Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

UPC Court of Appeal
UPC_CoA_446/2025
APL_24205/2025 (appeal)
UPC_CoA_520/2025
APL_27935/2025 (cross-appeal)

ORDER

of the Court of Appeal of the Unified Patent Court
issued on 13 August 2025
concerning an Application for provisional measures (R. 206 RoP)

HEADNOTES:

- In the context of marketing of generic medicines, the mere application for a marketing authorisation by a generics company does not amount to an imminent infringement, nor does the grant of such an authorisation create one.
- Completion of the national procedures for health technology assessment, pricing and reimbursement for a generic medicine can amount to an imminent infringement. The assessment must be made with due regard to the national regulatory and legislative context and considering the circumstances of the case.
- A request for an order to communicate information in a case of alleged imminent infringement has been denied since there is no indication that the requested information actually exists and that moreover any explanation that the requested information is reasonably necessary for the purpose of advancing that party's case is lacking.
- Although national law is a source of law pursuant to Art. 24 UPCA, it is for the parties to bring forward facts and evidence about the content of national law and its application.

KEYWORDS:

- Provisional measures, imminent infringement, generic medicines, order to communicate information

APPELLANT AND RESPONDENT IN THE CROSS-APPEAL (AND APPLICANT BEFORE THE COURT OF FIRST INSTANCE)

Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany

(hereinafter 'Boehringer Ingelheim')

represented by attorney-at-law Joana Piriquito Santos, Piriquito Santos & Associados, Lisbon, Portugal, and other representatives from that firm

RESPONDENT AND CROSS-APPELLANT (AND DEFENDANT BEFORE THE COURT OF FIRST INSTANCE)

Zentiva Portugal, LDA., Algés, Portugal

(hereinafter 'Zentiva')

represented by attorney-at-law Patrícia Paias, Antas da Cunha ECIJA, Lisbon, Portugal, and other representatives from that firm

PATENT AT ISSUE

EP 1 830 843

PANEL AND DECIDING JUDGES

Panel 2
Rian Kalden, presiding judge and legally qualified judge
Ingeborg Simonsson, legally qualified judge and judge-rapporteur
Patricia Rombach, legally qualified judge
Andreas Gustafsson, technically qualified judge
Carola Wagner, technically qualified judge

IMPUGNED ORDER OF THE COURT OF FIRST INSTANCE

Local Division Lisbon, 8 May 2025, application for provisional measures, ORD_18599/2025, ACT_3186/2025, UPC_CFI_41/2025

LANGUAGE OF THE PROCEEDINGS

English

ORAL HEARING

21 July 2025, on-site in Luxembourg

SUMMARY OF THE DISPUTE

The patent and the patentee's product

1. Boehringer Ingelheim is the proprietor of European patent 1 830 843 “Indolidone derivatives for the treatment or prevention of fibrotic diseases” (hereinafter the patent). The patent is validated and in force in the following UPC territories: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Portugal, Romania, Slovenia and Sweden. Boehringer Ingelheim is the registered owner in these Member States except in Germany, France and Italy, where it is held by another company within the same group. Boehringer Ingelheim Pharma GmbH & Co. KG as patent owner of the German part authorised Boehringer Ingelheim to enforce the German part of the patent in its own name against Zentiva and confirmed that Boehringer Ingelheim is entitled to enforce the French and Italian parts of the patent against Zentiva. The patent is in force until 21 December 2025.

2. Claims 1 and 2 of the patent are second medical use claims. The content of patent claims 1 and 2 has been set out by the Lisbon Local Division in paras 17 and 18 of the impugned order, to which reference is made.

3. On 9 May 2023, Boehringer Ingelheim filed an application with the UPC Registry to opt out the patent. A subsequent withdrawal of the opt-out was registered and regarded as effective from 17 January 2025.

4. Boehringer Ingelheim sells its medical product under the tradename Ofev® in Portugal, in the pharmaceutical form of soft capsules for oral administration containing 100 mg or 150 mg of nintedanib as esilate. Ofev® is indicated for (inter alia) the treatment of idiopathic pulmonary fibrosis (IPF).

5. It is common ground that in Portugal, medicines containing nintedanib as an active substance are restricted prescription medicines for hospital use only. They cannot be sold to the public in pharmacies but are dispensed in hospital pharmacies.

The contested embodiments and the CFI proceedings

6. Since 30 August 2024, Zentiva holds two marketing authorisations in Portugal for generic medicines comprising nintedanib (as esilate salt) as active ingredient, having Ofev® as reference medicine. The marketing authorisations, granted by INFARMED, the National Authority of Medicines and Health Products, are for Nintedanib Zentiva soft capsules 100 mg and 150 mg, indicated for use in adults for the treatment of IPF, the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype and the treatment of SSc-ILD. These products are hereinafter referred to as the Zentiva generics, or simply the generics.

7. In addition Zentiva applied to INFARMED for an agreed price, an agreed reimbursement rate and establishment of the conditions for the acquisition of medicines by the public hospitals. The application was granted on 6 December 2024 and the results communicated in a notice to the national health care system by INFARMED on 12 December 2024. The notice included the following: “As of the date of this notification, entities under the supervision of the Government official responsible for the health sector will be able to purchase this medicine, under the terms of article 26(2), for use in the indication that has now been approved, and under the terms of article 27-A, the MA holders have one year to start commercialising it.”

8. Boehringer Ingelheim applied to the Lisbon Local Division for provisional measures against Zentiva, and for an order to communicate information. It alleged that the generics fall within the scope of the patent and that there is a serious threat of infringement by Zentiva, through the offer and/or placing on the market of the generics on the Portuguese market.

