Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

**LISBON – LOCAL DIVISION**

**UPC_CFI_41/2025**

**ACT 3186/2025**

**ORDER**

of the Court of First Instance of the Unified Patent Court

issued on 8 May 2025

APPLICANT IN THE PRELIMINARY INJUNCTION PROCEEDINGS:

BOEHRINGER INGELHEIM INTERNATIONAL GMBH
Binger Straße 173 - D-55216 - Ingelheim am Rhein
Germany

represented by
Ms. Joana Catarina Piriquito Santos
Ms. Sara Nazaré
Ms. Beatriz Lima

DEFENDANTS IN THE PRELIMINARY INJUNCTION PROCEEDINGS:

ZENTIVA PORTUGAL, LDA
Alameda Fernão Lopes, n.º 16-A, 8.º A - 1495-190 – Algés
Portugal

represented by
Ms. Patrícia Paias

*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

*ORAL PROCEEDINGS*: 9 APRIL 2025

*SUBJECT-MATTER OF THE PROCEEDINGS*

Application for a preliminary injunction and other provisional measures pursuant to Rules 206.1 and 211.1 of the Rules of Procedure (hereinafter "RoP").

*PROCEDURAL HISTORY*

**1** On 23 January 2025, Applicant *BOEHRINGER INGELHEIM INTERNATIONAL GMBH* (hereinafter "Boehringer" or "Applicant") lodged an application (hereinafter "Application") for a preliminary injunction (hereinafter "PI") against Defendant *ZENTIVA PORTUGAL, LDA* (hereinafter "Zentiva" or "Defendant") at the Lisbon Local Division of the Unified Patent Court (hereinafter "UPC") based on an alleged infringement of EP 1 830 843 B1 (hereinafter "EP 843" or "the Patent").

**2** Boehringer asserts that, since 12 December 2024, there has been a risk of imminent infringement of its Patent, which protects the use of *nintedanib* or *nintedanib esylate* for use in the treatment of idiopathic pulmonary fibrosis, arising from a communication issued by the INFARMED – National Authority of Medicines and Health Products, I.P. (hereinafter "Infarmed") - to the Central Administration of the public Health System, stating that *Zentiva Generics* could be purchased as from that date.

**3** On 3 March 2025, the Defendant lodged an objection, arguing that the UPC lacked competence and requesting a stay of the proceedings due to a parallel case pending before the Lisbon Intellectual Property Court. Furthermore, it denied the existence of any imminent infringement and argued that provisional measures were unnecessary, asserting that the balance of interests should favour the Defendant.

**4** The Applicant replied to the Objection, and the Defendants lodged a rejoinder.

On 28 March 2025, the Defendant requested that the Application for provisional measures (Generic Application 15412/2025) be dismissed, arguing that, on 25 March 2025, the Portuguese Intellectual Property Court had issued an Order granting an application for a preliminary injunction lodged by Boehringer Portugal against the Defendant concerning the same product, *Nintedanib Zentiva*, thereby rendering these proceedings unnecessary.

**5** On 8 April 2025, at 20:06, the Defendant lodged a Generic Application, submitting documents concerning a centralized public procurement procedure for the purchase of *nintedanib*, which was awarded exclusively to Boehringer Ingelheim Portugal, Lda. 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 considers that said application must be declared inadmissible pursuant to R. 9.2 RoP and the principle of a fair trial (Preamble to the RoP, point 5).

**6** An oral hearing took place on 9 April 2025 in Lisbon.

**7** At the oral hearing, the Defendant clarified that, further to its request of 28 March 2025 and in light of the Portuguese Intellectual Property Court's Order, it no longer sought a stay of these proceedings.

*ORDER SOUGHT BY THE PARTIES*

**8** The Applicant requests that the Court:

> 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 to provide the Applicant, within four (4) weeks after service of the order rendered, appropriate documentation of: a. the quantities of the Zentiva Generics ordered, imported and/or stored, notably by the Defendant, in the Contracting Member States in which the Patent is in force; b. the origin of the Zentiva Generics, including the full names and addresses of the legal entities that are involved in the supply to the Defendant of the Zentiva Generics, and the amount of Zentiva Generics supplied to the Defendant by each of those entities in the Contracting Member States in which the Patent is in force; c. any orders for the supply

of the Zentiva Generics in the 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.

