



LISBON – LOCAL DIVISION

UPC_CFI_858/2025

ORDER

of the Court of First Instance of the Unified Patent Court
issued on 10 April 2026

CLAIMANT

BOEHRINGER INGELHEIM INTERNATIONAL GMBH (hereinafter the Claimant)

Binger Straße 173 - D-55216 - Ingelheim am Rhein

Germany

represented by

Ms. Joana Catarina Piriquito Santos

Sara Nazaré

Beatriz Lima

(NLP - NAZARÉ, LIMA, PIRIQUITO SANTOS & ASSOCIADOS SOCIEDADE DE ADVOGADOS)

DEFENDANT

ZENTIVA PORTUGAL, LDA (hereinafter Zentiva or the Defendant)

Alameda Fernão Lopes, n.º 16-A, 8.º A - 1495-190 – Algés

Portugal

represented by

Ms. Patrícia Paias

Ms. Daniela Guimarães

(ANTAS DA CUNHA ECJJA)

PATENT AT ISSUE:

EUROPEAN PATENT NO EP1830843

PANEL:

Presiding judge and

Judge-rapporteur: Rute Lopes

Legally qualified judge: Camille Lignières

Legally qualified judge: Petri Rinkinen

LANGUAGE OF THE PROCEEDINGS: English

SUBJECT: Order pursuant to R. 360 RoP.

SUMMARY OF THE PROCEDURE AND PARTIES' REQUESTS

- 1** On 23 January 2025, the Claimant filed a preliminary injunction application (UPC_CFI_41/2025) asserting that there was a risk of imminent infringement of its Patent EP1830843, arising from a communication issued by the INFARMED – National Authority of Medicines and Health Products, I.P. to the Central Administration of the public Health System, stating that the Defendant generic medicine could be purchased as from that date, and requested that the Court granted provisional measures to impede any infringement.
- 2** On 13 August 2025, the Court of Appeal granted the requested provisional measures (UPC_CoA_446/2025).
- 3** On 12 September 2025, the Claimant filed this action on the merits against the Defendant, in compliance with R. 213 RoP, following the Order of the Court of Appeal.
- 4** The Claimant requests that the Court (emphasis added):

I. 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 esylate) for use in the

prevention or treatment of idiopathic pulmonary fibrosis, in particular the Zentiva Generics, while EP '843 is in force.

II. 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 € 10,000.00 for each package of the products with which the order is violated.

III. Order Zentiva to pay the costs of the proceedings.

IV. Declare that the practice of any of the acts prohibited by Article 25(a) UPCA by Zentiva while EP '843 is in force in the relevant Territories would amount to an act of infringement and therefore subject to compensation through the award of damages to be calculated.

5 Zentiva filed a Statement of Defence, but not a counterclaim for revocation.

6 In its Statement of Defence, Zentiva requested that the Court:

1. Dismiss the Claimant's infringement action in its entirety, finding that the Defendant has not committed any act capable of constituting any legally relevant threat of infringement of European Patent No. 1 830 843 ("EP 843") and, consequently:

a) record that the provisional measures ordered by the Court of Appeal by decision of 13 August 2025 were unjustified.

b) declare, pursuant to Rule 213 of the Rules of Procedure, that the Defendant is entitled to appropriate compensation for all injury caused by the grant of those provisional measures.

c) reserve the allegation and determination of the damages, and the respective amount of compensation to separate proceedings for the determination of damages under the Rules of Procedure.

2. Order that the Claimant bear the Defendant's reasonable and proportionate legal costs and other expenses incurred in both the provisional-measures proceedings and this action, subject to assessment, together with such further or other relief as the Court considers just.

3. In the event that doubts remain regarding the interpretation and application of EU law, request the Court of Justice for a preliminary ruling, for which, in a spirit of cooperation with that Court, the Defendant suggests the following wording:

In circumstances such as those of the present case, must Article 102 TFEU be interpreted as meaning that a patent and/or SPC holder, which holds a dominant position in the national market for a prescription-only, hospital-only medicinal product (at molecule level), may abuse that position where it:

i. brings and/or threatens proceedings seeking injunctive relief based on an indication-specific patent in order to prevent or delay generic entry, notwithstanding that the competent public procurement authority has acknowledged the continuing effect of a product-level SPC and has expressly

committed not to contract for supply of the relevant molecule until the SPC expires; and

ii. in parallel, makes omissions and/or inconsistent representations in interim or main proceedings concerning material facts capable of affecting the assessment of imminence/threat and necessity (including exclusive-supply framework agreements, centralised procurement arrangements, and the authority's pledge to respect the SPC), such that the litigation is liable to be objectively unfounded and to form part of a strategy to exclude or delay competition within the meaning of the ITT Promedia criteria?

