC_CoA_446/2025, recitals 86-89).

Comparison with German law

From a German law perspective, the decision is particularly interesting when compared with the traditional concept of imminent infringement (»Erstbegehungsgefahr«). German courts likewise require concrete circumstances indicating that a patent infringement is sufficiently likely to occur in the near future. However, the **mere application for or grant of a marketing authorization generally does not establish such a risk while conflicting patent protection remains in force**.

German case law has traditionally placed particular emphasis on acts that already amount to an offer of the medicinal product, such as **advertising, specific launch announcements, or the listing of the product in pharmaceutical databases such as the Lauer-Taxe**.

Recent decisions of the Regional Court Munich I suggest that German courts may also be willing, at least in certain circumstances, to infer a risk of first infringement from a broader set of launch preparations in the pharmaceutical sector. In particular, in the Eylea® biosimilar litigation concerning aflibercept, the court emphasized that the requirements for establishing a risk of first infringement must not be overstretched. According to the Court, it may be sufficient that a marketing authorization has been obtained or applied for and that a distribution structure enabling market entry exists, especially in light of the significant investments typically associated with biosimilar development (Regional Court Munich I, judgments of 25 September 2025, 7 O 16055/24 and 7 O 9383/25; appeal pending).

Notably, the Munich Court assumed a risk of first infringement not only for Germany **but also for numerous additional European countries** (altogether 22), considering it sufficiently plausible that the biosimilar would be launched across several markets once regulatory and commercial preparations had been completed.

Against this background, the UPC Court of Appeal's reasoning appears **broadly compatible** with the evolving German approach, as both emphasize a case-by-case assessment of whether the alleged infringer has already completed the preparations necessary for market entry. At the same time, the UPC decision suggests that regulatory and market-access steps may carry particular weight in the UPC's analysis if they enable immediate market entry without further substantial preparations.

Conclusion

The UPC Court of Appeal's decision provides important clarification on how the UPC assesses imminent infringement in the pharmaceutical sector. While confirming that the mere grant of a marketing authorization does not in itself establish imminent infringement, the UPC Court of Appeal emphasized that the decisive question is whether the alleged infringer has already completed the steps necessary to enable immediate market entry.

In the present case, the completion of the national pricing, reimbursement, and procurement framework through the Portuguese PEP meant that Zentiva had effectively »set the stage« for market entry. From the Court of Appeal's perspective, no further regulatory or commercial steps were required before the generics could be offered to public hospitals.

The decision therefore shifts the focus towards »launch readiness«. **Once a generic manufacturer has completed the relevant regulatory and market-access procedures to such an extent that market entry could occur at any time, the UPC may consider infringement to be imminent even before the product is actually offered on the market**.

At the same time, the judgment confirms that the assessment of imminent infringement remains **highly dependent on the specific regulatory framework of the relevant Member State**. National procedures for pricing, reimbursement, and public procurement may therefore play a decisive role in determining whether market entry is realistically possible at any time.

For originator companies, the decision highlights the importance of closely monitoring regulatory developments and market-access procedures. For generics manufacturers, it underscores the litigation risks associated with completing regulatory and reimbursement steps well before conflicting patent expiry.

Finally, the case illustrates the strategic impact of UPC proceedings. Even where the alleged imminent infringement concerns only one national market, the UPC may grant injunctions with effect across all participating Member States in which the patent is in force. As UPC case law continues to evolve, further decisions will likely refine how the concept of imminent infringement is applied in the highly regulated pharmaceutical sector.

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