III. 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.

IV. Order Zentiva to pay the interim costs of the proceedings.

**9** The Defendant requests that the Court (with clarification provided at the Oral hearing):

I. Decline jurisdiction over the application for provisional measures and dismiss the application as inadmissible, pursuant to Articles 71a (2) and 1 of the Brussels I Recast Regulation.

*On an auxiliary basis,*

II. Dismiss the Application;
III. Impose the costs of the proceedings on the Applicant.

*FACTS*

**10** In its order, the Court considers the facts listed below, which it considers to be acknowledged by the parties in their written submissions and/or established by the evidence (annexes) presented by the parties.

*The Patent and SPC 679*

**11** Applicant and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG (hereinafter Boehringer Pharma) are the co-proprietors of European Patent number EP 1 830 843 B1, entitled "*Indolidone derivatives for the treatment or prevention of fibrotic diseases".*

**12** Boehringer Pharma authorized the Applicant to initiate these proceedings for the German part and confirmed that the Applicant is entitled to bring proceedings for the French and Italian parts of EP 843.

**13** The Patent has been validated and is 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.

**14** The Patent was applied for before the European Patent Office (hereinafter "EPO") on 21 December 2005 under European patent application number 05823930.2, claiming priority from EP 04030770, dated 24 December 2004. It was first published as WO 2006/067165 on 29 June 2006. The grant was mentioned in the European Patent Bulletin, No. 2012/45, on 7 November 2012. It will remain in force until 21 December 2025.

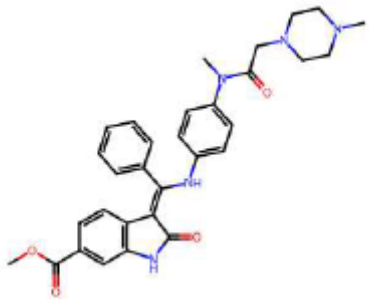
**15** The Patent was subject to opposition proceedings before the EPO. The Opposition Division dismissed the Opposition, and no appeal was filed before the EPO Boards of Appeal.

**16** The invention concerns the use of *nintedanib* or *nintedanib esylate* for use in the treatment of idiopathic pulmonary fibrosis.

**17** The title of the Patent is: "*Indolidone derivatives for the treatment or prevention of fibrotic diseases",* and it contains the following claims:

> *1. Compound 3-Z-[1-(4-(N-((4-methyl-piperazin-1-yl)-methylcarbonyl)-N-methyl-amino)-anilino)-1-phenylmethylene]-6-methoxycarbonyl-2-indolinone or a tautomer, a diastereomer, an enantiomer, the mixtures thereof or a salt thereof, for use in the prevention or treatment of idiopathic pulmonary fibrosis*.
>
> *2. Monoethanesulfonate salt of the compound 3-Z-[1-(4-(N-((4-methyl-piperazin-1-yl)-methylcarbonyl)-N-methyl-amino)-anilino)-1-phenyl-methylene]-6 methoxycarbonyl-2-indolinone, for use in the prevention or treatment of idiopathic pulmonary fibrosis according to claim 1.*

**18** 3-Z-[1-(4-(N-((4-methyl-piperazin-1-yl)-methylcarbonyl)-N-methyl-amino)-anilino)-1 phenylmethylene]-6-methoxycarbonyl-2-indolinone, as provided in claims 1 and 2 of EP 843, is one of the chemical names of *nintedanib*, depicted below:



**19** *Nintedanib esylate* is the monoethanesulfonate salt of *nintedanib*.

**20** Boehringer Pharma is also the registered owner of SPC 679, granted by the Portuguese Industrial Property Office (Instituto Nacional da Propriedade Industrial) on 7 September 2015, under Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009.