9. Zentiva replied that the proceedings for provisional measures were unnecessary because on 25 March 2025, the Portuguese Intellectual Property Court issued a decision by default against Zentiva, thereby granting an application for a preliminary injunction lodged by Boehringer Ingelheim's group company Boehringer Portugal concerning the same product, Nintedanib Zentiva.

10. In substance, Zentiva argued that Boehringer Ingelheim had not sufficiently provided, at that stage, facts and reasonable evidence to support that all pre-launch preparations have been completed in such a way that an offer/place on the market can be made at any time, and that there is no necessity for provisional measures.

THE IMPUGNED ORDER (INSOFAR AS RELEVANT)

11. The Lisbon Local Division found no basis for dismissing the proceedings on the grounds of lack of necessity. It found that the injunction issued by the Portuguese Intellectual Property Court was based on another intellectual property right and that the parties to the respective proceedings were not identical. Furthermore, the requests in the Portuguese national proceedings were territorially limited to Portugal. By contrast, Boehringer Ingelheim's Application applies to all Contracting Member States (CMS) of the UPC in which the patent is in force. It further noted that the Portuguese Intellectual Property Court's order may be subject to appeal.

12. The Lisbon Local Division denied provisional measures, holding that a risk of imminent infringement had not been demonstrated. The reasons for the order can be summarised as follows:
    - It is undisputed that the Zentiva generics contain nintedanib and are suitable for the prevention or treatment of IPF. Accordingly, they fall within the scope of the patent.
    - In Portugal, holding a marketing authorisation is sufficient to sell to private hospitals (although there is no direct or indirect indication of any action taken in that regard). However, if the marketing authorisation holder wishes to supply its medicine to public hospitals and seek reimbursement, a Prior Evaluation Procedure (PEP), the purpose of which is to establish the conditions under which relevant public entities can acquire medicines (e.g. maximum prices and reimbursement by the State), as well as their therapeutic indications, must be requested. This applies to nintedanib medicines. It is customary for generic pharmaceutical companies in Portugal to request a PEP before the expiration of a patent.
    - The Local Division considered that requesting a marketing authorisation or PEP are mere administrative actions that do not, in themselves, establish a risk of imminent infringement.
    - Boehringer Ingelheim had not presented any arguments for imminent infringement, indicating that Zentiva, has engaged in any conduct indicating that it will likely place the product on the market.

13. The Local Division set the value of the case at € 1.000.000 and ordered Boehringer Ingelheim to pay to Zentiva interim costs of the proceedings in the amount of € 92.944,15.

Other points of dispute before the Local Division (insofar as relevant)

14. On 8 April 2025, in the evening before the oral hearing, Zentiva lodged an application (App_17165/2025) to submit documents concerning a centralised public procurement procedure for the purchase of nintedanib, which was awarded exclusively to Boehringer Ingelheim Portugal. It is recorded in the impugned order that the Court rejected the generic application as it was submitted too late in the proceedings, depriving the opposing party of the opportunity to respond in time. Therefore, the Court considered that said application must be declared inadmissible pursuant to R. 9.2 RoP and the principle of a fair trial.

SUMMARY OF THE PARTIES' REQUESTS

The appeal

15. Boehringer Ingelheim has appealed and requests the Court of Appeal to set aside totally the impugned order and substitute it by its own order so that the Application for provisional measures is granted and therefore:

1) order Zentiva to refrain from, within the territory of the Contracting Member States in which the patent is in force, namely Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Portugal, Romania, Slovenia and Sweden, from making, offering, placing on the market or using, or importing or storing for those purposes, any product comprising nintedanib (or a tautomer, a diastereomer, an enantiomer, the mixtures thereof or a salt thereof, including nintedanib esilate) for use in the prevention or treatment of idiopathic pulmonary fibrosis, in particular the Zentiva Generics, while EP '843 is in force.

2) order Zentiva to provide the Boehringer Ingelheim, within four (4) weeks after service of the order rendered, appropriate documentation of:
• the quantities of the Zentiva generics ordered, imported and/or stored, notably by Zentiva, in the Contracting Member States in which the patent is in force;
• the origin of the Zentiva generics, including the full names and addresses of the legal entities that are involved in the supply to Zentiva of the Zentiva generics, and the amount of Zentiva generics supplied to Zentiva by each of those entities in the Contracting Member States in which the patent is in force;
• any orders for the supply of the Zentiva generics in the Contracting Member States in which the patent is in force that have been received, including the full names and addresses of the legal entities that placed said orders and the exact quantities of Zentiva generics ordered in each case.

3) order Zentiva, for the Contracting Member States in which the patent is in force, to comply with the orders rendered above, subject to a recurring penalty payment to the Court of € 250,000.00 for each violation of, or non-compliance with, the referred order(s), or another amount as the Court may order;

4) substitute Local Division Order 2) by its own order that Zentiva is ordered to pay to Boehringer Ingelheim the interim costs of the proceedings at first instance and on appeal in an amount of € 199,000.00;

5) declare these orders effective and enforceable immediately.

16. Zentiva requests that the appeal be dismissed, that the impugned order be upheld and that Boehringer Ingelheim be ordered to bear the costs of the appeal.