- 7** The patent in suit has expired on 21 December 2025.
- 8** In its Reply to the Statement of Defence, the Claimant requested that the Court issue and dispose of the action by way of an order under R. 360 RoP, as it finds that there is no need to adjudicate, because the patent has expired.
- 9** Zentiva responded in the Rejoinder against the Claimant's request under R. 360 RoP, arguing that the present action on the merits is not devoid of purpose because, if it were the case, the Defendant could not rely on provisions like R. 213 or 354 RoP to claim damages against the Claimant.

GROUNDS FOR THE ORDER

- 10** Pursuant to R. 360 RoP, if the Court finds that an action has become devoid of purpose and that there is no longer any need to adjudicate on it, it may at any time, on the application of a party or of its own motion, after giving the parties an opportunity to be heard, dispose of the action by way of order.
- 11** This provision gives the Court broad discretion to consider whether the prerequisites for disposing of the action are present. The assessment is not in the hands of the parties, although the facts and arguments brought forward by them can have an impact on the Court's decision – CoA, 12 May 2025, UPC_CoA_328/2024, para. 42.
- 12** To assess if an action is devoid of purpose, the Court must take into consideration the interest of the party that filed the action. In fact, as the CoA has pointed out, an action is not devoid of purpose if the party filing the action has a legal interest. A legal interest exists where the interested party, if successful, benefits from an advantage – CoA, 9 January 2025, UPC_CoA_584/2024. In this regard, the Court notes that in R. 360 RoP, contrary to the withdrawal under R. 265.1 RoP, the interest of the other party stated in a Statement of Defence is not autonomously taken into consideration. The assessment is made in light of the interest of the party filing the action.
- 13** As already noted, this action was filed by the Claimant to comply with R. 213 RoP. Had the Claimant not filed this action, the provisional measures granted by the CoA could have been revoked. In the preliminary injunction, the claimant never asserted infringement; it only asserted a risk thereof.

- 14** The requests submitted by the Claimant in this main action were directly related to the patent being in force as follows (the Court excludes requests II and III, the first is instrumental, related to the penalty for the violation of the order, and the second is related to costs):
- The order requested under I was formulated *while EP '843 is in force.*
 - The request for the Court to declare the possibility of an award of damages in case an infringement is found is also formulated *while EP '843 is in force.*
- 15** Since the patent is no longer in force, the Court acknowledges that by requesting an order under R. 360 RoP, and not having claimed a declaration of infringement in the action, the Claimant is asserting, albeit implicitly, that no infringement occurred during the period the patent was in force.
- 16** In that regard, it must be acknowledged that the Claimant will no longer benefit from any advantage resulting from the granting of its requests, in a scenario of a successful outcome. In fact, a successful outcome will be irrelevant to the Claimant in light of its requests and the patent's expiry.
- 17** The arguments put forward by Zentiva against the order under R. 360 RoP cannot be followed.
- 18** According to Zentiva, if the action is dismissed, it will no longer be able to be compensated under R. 213 or 354 RoP.
- 19** R. 213.2 RoP applies to provisional measures. It provides that the defendant may be entitled to compensation for damages if provisional measures are revoked, lapse due to any act or omission of the applicant, or are subsequently found to have been unfounded, either on appeal or review under R. 212.3 RoP.
- 20** Even though R. 213 RoP does not apply to the proceedings on the merits, being therefore irrelevant to refer to it here, it is further added that no revocation of the granted provisional measures has ever occurred in the present case. In that regard, there is no possibility of compensation for damages based on such revocation.
- 21** As for R. 354.2 RoP, according to which a defendant may be provided with appropriate compensation for any injury caused by the enforcement of an order or decision issued in an action, if such an order or decision is subsequently varied or revoked, it must be noted that no such enforcement has been made, rendering this rule inapplicable to the present case. Furthermore, the Court notes, in a pure theoretical exercise, that even if the action were to proceed, no enforcement would ever take place, regardless of a successful outcome to the Claimant or to the Defendant. In the Claimant's case, the decision would be irrelevant in light of its requests and the patent's expiry, as previously noted. In the case of the Defendant, the dismissal of the Claimant's requests would obviously amount to no enforceable decision. The conclusion must be drawn that no scenario would allow the Defendant to be awarded damages under R. 354.2 RoP.