**21** SPC 679 was granted on the basis of EP 1 224 170 and with reference to the first Marketing Authorization (hereinafter "MA") for a product containing *nintedanib.*

**22** SPC 679 will expire on 9 April 2026.

*Other disputes concerning nintedanib.*

**23** On 20 January 2025, Boehringer Pharma lodged an application for a preliminary injunction against the Defendant (Case No. 57/25.1YHLSB) under Article 345 of the Portuguese Industrial Property Code before the Portuguese Intellectual Property Court.

**24** In the said proceedings, following the request for and grant of two MAs for the medicinal product *Nintedanib Zentiva* - one for the 150 mg dosage and another for the 100 mg dosage - and further request and granting of a PEP, Boehringer Pharma requested the issuance of the following provisional measures:

> a) An injunction ordering the Defendant to refrain, within Portuguese territory, from manufacturing, offering, storing, placing on the market, selling, and/or using the medicinal product *Nintedanib Zentiva*, or any other medicinal product under a different commercial name that contains *nintedanib* as its active substance, as well as an injunction prohibiting its immediate importation or possession for any of the purposes above, until the expiration of Supplementary Protection Certificate (hereinafter "SPC") No. 679.
>
> b) An injunction ordering the Defendant to immediately cease, until the expiration of SPC No. 679, the manufacturing, offering, storing, placing on the market, selling, and/or using the medicinal product *Nintedanib Zentiva*, or any other medicinal product under a different commercial name that contains *nintedanib* as its active substance, as well as its importation or possession for any of the purposes above within the Portuguese market, should the Defendant have already initiated any such acts at the time of the filing of the present provisional measures request or the issuance of the Court's decision.

**25** The Defendant did not file an opposition, and on 23 March 2025 the Portuguese Intellectual Property Court issued a decision by default, partially granting the provisional measures.

*The parties, market situation, and allegedly infringing acts*

**26** The Applicant is part of the Boehringer Ingelheim group, headquartered in Ingelheim, Germany. It operates in over 130 markets and employs a staff of around 53,500 worldwide. In 2023, the Group's net sales were approximately EUR 25.6 billion. Boehringer invested approximately EUR 5.8 billion in R&D activities in 2023, focusing on various disease areas, including mental health, oncology, immunology, respiratory diseases, fibrosis, and cardiovascular, renal, and metabolic (CRM) diseases.

**27** In 2023, Boehringer's second most successful product in terms of net sales was the medicine Ofev®, which the Applicant holds under MA reference EMEA/H/C/003821.

**28** Ofev® comprises *nintedanib* (as *esylate*) as the active substance and is indicated for the treatment of idiopathic pulmonary fibrosis (IPF). Ofev® is also indicated in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype, as well as for the treatment of systemic sclerosis-associated interstitial lung disease (SSc-ILD).

**29** The Applicant's product, Ofev®, is sold in Portugal as a pharmaceutical soft capsule for oral administration containing 100 mg or 150 mg of *nintedanib*.

**30** Zentiva is a Portuguese pharmaceutical company belonging to the Zentiva International corporate group. It focuses on the commercialization of generic products.

**31** Since 30 August 2024, Zentiva has held the following two MAs in Portugal, granted by Infarmed for generic medicines comprising *nintedanib* (as *esylate salt*) as active ingredient (hereinafter "Zentiva generics**"**), having Ofev® as reference medicine:

| Medicine name | MA holder | Active substance | Strength | Pharmaceutical form | Reference medicine | Procedure Number |
|---|---|---|---|---|---|---|
| Nintedanib Zentiva | Zentiva Portugal, Lda. | Nintedanib | 100 mg | Soft capsules | Ofev® | IS/H/0548/001/DC |
| Nintedanib Zentiva | Zentiva Portugal, Lda. | nintedanib | 150 mg | Soft capsules | Ofev® | IS/H/0548/002/DC |

**32** Zentiva generics are indicated for use in adults for:

– The treatment of IPF.

– The treatment of other chronic fibrosing ILDs with a progressive phenotype.
– The treatment of SSc-ILD.