Zentiva's cross-appeal

17. By cross-appeal, Zentiva requests that the Court of Appeal
i. set aside the decision delivered by the Court of First Instance declaring the generic application of 8 April 2025 inadmissible;
ii. admit into the record the documentation submitted with Zentiva's generic application of 8 April 2025, or in the alternative, allow the introduction of such evidence into the appeal proceedings;
iii. take full account of the submitted procurement documents when assessing the lack of any imminent threat of infringement;

iv. acknowledge the legal and evidentiary relevance of the preliminary injunction issued by the Portuguese Intellectual Property Court on 26 March 2025, in Case No. 57/25.1YHLSB, and dismiss the application on the grounds that the requested provisional measures are not needed;
v. on the basis of the documentary and judicial evidence before it, uphold the decision of the Court of First Instance insofar as it declined to find an imminent threat of infringement under Art. 62(1) UPCA, and, accordingly, maintain the refusal to grant provisional measures against Zentiva;
vi. order Boehringer Ingelheim to bear the costs of this cross-appeal, in accordance with R. 118.2 RoP, and in view of the procedural conduct and substantive outcome.

18. Boehringer Ingelheim requests that the cross-appeal be rejected as being inadmissible both (i) in respect to the Court of First Instance's refusal to acknowledge the relevance of the Portuguese Court Order and (ii) against the procedural order rejecting Zentiva's generic application submitted on 8 April 2025; or, in cany case, dismiss the cross-appeal as a whole for being unfounded. Boehringer Ingelheim submits that Zentiva should bear the costs incurred, including any legal fixed fees paid.

Procedural request

19. On 18 July 2025, Boehringer Ingelheim requested (App_33288/2025) pursuant to R. 222 RoP to be allowed to submit new documents into the procedure, concerning the launch of a new public tender for the formation of a new framework agreement for the acquisition of several medicines including nintedanib. Zentiva has opposed the request.

THE PARTIES' SUBMISSIONS

Boehringer Ingelheim's submissions (in summary and insofar as relevant)

20. Zentiva is an authorised and registered wholesale distributor of medicines. The Zentiva generics were subject to a) granted marketing authorisations b) an agreed price, c) an agreed reimbursement rate and d) the conditions for the acquisition of medicines by the public hospitals. As from 12 December 2024, following the notice issued by INFARMED, the Portuguese national entities supervised by the member of the Government responsible for the health area know that they can purchase the Zentiva generics for use in the indications that have now been approved. Since a prior evaluation contract has been signed, the entities in question are already able to acquire Zentiva's medicine. Zentiva has completed all pre-launch preparations to be able to, at any time, make an offer to the national health services or any entity of the national health services that wish to acquire this medicine.

21. Zentiva requested (and completed) the PEP prematurely and without informing the national authority of any obstacles which could prevent it from commercialising the product. This shows an intent, without reservations, to commercialise the generics before patent expiry. Furthermore, Zentiva must do so within one year to avoid the lapse of the pre-evaluation.

22. As regards the necessity of provisional measures:
    - Zentiva can now offer and/or place on the market its nintedanib generic products without any control of Boehringer Ingelheim.
    - Up until now, Boehringer Ingelheim, through its Portuguese subsidiary, is the only supplier of nintedanib medicines to the hospital market, and at the price of Ofev®.

- The price of the Zentiva generics will be at least 30% lower than Ofev®.
- A typical effect of a generic product being offered (promoted as being soon available) or placed on the market is the immediate suspension of the acquisitions, or the acquisition of a much lower quantity, of the reference medicine by the normal or potential purchasers of such products. With Zentiva generics being available at a much lower price, the most likely scenario is that there will be a complete, or at least very close to complete, switch from Ofev® to Zentiva generics.
- The (much) lower price of the Zentiva generics could even have negative effects on the price of Ofev® in other countries which conduct international reference pricing based on the cheapest nintedanib product on the market in Portugal (i.e. countries which determine the price of Ofev® based on a country basket including Portugal), resulting in a spillover effect to other countries.

23. As regards to urgency, Boehringer Ingelheim obtained information about the outcome of the PEP on 19 December 2024. Following actions to investigate Zentiva's conduct and gather information, it brought action one month thereafter. Boehringer Ingelheim requests the Court of Appeal to reject Zentiva's argument on lack of urgency for being inadmissible and, in any case, dismiss it for being unfounded.

24. The recent disclosure that Zentiva's parent company is covering all representation costs in these proceedings, is clear evidence of the international dimension of Zentiva's acts, whose activities appear to be part of a broader, coordinated European action plan.

25. While it is not disputed that there is a Framework Agreement in place for nintedanib in Portugal, and that currently Boehringer Ingelheim Portugal is the only entity listed for the acquisition of nintedanib, contracting entities can purchase outside the framework agreement, if they can demonstrate that there is an alternative with a price at least 10% lower for an object with the same characteristics and level of quality. Furthermore, new framework agreements can be opened at any time. In addition, other procedures, such as prior consultation or direct awards, can be initiated by contracting entities and private hospitals can negotiate directly with Zentiva the terms of an acquisition of nintedanib.

26. It is incorrect to say, as the Local Division did, that "further administrative procedures are still required" and that "the Applicant also recognised that such further administrative procedures are still needed".

27. Moreover, the Local Division (para 62 of the impugned order) relied on the uncontested fact that it is customary for generic pharmaceutical companies in Portugal to request a PEP before the expiration of a patent, but failed to acknowledge that Zentiva was the first and the only generic company that requested and concluded the PEP for nintedanib. To the best of Boehringer Ingelheim's knowledge, no other nintedanib generics with a granted marketing authorisation applied for a PEP, even 5 months after the filing of the Application for provisional measures, which shows that in fact such practice is not "customary for generic pharmaceutical companies in Portugal" this early.

28. Concerning the Bolar exemption, nothing is said in Art. 27(d) UPCA or in Art 10.6 of Directive 2001/83/EC about activities such as health technology assessment, pricing and reimbursement.

29. In relation to the application for an order to communicate information, the Zentiva generics are manufactured by other companies, both headquartered in Malta and in Greece. Boehringer Ingelheim seeks to know the arrangements in place or planned for the sale of the infringing products to public

and/or private hospitals, as well as the amounts of infringing products imported by and/or in possession of Zentiva (and the respective origin).