- 22** In light of the above, the Court finds the action devoid of purpose, so there is no longer a need to adjudicate.

COSTS

- 23** Art. 69 UPCA provides the general principle that the losing party must bear the successful party's costs (comprising reasonable and proportionate legal costs and other expenses incurred by the successful party). Only exceptional circumstances of equity may provide differently. The same principle is derived from Art. 14 of Directive 2004/48.
- 24** As the Court of Appeal has stated, the disposal of an action pursuant to R. 360 RoP does not necessarily preclude the application of the general rule – CoA, 4 October 2024, UPC_CoA_2/2024. Which party is the successful party within the meaning of Art. 69(1) UPCA in the context of a disposal of an action must be determined based on the specific characteristics of the case and, in particular, the requests of the parties and the content of the undertaking. The Court of Appeal applied a similar criterion in an order dated 12 May 2025, UPC_CoA_328/2024 (par. 60).
- 25** According to the aforementioned COA case law, the following understanding may be inferred:
- If it is possible to determine from the specific characteristics of the case and, in particular, the requests of the parties, who is the successful party, even if the action becomes devoid of purpose, then the rule outlined in Article 69 UPCA applies.
 - If such a determination is not possible, the exception provided for in Art. 69.1 and 2 UPCA apply.
- 26** The Court finds that the specific circumstances that rendered the lawsuit moot make it impossible to define which party is the successful party.
- 27** The evaluation of the successful party would be clearer if the Defendant would have committed infringing acts. In the present case Zentiva was preliminarily enjoined from committing infringing acts by the order of the Court of Appeal based on the threat of infringement in the preliminary injunction proceedings. This threat itself - the filing of the so-called PEP-application and the following issuance of communication by the INFARMED (see para 1 of this order) - cannot as such be considered patent infringement based on Art. 25 UPCA, as they are only setting the stage for further actions that might be patent infringing.
- 28** At the same time, if the Claimant had not applied for the preliminary injunction, there was the risk that the threat would have proceeded to infringement. When the

Claimant filed for the preliminary injunction and it was granted by the Court of Appeal, the Claimant was obliged, based on R. 213 RoP, to file the Statement of Claim in order to keep the preliminary injunction in force.

- 29** Even though Zentiva, in such a situation, did not in fact infringe the patent, that alone cannot be considered to shift the risk of the costs fully to the Claimant because the threat of infringement was recognised by the Court of Appeal in the preliminary injunction decision.
- 30** In reality, the fact that the action has lost its purpose due to the objective circumstance of the patent’s expiration—a circumstance not attributable to the conduct of either party—requires that, also about costs, an objective approach consistent with equity be adopted. It would not be fair to require only one of the parties to bear the full costs in a situation where the proceedings have become moot for objective reasons beyond the control of either party in this action on the merits.
- 31** In conclusion, for the reasons stated, the Court finds that both parties should bear their own costs.

ORDER:

The Court:

1. Orders to dispose of action UPC_CFI_858/2025 pursuant to R. 360 RoP.
2. Orders that the value of the proceedings is set at EUR 1.000.000,00.
3. Orders that both parties shall bear their own costs.

<p>RUTE LOPES PRESIDING JUDGE AND JUDGE RAPPORTEUR</p>	<p>RUTE ALEXANDRA DA SILVA SABINO LOPES</p> <p>Assinado de forma digital por RUTE ALEXANDRA DA SILVA SABINO LOPES Dados: 2026.04.10 13:43:41 +01'00'</p>
<p>PETRI RINKINEN LEGALLY QUALIFIED JUDGE</p>	<p>Petri Rinkinen</p> <p>Allekirjoittaja Petri Olavi Rinkinen Päivämäärä: 2026.04.10 09:03:15 +03'00'</p>
<p>CAMILLE LIGNIÈRES LEGALLY QUALIFIED JUDGE</p>	<p>Camille Lignières</p> <p>Date : 2026.04.10 11:08:13 +02'00'</p>
<p>REGISTRY CLERK</p>	<p>Maria da Luz Pedro Delgado</p>

Information about appeal

An appeal against the present Order may be lodged at the Court of Appeal, by any party which has been unsuccessful, in whole or in part, in its submissions, within two months of the date of its notification (Art. 73(1) UPCA, R. 220.1(a), 224.1(a) RoP and R. 363.2 RoP).