**33** Zentiva Generics comprise the active ingredient *nintedanib* (in the form of the esylate salt).

**34** In Portugal, medicines containing *nintedanib* as an active substance – Ofev® and generics of Ofev®, such as Zentiva Generics – are restricted to prescription for hospital use only.

**35** Almost all purchases of Ofev® in Portugal (over 98%) are made by public hospitals within the National Health System (hereinafter "NHS").

**36** Medicines restricted to hospital use only are governed by a specific set of rules, established under Decree-Law No. 97/2015 of 1 June 2015, as amended by Decree-Law No. 115/2017, of 7 September 2017.

**37** Prescription-only medicines, which must be acquired by entities supervised by the member of the Government responsible for the health sector (as is the case with *nintedanib* medicines), are subject to a Prior Evaluation Procedure (hereinafter "PEP").

**38** The purpose of the PEP evaluation 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.

**39** On 12 December 2024, following the granting of a PEP requested by the Defendant regarding the medicine *Nintedanib Zentiva*, Infarmed, issued a Notice (Ofício Circular n.º 0689/2024, hereinafter "Notice") and sent it to the following health public entities: Pharmaco-therapeutic commissions; Health Regional Administrations; Central Administration of the Health System; General Directorate of Health and Shared Services of the Health Ministry.

**40** The Notice stated the following:
*«Dear Sirs / Madams,*
*Decree Law no. 97/2015, of 1 June, in its current version, determines the obligation of prior evaluation of prescription-only medicines that are to be acquired by the entities supervised by the member of the Government responsible for the health area.*
*The first generic medicine with INN Nintedanib, Nintedanib Zentiva, 60 soft capsules, in dosages of 100 mg and 150 mg, was subject to prior evaluation, in the following therapeutic indications:*
*- treatment of idiopathic pulmonary fibrosis (IPF) in adults;*
*- treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype in adults;*
*- treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD) in adults.*

*Since the prior evaluation procedure has been completed, we hereby inform you of the decision of approval, issued on 06/12/2024, by the Board of Directors of INFARMED, I.P.*
*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.*
*Best regards,*
*The President of the Board of Directors*
*[…]»*

**41** After being granted a PEP, the holder must comply with pre-contractual procedures when offering or selling the medicine to the NHS, such as centralized framework agreements relating to public procurement procedures, prior consultation, or direct awards.

**42** A framework agreement is a contract concluded between one or more contracting entities to be established for a specific period of time, with the respective terms fixed in advance.

**43** Framework Agreement 491/2023 is in effect for the acquisition of *Nintedanib* medicines in Portugal until September 2025, and is subject to automatic renewal for 12 months, i.e., until September 2026.

**44** Boehringer Ingelheim Portugal, Lda is the sole contractor listed in the Framework Agreement for the provision of *nintedanib* products.

*GROUNDS FOR THE ORDER*

*1. Jurisdiction and Competence*

**45** The Defendant objects to the jurisdiction of the UPC, arguing that the alleged conduct supporting the claim of imminent infringement arises from an act carried out by a public administrative body – Infarmed – and, as such, only a Portuguese administrative court would be competent to hear the case.

**46** The Defendant's objection is unfounded. The UPC has jurisdiction and competence under Arts. 31 and 32 UPCA. Furthermore, this Local Division is competent to hear the case (Art. 33(1) UPCA). Art. 31 UPCA establishes the international jurisdiction of the UPC in accordance with Regulation (EU) No 1215/2012 as amended by EU Regulation 542/2014 (hereinafter "BR"). Pursuant to Art. 4(1), 35, 71, 71a and 71b BR and 32(1)(c) and 83(2) UPCA, the UPC has jurisdiction to hear cases regarding European patents that have not been opted

out of its jurisdiction. Moreover, under Art. 32(1)(a)(c) UPCA, the UPC is exclusively competent to decide on applications for provisional measures in cases of actual or threatened infringements of European patents.

**47** It is irrelevant that an administrative entity issued the Notice from which the imminent infringement arises. According to the Applicant, the imminent infringement of its European Patent is what prompts the need for provisional measures, as the Defendant is currently in a position to offer or place its infringing products on the market at any moment. This factual assertion is, in light of the above-mentioned legal framework, sufficient to establish the jurisdiction and competence of the UPC.