Zentiva's submissions (in summary and insofar as relevant)

30. The Portuguese Intellectual Property Court's decision against Zentiva, partially granting provisional measures based on Supplementary Protection Certificate No. 679, means that Boehringer Ingelheim's Application has lost its utility and legal basis. Zentiva is already prevented from conducting any of the activities relating to nintedanib, pursuant to the Application, until SPC 679 expires, which will occur after the expiry of EP '843. Furthermore, the marketing authorisations granted to Zentiva are territorially limited to Portugal, which is already covered by the Portuguese court order.

31. There is no imminent infringement:
    - The granting of authorisation to place a generic on the market does not constitute, in itself, patent infringement (Art. 25 UPCA).
    - National law ensures that the generic companies can carry out all the formalities to put their products on the market, such as the request and grant for the marketing authorisations, prices and reimbursement, before the expiry of the intellectual property rights over the originator product.
    - Therefore, Zentiva could apply for the granting of the marketing authorisations and INFARMED could grant it, as it did, without thereby infringing the patent.
    - The granting of price and reimbursement or prior hospital evaluation does not constitute patent infringement and thus does not fall within any of the actions prohibited by Art. 25 UPCA.
    - As regards the communication issued by INFARMED on 12 December 2024, it was issued by INFARMED and not by Zentiva. Zentiva has not sent any letter to hospitals or any entity from the national health services.
    - Prior Hospital Evaluation enables the financing of medicines by national health services hospitals, determining the conditions for their use. However, it is still needed to comply with pre-contractual procedures applicable to the acquisition of medicines. Nintedanib products can only be acquired by hospitals of the national health service through public procurement procedures.
    - Zentiva would not be bound to submit a tender in a public procurement procedure, but would in fact be prevented from doing so, because according to the Portuguese Public Contracts Code (Decree-law 18/2008, of 29 January), only contracting parties with the capacity to perform the contract in question should be consulted.
    - There is a Framework Agreement in place for the acquisition of nintedanib medicines (Framework Agreement no 491/2023) in Portugal until September 2025, subject to an automatic renewal for further 12 months, i.e. until September 2026, where the only contractor listed is Boehringer Ingelheim Portugal.
    - In view of this, any tendering procedures related to public contracts for the supply of nintedanib products to the national health services will be granted to Boehringer Ingelheim Portugal.
    - Since SPC 679, granted on the basis of a prior patent EP 1 224 170, is in force until 9 April 2026, any contractor´s tender from Zentiva would be, in any event, excluded under national law.
    - It is not mandatory to market the product within one year as of the date of notification of the grant of reimbursement/ prior evaluation. The lapse of the one-year period will not lead to expiry of the prior hospital evaluation when the non-marketing of the product is imposed by law (for instance the existence of patent rights).

- The granting of marketing authorisations and PEP cannot isolated and theoretically speaking be considered an actual imminent threat.
- According to the revised "Bolar Exemption" not only studies and trials to studies, trials and the consequential practical requirements which are necessary to obtain the marketing authorisation will be exempted, but also those necessary for the obtention of health technology assessment and pricing and reimbursement.

32. In relation to the application for an order to communicate information, the sought after documents, if they existed, would be subject to confidentiality protection.

33. Zentiva has also objected against the amount suggested for recurring penalty payments.

34. As utmost precautionary pleading, Zentiva requests that the application be dismissed on the grounds that balance of interests is in favour of Zentiva (Art. 62 (2) UPCA) and that it be dismissed on the basis of lack of urgency where it relates to private hospitals (R. 209.2 (b) RoP).

Zentiva's grounds of appeal in the cross-appeal

35. Zentiva submits that the Local Division erred in law and procedure by:
    - misapplying R. 9.2 RoP in rejecting Zentiva's generic application of 8 April 2025;
    - failing to consider proportionate procedural alternatives that would have preserved Zentiva's rights without compromising the fairness of the proceedings;
    - undervaluing the relevance and legal impact of the Portuguese Intellectual Property Court's preliminary injunction.
    - incorrectly assessing the absence of imminent infringement under Art. 62(1) UPCA by disregarding key factual and legal developments.

Boehringer Ingelheim's response to the cross-appeal

36. Boehringer Ingelheim takes the view that in substance all the assessments by the Court of First Instance on the Portuguese Intellectual Property Court's order of 25 March 2025 are correct.

37. For Zentiva's cross-appeal against the procedural order that rejected its generic application of 8 April 2025, the requirements of Art. 73.2(b)(i) UPCA and R. 220.2 RoP are not met, because:
    - Zentiva is not allowed to bring any appeal or a cross-appeal against the order of the Court of First Instance issued on 8 May 2025 that dismissed the request for provisional measures as Zentiva is not a party adversely affected by it;
    - Zentiva did not lodge an application for leave to appeal against the procedural order issued during the oral hearing on 9 April 2025 in Lisbon that rejected Zentiva's generic application submitted on 8 April 2025 (which should have been done, by analogy with R. 221.1 RoP, within 15 days of the notification of the order in question). No leave to appeal against the order has been requested or granted.

38. Moreover, the Court of First Instance was right to reject these documents, for they are irrelevant to the decision of the case, which is why the cross-appeal should be dismissed (if it is not rejected on the basis of being inadmissible).

GROUNDS FOR THE ORDER

39. For the reasons set out by the Lisbon Local Division, the Court of Appeal upholds the findings that there is no basis for dismissing the proceedings on the grounds of lack of necessity because of the injunction issued by the Portuguese Intellectual Property Court based on SPC 679.

