



LISBON – LOCAL DIVISION

UPC CFI 858/2025

ORDER

of the Court of First Instance of the Unified Patent Court
issued on 17 November 2025

CLAIMANT

BOEHRINGER INGELHEIM INTERNATIONAL GMBH
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
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 ECIIJA)

PATENT AT ISSUE:

PANEL:

Presiding judge and
Judge-rapporteur: Rute Lopes
Legally qualified judge: Camille Lignieres
Legally qualified judge: Petri Rinkinen

DECIDING JUDGE:

This order was issued by Judge Rute Lopes acting as judge-rapporteur.

LANGUAGE OF THE PROCEEDINGS: English

SUBJECT: Patent infringement action – Preliminary objection pursuant to R. 19.1(a) RoP and R. 20.1 RoP.

SUMMARY OF THE PROCEDURE

- 1 The Claimant has lodged an infringement action against the Defendant requesting that the Defendant is ordered to refrain, within the territory of the Contracting Member States in which the Patent is in force, 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. To support its request, the Claimant argued that following the issue of Notice no. 0689/2024 by the INFARMED – National Authority of Medicines and Health Products, I.P., there is a threat that the Defendant will infringe the Claimant's Patent.

Defendant's requests and arguments

- 2 The Defendant was served on 24 September 2025 and lodged a preliminary objection on 24 October 2025, requesting that the Court:
 - I) Declare that it lacks jurisdiction to hear the present action;
 - II) Dismiss the action in its entirety.
- 3 The Defendant argues the following, to the extent relevant to the preliminary objection:
 - The alleged threat and/or infringement arises exclusively from Communication No. 0689/2024, an administrative act issued by INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P., a public administrative authority in the exercise of its administrative powers under Portuguese law.

- The Claimant’s attempt to rely on that Communication as the basis of a threat of infringement necessarily requires the Court to review the legality and effects of an administrative decision by a national authority.
- The issue in dispute is of an administrative nature. The jurisdiction of the UPC does not extend to administrative matters. Such a dispute falls exclusively within the jurisdiction of the Portuguese administrative courts (Art. 1(1) and 71a(2) of the Brussels Recast Regulation (hereinafter BR)), which have jurisdiction over contentious actions and appeals aimed at resolving disputes arising from administrative legal relations.
- Although the INFARMED’s Communication refers to the “purchase” of medicines “for use in the indication”, it has neither been alleged nor demonstrated that the Defendant has undertaken any acts of manufacture, offer, placing on the market, importation, storage, or use of *Nintedanib Zentiva*.

Claimant’s requests and arguments

- 4 The Claimant responded on 5 November 2025, requesting that the Preliminary Objection be rejected in its entirety, and the jurisdiction/competence of the Lisbon Local Division of the Court of First Instance of the UPC be confirmed.
- 5 The Claimant argued that:
 - The UPC’s jurisdiction/competence to hear this action is unquestionable, in light of Art. 31 and 32 of the UPCA.
 - The Claimant is enforcing a so-called classic European patent which is currently not opted out from the exclusive competence of the UPC, having filed an action on the merits that follows the Order of the Court of Appeal, which granted the requested provisional measures. It’s an action based on the threat of infringement of EP ‘843 by Zentiva in the territory of the Contracting Member States in which the patent has effect.

GROUNDS FOR THE ORDER:

- 6 Except for the argument that no infringement has been alleged or demonstrated, which will be addressed further down, the Preliminary Objection meets the requirements of Rule 19 RoP: It concerns the competence of the Court, and was lodged within one month of service of the Statement of Claim.
- 7 Pursuant to Art. 71, 71a, and 71b BR and 32(1)(a) and 83(3) UPCA, the UPC has exclusive competence in respect of actions for actual or threatened infringement, regarding European patents that have not been opted out of its jurisdiction.
- 8 So, to establish the competence of the Court in light of the mentioned legal framework, in the action lodged at the UPC, a Claimant has to argue that there is an infringement or a threat thereof of a European Patent that has not been opted out from the exclusive jurisdiction of the Court.

- 9 The Claimant has lodged this infringement action against the Defendant, arguing that it owns a European patent and there is a threat of infringement of its rights by the Defendant, and requesting that the Defendant be ordered to refrain from acting in a way that infringes its Patent. No opt-out from the exclusive competence of the Court in relation to the Patent is in effect. The UPC is therefore exclusively competent to decide the dispute as defined by the Claimant.
- 10 It is undisputed that national courts have exclusive competence in respect of administrative matters, including administrative relations, that lead to administrative disputes (Art. 1(1) BR).
- 11 However, the action lodged by the Claimant does not concern an administrative matter. The Defendant's argument that administrative Portuguese courts have exclusive jurisdiction to hear this case is based on an erroneous assessment of the dispute. According to the Statement of Claim, the dispute does not arise from an administrative relation, but from a threat of infringement by the other party. It is a dispute between two private competitors. The issuance of the Communication constitutes grounds, according to the Claimant, for establishing such a threat, but it is not itself the threat or its basis.
- 12 Additionally, contrary to the Defendant's allegation – however not grounded as the Defendant has not provided any reasoning for stating so -, there is no need for the Court to assess the legality of the Communication. The parties did not question it, and the Court sees no need for it.
- 13 The factual assertion made by the Claimant in its Statement of Claim, in the light of the legal framework referred to above, is sufficient to establish the exclusive jurisdiction and competence of the UPC, as pointed out. The dispute does not concern the decision of the Portuguese administrative authority, nor does it involve an assessment of its legality. It is based solely on the threat of infringement. It is an action to enforce a European Patent in light of Art. 32(1)(a) UPCA.
- 14 The additional argument put forward by the Defendant— that it has not been alleged or demonstrated that the Defendant has carried out any acts of manufacture, offer, placing on the market, import, storage or use of *Nintedanib Zentiva* — does not fall within the scope of R. 19 RoP, which exhaustively sets out the list of grounds for Preliminary Objection (cf. Order of 3 September 2024, UPC_CoA_188/2024, paragraph 32 — Aylo/Dish). It cannot, therefore, be accepted. Furthermore, this is a substantive argument to be assessed on the merits of the case, after the Court's jurisdiction has been established. It is not a Preliminary Objection defence.
- 15 It follows from the foregoing that the Court has competence and the Preliminary Objection must be rejected.

ORDER

1. The Preliminary Objection is rejected.
2. The proceedings will be continued.

INFORMATION ABOUT THE APPEAL

An Appeal against the Order may be lodged in accordance with Rule 21.1 RoP in conjunction with Rule 220.2 RoP within 15 days of service of the Order.