*2. Relevance of the Portuguese Court Order to this PI*

**48** The Defendant argues that following the injunctions issued by the Portuguese Court, this PI has lost its utility and legal basis. The Defendant is already prevented from conducting any of the activities relating to *nintedanib*, pursuant to the Applicant's request, until SPC 679 expires, which will occur after the expiry of EP 843. Furthermore, the MAs granted to the Defendant are territorially limited to Portugal, which is already covered by the Portuguese Court Order.

**49** Once again, the Defendant is not correct in its position.

**50** It is undisputed by the parties that the asserted rights in the two proceedings are not the same (SPC 679 in the Portuguese proceedings; EP 843 in the present application), nor are the parties identical (the Applicant in this PI is Boehringer Ingelheim International GmbH; in the Portuguese proceedings, Boehringer Portugal). Furthermore, although it is accepted that both cases refer to an MA and a PEP granted for the Portuguese territory, it is undeniable that the request in the Portuguese PI is territorially limited to Portugal. By contrast, the present PI applies to all Contracting Member States of the UPC in which the patent is in force.

**51** The Court further notes that the Portuguese Court's Order may be subject to appeal. Even if no appeal is lodged, the provisional measures were granted on a *prima facie* basis, subject to the requirement that an action on the merits be brought - failing which the measures risk being revoked. Finally, even the IP right on which the Order was based may be subject to judicial amendment or revocation.

**52** For the reasons set out above, the Court finds no basis for dismissing these proceedings on the grounds of lack of utility in light of the Portuguese Court's Order.

*3. Imminent infringement*

**53** The Applicant is the proprietor of EP 843, which protects *nintedanib* or *nintedanib esylate* for use in the treatment of idiopathic pulmonary fibrosis. It is undisputed that Zentiva's medicines contain *nintedanib* and are suitable for the prevention or treatment of idiopathic pulmonary fibrosis. Accordingly, such medicines fall within the scope of EP 843.

**54** The Applicant has lodged the present application for a PI, arguing that there is an imminent risk that the Defendant will offer or place its medicine on the market. Such acts are listed in Art. 25 UPCA as acts of infringement. According to Art. 62 UPCA, the Court may grant injunctions to prevent any imminent infringement.

**55** This dispute concerns the pharmaceutical market, which operates in a highly regulated field that constantly requires interaction with administrative entities. Before being placed on the market, a medicine must undergo several successive administrative steps, including the application for an MA, sales price determination, and reimbursement negotiations with health authorities. Furthermore, public tenders or public procurements may also be conducted. The Court further acknowledges that administrative procedures, legislation and their interaction with market access vary depending on the Contracting Member State. However, this should not be relevant to the direct assessment of the risk of infringement. As the Local Division Düsseldorf observed (Order, 6 September 2024, UPC_CFI_166/2024, ACT_18551/2024, Novartis/Genentech v. Celltrion), when dealing with European patents, the UPC must assess imminent infringement independently, solely based on the interpretation of the UPCA, and not on national legislation. In that regard, the Court must evaluate the risk of infringement in light of Art. 62 and 25 UPCA.

**56** The Court further notes that the risk of infringement cannot be established through an abstract assessment. An infringement is deemed imminent if, in light of the overall circumstances of the case, it can be concluded that the potential infringer has engaged in conduct that is likely to result in an infringement under Art. 25 UPCA.

**57** In this regard, it must be established on a case-by-case basis that the potential infringer has carried out acts that make it more likely than not that it intends to offer or place the product on the market before the patent expires (LD Düsseldorf, 6 September 2024, UPC_CFI_166/2024, ACT_18551/2024, Novartis/Genentech v. Celltrion). Imminent infringement must then be assessed from the point of view of the concrete likelihood that, in light of the circumstances of the case, the Defendant is more likely than not to commit an act of infringement.

**58** The Applicant bears the burden of providing the Court with evidence that the Defendant, in light of the specific circumstances of the case, has acted in a way that gives rise to the conclusion that it is highly likely to imminently enter the market with its *nintedanib* medicines.