Procedural issues

40. The Court of Appeal upholds the finding of the Lisbon Local Division that the new facts and evidence lodged by Zentiva on 8 April 2025, in the evening before the oral hearing, were submitted too late in the proceedings, and sees no reason to exercise its discretion to allow it into the appeal proceedings pursuant to R. 222 RoP.

41. Zentiva has not justified why the evidence submitted on 8 April 2025 could not reasonably have been submitted timely during the proceedings of the Court of First Instance. The submission concerns documents from a centralised public procurement procedure for the purchase of nintedanib from February 2025 or earlier. Zentiva argues that it only obtained them on the evening before the first instance oral hearing. However, the speed required for gathering evidence must follow the short timeframes for proceedings for provisional measures. The relevance of the documents for the decision on the appeal cannot justify that it be admitted either.

42. For similar reasons, Boehringer Ingelheim's new facts and evidence, submitted on Friday 18 July 2025, shall be disregarded. According to Boehringer Ingelheim, the launch of a new public tender for the formation of a new framework agreement (among other medicines) regarding nintedanib was published on 10 July 2025, and it became aware of this on 16 July and obtained access to the documents only on 18 July. The Court of Appeal considers that the gap between 10 July and 16 July 2025 has not been sufficiently explained by Boehringer Ingelheim. The documents were launched outside office hours on the Friday evening immediately before the oral hearing which took place on Monday morning. Admitting the documents would not be fair towards Zentiva and the relevance of the documents do not speak in any other direction.

43. In its Statement of response, Zentiva has alleged that it is obvious that Boehringer Ingelheim failed to demonstrate before the Court that provisional measures were lodged without unreasonable delay, as it took around 6 months to lodge the proceedings after the Portuguese marketing authorisations were granted to Zentiva. The Court of Appeal will disregard this submission as well, as there is no reason why this could not have been brought at first instance.

Imminent infringement; legal standard

44. Pursuant to Art. 62(1) and (4) UPCA, insofar as relevant, the Court may, by way of order, grant injunctions against an alleged infringer, intended to prevent any *imminent* infringement. The Court may require the applicant to provide any reasonable evidence in order to satisfy itself with a sufficient degree of certainty that the applicant's right is being infringed, or that such infringement is *imminent* (emphasis added).

45. Provisional measures can be ordered to prevent a threatened infringement (R. 206.2 (c) RoP, see also R. 213.2 RoP). It follows from R. 211.2 RoP that, in taking its decision on provisional measures, the

Court may require the applicant to provide reasonable evidence to satisfy the Court with a sufficient degree of certainty that his right is being infringed, or that such infringement is *imminent* (emphasis added).

46. The Court of Appeal agrees with Boehringer Ingelheim's contention that a situation of 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. .

47. In the context of marketing of generics, the mere application for a marketing authorisation by a generics company does not amount to an imminent infringement, nor does the grant of such an authorisation create one.

48. Completion of the national procedures for health technology assessment, pricing and reimbursement for a generic medicine can amount to an imminent infringement. The assessment must be made with due regard to the national regulatory and legislative context and considering the circumstances of the case.

The Bolar exemption

49. According to Art. 27 (d) UPCA, the rights conferred by a patent shall not extend to the acts allowed pursuant to Article 13(6) of Directive 2001/82/EC or Article 10(6) of Directive 2001/83/EC in respect of any patent covering the product within the meaning of either of those Directives. The so-called Bolar exemption is stipulated in Art. 10(6) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and reads: "Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products."

50. Art. 85 of the pending "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," dated 26 April 2023 (COM(2023) 192 final, 2023/0132 (COD) envisages that patent rights, or supplementary protection certificates shall not be regarded as infringed when a reference medicinal product is used for the purposes of *inter alia* (iii) pricing and reimbursement.

51. Zentiva does not contend that its actions fall within the existing Bolar exemption, nor that the legal standard envisaged in the draft actually applies, but argues that the Court's interpretation of what constitutes imminent infringement must be in line with the draft. Contrary to what Zentiva is advancing, the draft Art. 85 will come into play if and when it is enacted (and subject to any provisions on entering into force and/or transitional periods). The Court of Appeal applies the existing legislation.

Standard of proof and burden of proof

52. This case is based entirely on an alleged imminent infringement. The standard of proof is whether there is a sufficient degree of certainty, so that the Court is satisfied that on the balance of probabilities it is more likely than not that a patent infringement is imminent. Insofar as is relevant here, Boehringer

Ingelheim has the burden of presentation and proof for facts establishing the imminent infringement of the patent, as well as for all other circumstances supporting its request.

Imminent infringement; application of the said principles to the case

53. The appeal is successful. Boehringer Ingelheim is justified in alleging that there is an imminent infringement through Zentiva's actions with the nintedanib generics on the Portuguese market.

54. As explained, the legal test when an infringement has not yet occurred, is whether the potential infringer has already set the stage for it to occur, so that the infringement is only a matter of starting the action because the preparations for it have been fully completed. In the present case it is disputed what action, if any, could be started without further preparations by Zentiva.

55. As set out in the impugned order (para 38), the purpose of a PEP evaluation in Portugal is to establish the conditions under which relevant public entities can acquire medicines (e.g. maximum prices and reimbursement by the State), as well as their therapeutic indications.

56. Zentiva made its PEP application sometime between the granting of the marketing authorisation, which was on 30 August 2024, and the day when the PEP was approved by INFARMED, which was on 6 December 2024. The patent at issue is in force until 21 December 2025. This places Zentiva's PEP application more than a year ahead of patent expiry.

57. It was established in the impugned order, and not contested on appeal, that it is customary for generics companies in Portugal to apply for a PEP before the expiration of a patent, but – at the same time – that Zentiva concluded this procedure prematurely (see the impugned order at para 62). The significance of this was not explored further.