**59** The risk of imminent infringement, according to the Applicant, is based on the following:

- The Defendant requested and obtained two MAs for its medicine;
- The granting of those MAs enabled the Defendant to pursue the PEP;
- The granting of the PEP was the final administrative step necessary for the Defendant to offer and sell its product to the public hospitals; and
- Accordingly, there is a risk of imminent patent infringement.

**60** The Defendant disagrees that such risk arises following the issue of the PEP, stating that further administrative procedures are still required. Although the Applicant also recognized that such further administrative procedures are still needed, it considered them irrelevant to the risk of infringement, and argued that any action taken by the Defendant following the grant of the PEP already constitutes an act of infringement.

**61** It is uncontested that the Defendant has held two MAs for its *Nintedanib* Zentiva medicines since 30 August 2024. In Portugal, holding an MA 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 MA holder wishes to supply its medicine to public hospitals and seek reimbursement from the SNS, a PEP must be requested.

**62** The Court acknowledges that the Applicant did not argue that the administrative steps taken by the Defendant – requesting an MA and a PEP – constitute acts of infringement. Instead the Applicant argues that once the PEP is granted, there is a risk of imminent infringement. The Court considers that requesting the said MA or PEP are mere administrative actions that, even when they are prerequisites for potentially infringing actions such as offering or selling, do not, in themselves, establish such a risk. This view is supported by the uncontested fact, provided by the Defendant, that it is customary for generic pharmaceutical companies in Portugal to request a PEP before the expiration of a patent. The primary difference with respect to customary Portuguese practice in this case is that, according to the Applicant, the PEP was requested prematurely – more than a year before the patent term expires. The Applicant argues that the purpose of this early request is to initiate infringing actions before the patent term expires.

**63** The Court, however, disagrees with the Applicant’s assertion that the mere issuance of the PEP by Infarmed has created a risk of imminent infringement. Such an interpretation is inconsistent with Arts. 62 and 25 UPCA, which require that the risk of infringement arise from the Defendant's conduct. If, as in this case, the Defendant has not taken any other steps that indicate it will market the medicine, the administrative steps alone taken by the Defendant do not establish a risk of imminent infringement.

**64** This conclusion is not affected by the Applicant's argument that the Defendant requested the PEP prematurely, as this argument was not substantiated sufficiently to convince the Court. The Applicant stated that it was not aware of any PEP being requested so early, while the Defendant argued that it does not

have control over the granting procedure, which involves extensive negotiations, nor the time it takes for the administrative body to grant the PEP. Furthermore, according to a written statement from the "head of scientific affairs of the Defendant" submitted by the Defendant on 31 March 2025, the PEP request in this case followed the usual procedure adopted by the Defendant in similar cases and was submitted following the granting of the MAs. In light of the regulated nature of the pharmaceutical field, the Court finds no evidence that merely requesting the PEP after receiving the MAs indicates the timing of market entry for the Defendant's medicine. The timing of the PEP request at that date does not, under the specific circumstances presented to the Court, make it more likely than not that the Defendant intends to enter the market unlawfully before the expiration of EP 843.

**65** The Applicant presented a further argument, asserting that the Notice issued on 12 December 2024 by Infarmed stated that the Defendant had one year to begin commercializing the medicine, or the PEP would expire. The Defendant contested the relevance of this one-year time limit in the Notice. The Court finds that this argument does not indicate imminent infringement. The risk of the PEP expiring lies with the Defendant for requesting it prematurely. According to the written statement of the head of scientific affairs of the Defendant […], submitted on 31 March 2025: "Zentiva is not obliged to commercialize its products within 1 year since there are patent rights in force. Throughout my years of experience in the industry, I am not aware of a single case where the expiration on the one year led to the lapse of a prior hospital evaluation, when the non-marketing was due to the existence of patent rights". This statement makes it clear that the Defendant is aware of the risk, but this awareness alone does not indicate the market entry time.