58. Whether a premature PEP application can constitute imminent infringement depends on what can be done on the Portuguese market during the period of more than one year before the patent expires. This will be analysed, on the circumstances of this particular case, in relation to the question of whether any further administrative steps or procedures were required before Zentiva could offer and sell its generic products to public hospitals, whether a characterisation of the pharmaceuticals acquisition procedures as precontractual under Portuguese law matters, whether the nintedanib products can only be acquired by Portuguese public hospitals through public procurement procedures and whether Zentiva is effectively hindered from taking part in any proceedings for the acquisition of the generics.

– Whether Zentiva must take further administrative steps to commercialise the generics.

59. Zentiva has brought forward that a medicinal product will only be listed as "available" in INFARMED's database following the so-called pre-notification of marketing commencement by the holder of the marketing authorisation. The start of marketing shall coincide with the 1st day of each month and the pre-notification must be submitted between the 1st and the 15th (inclusive) of the preceding month.

60. Boehringer Ingelheim has counter-argued that pursuant to the Portuguese Medicines Act the pre-notification to INFARMED is just a notice before the generics can be delivered. Once the database listing of the Zentiva generic turns from grey to blue, it signifies that products are available for sales, or

that actual sales are made, thus constituting an offer or act of placing on the market. Boehringer Ingelheim undisputed by Zentiva pointed out that it is able to monitor this database, but that there is no transparent period in between a pre-notification made by Zentiva and the commencement of sales. The said information is only made publicly available in the INFARMED database at a later stage and at irregular intervals.

61. This statement on how the relevant provision of the Medicines Act is applied has not been contested as such by Zentiva. When questioned at the oral hearing, Zentiva confirmed that when the listing in the INFARMED database turns from grey to blue it can mean that the product is being marketed on the very same day in the sense that the company will be able to receive orders and even already deliver them.

62. The Court of Appeal concludes that the pre-notification to INFARMED is a formality which can be fulfilled by the supplier with relative ease and at short notice.[1] While similar systems are in place in other Member States, what seems to be particular for Portugal is that the originator (here Boehringer Ingelheim) has no way to ascertain from time to time if the generics are on the Portuguese market or are soon to be launched. When the product turns "blue" in the INFARMED database, ongoing deliveries can already be a fact. Boehringer Ingelheim is therefore unable to prevent that Zentiva actually places products on the market based on the information in the INFARMED database.

– Whether a characterisation of the pharmaceuticals acquisition procedures as precontractual under Portuguese law matters

63. Whether nintedanib products can only be acquired by public hospitals through public procurement procedures is disputed. This is addressed below. There is however an assumption on Zentiva's side that needs to be addressed first, namely that public procurement procedures are pre-contractual under Portuguese law. Furthermore, a distinction between different acts of infringement must be made.

64. The Court of Appeal emphasises that, while it is self-evident that participation in a public procurement proceeding necessarily precedes being awarded such a contract, this does not affect how the term "offering" in Art. 25 UPCA shall be interpreted. Taking part in public procurement procedures with the generics while the patent is still in force will generally constitute infringement through offering, regardless of whether a public procurement procedure is classified as pre-contractual under national law. The same applies whether or not direct awards or prior consultations are pre-contractual.

65. Even if it were true that making, placing on the market or using the generics, or importing or storing them for those purposes, could only happen after the completion of a public procurement procedure, 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.

[1] Pursuant to Art. 17 (1, 2 and 6) of Portuguese Decree Law 97/2015 the holder of the MA is obliged to communicate the start of the commercialisation of the reimbursed medicine on their initiative. The start of commercialisation coincides with the 1st day of each month, and the holder of the MA must send the respective communication between the 1st and the 15th of the immediately preceding month. After the communication referred to in paragraph 1, INFARMED, I.P. is responsible for including or excluding the medicine from the lists and files that publicise reimbursed medicines.

– Whether nintedanib products can only be acquired through public procurement procedures

66. Although it is uncontested that public procurement procedures are carried out in Portugal for the acquisition of medicines, the parties have adopted opposite positions when it comes to the possibility for public hospitals to acquire outside of such procedures.

67. Boehringer Ingelheim has demonstrated to the requisite standard, with reference to the Portuguese Public Procurement Code, that public hospitals can place orders up to € 5,000.00 as direct awards. Furthermore, prior consultation procedures can be initiated by the contracting authority, where it directly invites at least three entities of its choice to submit a tender and negotiate with them. In addition, contracting entities covered by a tied purchase system under a framework agreement shall under certain conditions be excepted from this obligation if they demonstrate that, *inter alia* for a given purchase, the use of the framework agreement would lead to the payment of a price, per unit of measurement, at least 10 % higher than the price demonstrated by the contracting authority for an object with the same characteristics and level of quality.

68. Zentiva's view that the purchasing entities can only acquire the nintedanib medicines through the Framework Agreement itself and not through direct awards or prior consultations is difficult to reconcile with the wording of the legislation referred to by Boehringer Ingelheim.[2]

69. Boehringer Ingelheim has thus made it more likely than not that the approved PEP will enable Zentiva to offer the generics to Portuguese public entities.

– Whether Zentiva is effectively hindered from taking part in any proceedings for the acquisition of the generics

70. Zentiva's argument that it is effectively hindered from taking part in any public procurement proceedings is unsuccessful. The evidence presented does not include any legal mechanisms that are in place to prevent Zentiva from offering the generics.