**66** Without any further evidence indicating that the Defendant's conduct makes infringement more likely than not, the Court must conclude that the Applicant did not provide evidence that the Defendant took any action suggesting that infringement became imminent immediately upon the granting of the PEP. As previously stated, the risk of infringement must arise directly from the conduct of the potential infringer. If the potential infringer's conduct does not constitute a risk of infringement, it cannot be asserted that such a risk was thereby created.

**67** Finally, the Court finds that the arguments mentioned above equally apply to private hospitals, which may constitute 2% of the overall market, as both parties agree. In this context, the Applicant has not presented any additional arguments for imminent infringement, indicating that the Defendant, which has been able to place its product on the private market since 30 August 2024, has engaged in any conduct indicating that it will likely do so.

**68** In conclusion, as no imminent infringement has been demonstrated, the request for provisional measures must be dismissed.

*4. VALUE OF THE CASE*

**69** The Applicant estimated the value of the case at EUR 1,000,000, which the Defendant accepted at the oral hearing.

**70** In this regard, as the Court has no reason to consider otherwise, and in accordance with the Guidelines for the Determination of the Court Fees and the Ceiling for Recoverable Costs, adopted by the Administrative Committee on 24 April 2023, D - AC/09/24042023_E, I.3, the value of the case is set at that amount.

**71** The Court further notes that, in applications for provisional measures, the value of the case is only relevant for determining recoverable costs, not for Court fees, as the latter are fixed in this case —cf. Guidelines for the Determination of the Court Fees and the Ceiling for Recoverable Costs, adopted by the Administrative Committee on 24 April 2023, D—AC/09/24042023_E, II.5.a.

*5. COSTS*

**72** The Defendant requested that provisional costs be set at EUR 250,000, comprising representation costs, for which it has provided an invoice amounting to EUR 92,944.15. The remaining costs requested were not substantiated.

**73** Art. 69 UPCA establishes the principle that the losing party must bear the successful party's costs (comprising reasonable and proportionate legal costs and other expenses incurred). Only exceptional circumstances based on equity may warrant a different allocation. This principle is also derived from Art. 14 of Directive 2004/48. Since this principle applies to all proceedings or sub-proceedings before the UPC, it also applies to PIs (cf. CoA, Order, 20 January 2025, UPC_CoA_297/2024, App_283/2025, SharkNinja/Dyson; CoA, Order, 3 March 2025, UPC_CoA_523/2024 APL_51115/2024, Sumi/Syngenta).

**74** Given the value of the case, the requested representation costs of EUR 92,944.15 (the only requested costs substantiated) falls within the recoverable costs ceiling as set by the Administrative Committee – Scale of Ceilings for Recoverable Costs adopted by the Administrative Committee on 24 April 2023, D - AC/10/24042023_E.Therefore, the costs must be awarded.

*ORDER:*

1. The Application for provisional measures is rejected.
2. The Court orders the Applicants to pay to the Defendant interim costs of the proceedings in the amount of EUR 92.944,15.
3. The value in dispute is set at EUR 1,000,000.

| | |
|---|---|
| RUTE LOPES<br>PRESIDING JUDGE | Rute Alexandra Da Silva Sabino Lopes<br>Assinado digitalmente por Rute Alexandra Da Silva Sabino Lopes<br>DN: cn=Rute Alexandra Da Silva Sabino Lopes, c=PT<br>Data: 2025.05.08 12:41:04 +01'00' |
| PETRI RINKINEN<br>LEGALLY QUALIFIED JUDGE | Petri Rinkinen<br>Allekirjoittaja Petri Olavi Rinkinen<br>Päivämäärä: 5/7/25 8:10:29 PM |
| CAMILLE LIGNIÈRES<br>LEGALLY QUALIFIED JUDGE | Camille Lignières<br>Date : 2025.05.07 18:02:35 +02'00' |
| REGISTRY CLERK | Maria da Luz Pedro Delgado<br>Assinado de forma digital por Maria da Luz Pedro Delgado<br>Dados: 2025.05.08 12:37:40 +01'00' |

ORDER DETAILS:
UPC number: UPC_CFI_41/2025
ACT_3186/2025
Application Type: Application for provisional measures.