71. Zentiva has maintained that it would be prevented from submitting a tender in a public procurement procedure, because according to the Portuguese Public Contracts Code, only the contracting parties with the capacity to perform the contract in question should be consulted. As a development of this

[2] Article 256-A para 1 of the Portuguese Public Contracts Code - Obtaining the most advantageous price outside the framework agreement – reads "Contracting entities covered by a tied purchase system under a framework agreement shall be excepted from this obligation if they demonstrate that, for a given purchase or lease of movable property or purchase of services, the use of the framework agreement would lead to the payment of a price, per unit of measurement, at least 10 /prct. higher than the price demonstrated by the contracting authority for an object with the same characteristics and level of quality, under the terms of the following paragraphs". Para 3 reads: "The demonstration referred to in paragraph 1 shall be made: a) In the case of a contract for the purchase or lease of movable property or the purchase of services where the price is not above (euro) 5000, by means of a pro forma invoice or equivalent document and a declaration by the invited entity that the good or service has the same characteristics and level of quality as the goods or services which are the subject of the framework agreement;". Article 16 – Contract formation procedures – lists in para 1b) Prior consultation. Both prior consultation and direct awards are regulated in Article 112 – Concept of prior consultation and direct award – which reads: "Prior consultation is the procedure in which the contracting authority directly invites at least three entities of its choice to submit a tender and may negotiate with them on aspects of the performance of the contract to be awarded." Direct award is the procedure in which the contracting authority directly invites an entity of its choice to submit a tender."

argument, Zentiva has put forward that contractors and contracting entities alike are bound by the respect for intellectual property rights, for example, the Specifications of the Framework Agreement requires the awarded bidder to guarantee compliance with intellectual and industrial property laws, including patents.

72. When questioned at the oral hearing about how this would be effected, Zentiva has stated in a general way that there would be liability and legal consequences if it still participated in public procurement procedures and that it could be excluded. The legal framework for this has however not been explained by Zentiva. Zentiva has made a reference to Article 77 of the Portuguese Public Contracts Code, without explaining its wording or content. Although national law is a source of law pursuant to Art. 24 UPCA, it is for the parties to bring forward facts and evidence about the content of national law and its application.

73. It is contested between the parties whether Portuguese public entities have any duty to assess compliance with patent rights when acquiring medicines, and Zentiva has not made it more likely than not that there is effectively such a duty.

74. Zentiva's defence ultimately comes down to the argument that any participation by it in public procurement procedures in relation to nintedanib prior to patent expiry would constitute patent infringement and that it could incur liability. This, however, means that self-restraint by Zentiva is the real mechanism for preventing infringement. This applies equally to the patent and SPC 679.

75. In addition and as already explained, there is more than one way for public hospitals and entities to purchase medicines.

76. The Court of Appeal does not find it more likely than not that Zentiva would be prevented from participating in procedures for the acquisition of nintedanib products in Portugal.

– Conclusions on imminent infringement

77. The Court of Appeal finds it more likely than not that the PEP approval by the national authority means that Zentiva can offer the generics to public hospitals in Portugal without any further administrative steps or procedures. The evidence so far does not support that there is anything in place nationally but self-restraint on Zentiva's side to prevent it from taking part in public procurement procedures, direct awards or prior consultations, acts that would likely constitute infringement by offering the products.

78. The undisputed existence of a Framework Agreement for the acquisition of nintedanib medicine in Portugal, in force until September 2025, where the only contractor listed is Boehringer Ingelheim Portugal, does not alter this. Boehringer Ingelheim has made it more likely than not that new Framework Agreements can be initiated. This can be seen from Clause 3.4 of the present Framework Agreement. In view thereof, Zentiva's argument that any tendering procedures related to public contracts for the supply of nintedanib products to the national health services will be granted to Boehringer Ingelheim Portugal cannot hold.

79. It must be said that Boehringer Ingelheim's allegation that according to the notification of 12 December 2012 the Zentiva generics must be commercialised within a year from the date of the grant of the PEP

to avoid the lapse of the PEP, is not supported to the requisite degree by the facts, or has at least been rebutted by Zentiva. The notice issued by the INFARMED on 12 December 2024 indeed reads “and under the terms of article 27-A, the MA holders have one year to start commercialising it.” Zentiva has pointed to a passage in Art. 18:2 of Decree-Law no. 97/2015 on the National Health Technology Assessment System (SiNATS), which addresses expiry due to non-commercialisation. It provides an exemption when non-commercialisation is imposed by law or court decision. This does, however, not alter the assessments made.

80. Zentiva has not offered any credible explanation why, absent patent infringement, it would be useful for it to obtain the PEP more than one year before the patent expires. The Court of Appeal concludes that the only way a completed PEP can be of any use for Zentiva from an objective point of view is for the offering of the generics.

81. On balance, it is more likely than not that Zentiva has set the stage for offering the generics in Portugal, so that the infringement is only a matter of starting the action because the preparations for it have been fully completed.

Necessity

82. Boehringer Ingelheim has essentially brought forward that pursuant to Art. 25 SiNATS, the price of the Zentiva generics will be at least 30% lower than Ofev® and that this will result in suspension of the acquisitions of Ofev®, or the acquisition of a much lower quantity, and a complete, or at least very close to complete, switch from Ofev® to Zentiva generics.

83. The lower price for the generics is accepted as a starting point by the Court of Appeal. A move from a market situation where only one product is available, to one where there are two competing products, can be expected to lead not just to price pressure but to a permanent price erosion. This risk is an important factor when considering whether a provisional injunction is necessary (CoA, order of 3 March 2025, UPC_CoA_523/2024, APL_51115/2024, Sumi vs Syngenta).

84. The Court of Appeal considers that the market will understand the national regulatory set-up and act accordingly. Absent any hard mechanism to stop Zentiva from offering the products, the pre-notification being not immediately visible to third parties such that Boehringer Ingelheim could prevent Zentiva from actually placing infringing products on the market, the premature PEP application and the notification of the PEP approval by the national authority creates expectations from public – as well as private – hospitals that the generics will be offered ahead of patent expiry.

85. On balance, the necessity requirement is met (R. 206.2 (c) RoP).

Urgency

86. According to R. 211.4 RoP, the Court shall have regard to any unreasonable delay in seeking provisional measures.

87. The delay within the meaning of R. 211.4 RoP shall be calculated from the day on which the Applicant became aware, or should have become aware, of the infringement that would enable him, in accordance with R. 206.2 RoP, to file an Application for provisional measures with a reasonable prospect of success. Thus, the decisive point in time is when the Applicant has, or should have had, after exercising due diligence, the necessary facts and evidence within the meaning of R. 206.2(d) RoP. (CoA, order of 25 September 2024, UPC_CoA_182/2024, APL_21143/2024, Mammut vs Ortovox).

88. The relevant point in time for Boehringer Ingelheim was consequently when INFARMED made public that the PEP for the Zentiva generics had been approved, which was on 12 December 2024.

89. The Application for provisional measures was lodged on 23 January 2025 and meets this criterion.

Recurring penalty payments

90. The Court of Appeal shall order penalty payments payable to the Court for the event that Zentiva fails to comply with the terms of the order (R. 354.3 RoP). Here, a penalty payment of € 10,000 for each package of the products with which the order is violated can be considered appropriate having regard to the importance of the order and the consequences of non-compliance.

The territorial scope of the order

91. According to Art. 34 UPCA, decisions of the Court shall cover, in the case of a European patent, the territory of those CMS for which the European patent has effect. This means that injunctions, as a rule, will cover all those CMS. A restriction would require the presence of certain circumstances, such as when a claimant has restricted the territorial scope of its action (Art. 76(1) UPCA). There are no such circumstances present in this case. Zentiva has stated that it does not hold any marketing authorisations outside Portugal, but that does not alter the Court of Appeal's conclusion. The order shall cover the territory of those CMS for which the patent at issue has effect.

The Application for an order to communicate information

92. Pursuant to Art. 67 UPCA, the Court may, in response to a justified and proportionate request of the applicant and in accordance with the RoP, order an infringer to inform the applicant of: (a) the origin and distribution channels of the infringing products or processes; (b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products; and(c) the identity of any third person involved in the production or distribution of the infringing products or in the use of the infringing process.

93. According to R. 191 RoP, the Court may in response to a reasoned request by a party order the other party or any third party to communicate such information in the control of that other party or third party as is specified in Art. 67 UPCA or such other information as is reasonably necessary for the purpose of advancing that party's case.

94. There is no allegation of any completed infringement in this case. There is no indication that the requested information actually exists and, moreover, any explanation that the requested information is reasonably necessary for the purpose of advancing that party's case is lacking. The Court of Appeal sees no reason in the present case to issue an order to communicate information as a result of an imminent infringement.

Costs

95. A cost decision shall be issued in these proceedings for provisional measures, since it concludes the action.

96. Boehringer Ingelheim is the successful party and Zentiva is the unsuccessful party who shall bear the costs. This applies regardless of the fact that the Application for an order to communicate information was unsuccessful, since this part of the action cannot be considered to have caused more than a marginal part of the costs incurred.

97. The Local Division's interim award of cost shall be reversed and Zentiva shall be ordered to pay Boehringer Ingelheim an amount of € 199,000.00 as an interim award of costs.

Conclusions

98. As a result of the assessments made, the impugned order must be set aside and be replaced by a provisional injunction, coupled with recurrent penalty payments. The Local Division's cost order must be reversed, as must the interim award of costs. All other applications and requests shall be rejected.

ORDER

The Court of Appeal sets aside the order of the Local Division Lisbon, 8 May 2025, ORD_18599/2025, ACT_3186/2025, UPC_CFI_41/2025 and:

I. orders Zentiva to refrain from, in the Contracting Member States in which the patent is in force, namely Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Portugal, Romania, Slovenia and Sweden, making, offering, placing on the market or using, or importing or storing for those purposes, any product comprising nintedanib (or a tautomer, a diastereomer, an enantiomer, the mixtures thereof or a salt thereof, including nintedanib esilate) for use in the prevention or treatment of idiopathic pulmonary fibrosis, in particular Nintedanib Zentiva soft capsules 100 mg and 150 mg, while EP 1 830 843 is in force,

II. orders Zentiva to comply with the order under (I) above, subject to a recurring penalty payment of up to € 10,000.00 for each package of the infringing products made, offered, placed on the market, used, imported or stored for these purposes,

III. orders Zentiva to bear the reasonable and proportionate legal costs and other expenses incurred by Boehringer Ingelheim in the proceedings at first instance and on appeal, also for the cross-appeal,

IV. orders Zentiva to pay Boehringer Ingelheim an amount of € 199,000.00 as an interim award of costs, within two weeks after this order has been served on Zentiva;

V. specifies the date as referred to in R. 213 RoP at 31 calendar days after service of this order,

VI. declares the order to be immediately enforceable,

VII. rejects all further applications and requests made by Boehringer Ingelheim or Zentiva.

Issued on 13 August 2025

Rian Kalden

Date: 2025.08.13 16:13:35 +02'00'

Rian Kalden, Presiding judge and legally qualified judge

Digitally signed by Åsa Ingeborg Simonsson
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Ingeborg Simonsson, legally qualified judge and judge-rapporteur

Patricia Ursula Rombach

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Peter Andreas Gustafsson

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Carola Wagner, technically qualified judge

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For the Registry: