Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Milan - Central Division - First Instance - central division

UPC_CFI_698/2024
Procedural Order
of the Court of First Instance of the Unified Patent Court
delivered on 27/03/2025

APPLICANT/S

1)	**ZENTIVA K.S.** (Applicant) - Praha 10 - Dolní Měcholupy, U kabelovny 130 - 10237 - Prague - CZ	Represented by Marc Lauzeral
2)	**ZENTIVA PORTUGAL, LDA** (Applicant) - Alameda Fernão Lopes, Miraflores, nº 16-A, 8º piso - 1495-190 - Algès - PT	Represented by Marc Lauzeral

RELEVANT PROCEEDING PARTIES

ACCORD HEALTHCARE B.V.
(Main proceeding party - Claimant) - Winthontlaan 200 - 3526 KV - Utrecht – NL

ACCORD HEALTHCARE S.L.U.
(Main proceeding party - Claimant) - Edificio Este, Planta 6, World Trade Center, Moll de Barcelona S/N - 08039 - Barcelona – ES

ACCORD HEALTHCARE LIMITED,
(Main proceeding party - Claimant) - Sage House, 319 Pinner Road, North Harrow - HA1 4HF - Middlesex - GB

NOVARTIS AG (Main proceeding party - Defendant) - Lichtstrasse 35 - 4056 - Basel - CH represented by: Gregory Bacon, Bristows (Ireland) LLP, Brian Cordery - Bristows (Ireland) LLP, Rutger Kleemans - Freshfields, Nina Bayerl - Freshfields, Daniela Ampollin -Trevisan & Cuonzo, Allard van Duijn - Freshfields

PATENT AT ISSUE

Patent no.	*Proprietor/s*
EP2501384	Novartis AG

HEADNOTES (ROP 313)

1) Parallelism between two cases or the allegation that the outcome of a judgment has a direct impact on another does not establish a legal interest to intervention pursuant to RoP 313.
2) The expression *'made in support, in whole or in part, of a claim, order or relief sought by one of the parties*' in Rule 313.2 RoP must be interpreted as meaning that the intervening party's remedies must be non-contradictory to those of the party who has been supported, and therefore in accordance with art. 67 ZPO and art. 105 It. CPC, and not in the sense of a partial identity.
3) *res judicata* does not extend beyond the parties involved in the proceedings, nor a judgment given between different parties is binding in another dispute where the parties were/are/have been not present.
4) Article 33 of the UPCA regulates numerous hypotheses of case connections on the same patent, providing for separate adjudications (bifurcation) as well as the stay of proceedings or joint decisions. These solutions are all part of UPC legal system and are not prejudicial to the right to defense. As a matter of fact, joint treatment of two proceedings is just one the possibilities of dealing with a case and does not constitute a prerequisite for the intervention of a party, since the intervention of a party in a proceeding (RoP 313) is not left to an case-by-case assessment at the judge's discretion, but must be based on a right that is jeopardized by the failure of the party to intervene.

DECIDING JUDGE: Judge rapporteur

LANGUAGE OF PROCEEDINGS: English

SUBJECT-MATTER OF THE PROCEEDINGS*:* Application to intervene (313 RoP)

GROUNDS FOR THE ORDER

1. By application lodged on 14 November 2024, three entities belonging to the ACCORD HEALHCARE GROUP (ACCORD in the following) applied to this Central Division for a DNI decision

against NOVARTIS AG (Novartis in the following), a company with its registered office in Switzerland.

2. Defendant is the owner of EP 3501384, filed on 17 November 2010 claiming priority as of 17 Novembre 2009 and granted on 17 February 2016 covering a "*Method of treating proliferative disorders and other pathological conditions mediated by BCR-ABL, C-KIT, DDR1, DDR2 or PDGF-R kinase activity*".

3. The Patent relates to a treatment for chronic myeloid leukemia ("CML"), in particular to a way of orally administering the compound internationally known as 'nilotinib' dispersed in applesauce. Paragraph [0004] of the Patent states in fact that certain patients have swallowing difficulties when taking nilotinib in the form of hard gelatin capsules: "*[0004] Certain patients, for instance elderly patients and pediatric patients, sometimes have difficulties to swallow hard gelatin capsules as a whole. For those patients, suffering from a proliferative disorder, particularly a solid and liquid tumor disorder, or other pathological conditions mediated by Bcr-Abl, c-Kit, DDR1, DDR2 or PDGF-R kinase activity, an alternative dosage form for nilotinib is required. For pediatric patients also dosage flexibility is desirable in order to allow dosage adjustment in accordance with body weight".*

4. The applicant requested this Court to declare that Accord's generic version of nilotinib does not infringe the Patent in activities such as making, offering, placing on the market, using and/or importing or storing, this in consideration of the fact that the pharmaceutical characteristics (SPC) of Accord Nilotinib Product clearly indicated that it was not suitable for use in dispersion and that patients should use other products for this purpose.

5. Regarding the previous relationships between the parties, on 6 July 2021, NOVARTIS had sent a letter to Accord's office in the United Kingdom offering a non-exclusive license under NOVARTIS' patent EP 2 501 384 B1. On 22 August 2024, NOVARTIS had sent another letter to ACCORD again offering a non-exclusive license under the Patent.

6. ACCORD replied to this letter maintaining that no license would be necessary because the Accord Nilotinib Product did not fall within the scope of the claim of the Patent. ACCORD also provided for the Summary of Product Characteristics for the Accord Nilotinib Product to show that all references to the oral administration of nilotinib dispersed in applesauce had been explicitly excluded from the Accord SmPC.

7. In a following communication NOVARTIS held that the healthcare practices in some European countries might lead to the Accord Nilotinib Product being administered with applesauce, despite the instructions in Accord SmPC and that would be considered an infringing activity.

8. On 10th February 2025, NOVARTIS filed a statute of defense in the merits to the DNI filed by ACCORD, highlighting that ACCORD could not avoid infringement of EP 384 (as to its marketed form TASIGNA®) simply by amending its SmPC and the Patient leaflet (PIL). The sole 'carve-out' was therefore insufficient – in its opinion - to prevent infringement, so that Accord would need to consider additional measures to prevent infringement. Significantly- pointed out NOVARTIS - the Munich 1st Regional Court had already issued preliminary injunction against some Germany-based producers regarding other Nilotinib generics with essentially the same wording in their SmPCs and PILs as Nilotinib-Accord, stating that, without additional measures being taken within Germany, there was an (imminent threat of) infringement of EP 384.

9. In fact, on 30.12.2024 the German company STADAPHARM G.m.b.H. filed with this Court a request pursuant to R. 262.1(b) RoP for access to the written pleadings and evidence filed in the UPC CMS, assuming to have a specific interest in gaining access to those documents since NOVARTIS on December 5th 2024 had obtained a preliminary injunction ("einstweilige Verfügung") against STADAPHARM before the Munich Regional Court (docket no.: 21 O 14561/24), based on the identical patent-in-suit. The request was dismissed with Order of 3 February 2025 considering that such an access could have thwarted NOVARTIS' right of defense. The Order was based on the "general interest of justice" mentioned in Article 45 UPCA, and the right to preserve the integrity of proceedings, ensuring that the parties might present their arguments and evidence independently and without influence or interference from third parties.

10. On 28.02.25 ZENTIVA k.s., a limited partnership under Czech law, and ZENTIVA PORTUGAL, LDA, a limited partnership under Portuguese law (ZENTIVA in the following), filed a request to intervene in these proceedings pursuant to Rule 313 RoP, highlighting that ZENTIVA too, like the companies belonging to ACCORD Group, sold Nilotinib in generic form in the treatment of chronic myeloid leukemia and therefore ZENTIVA had a parallel interest in intervening in the UPC proceedings that were aimed at defining the infringement perimeter of NOVARTIS' patent. ZENTIVA had been carving out, as well as ACCORD, references to the dispersion of Nilotinib capsules in apple sauce from the Summaries of Products Characteristics (SmPCs) relating to the Zentiva MAs. These include the language "*For patients with swallowing difficulties, including pediatric patients that are not able to swallow the hard capsules, other medicines containing nilotinib should be used instead of Nilotinib Zentiva"* translated in all languages of the countries where Nilotinib was distributed.

11. Based on the above, Zentiva points out the existence of an *"identity of factual and legal elements"* with respect to the subject matter of the Proceedings as:

a) Nilotinib Zentiva and Nilotinib Accord relate to the same medicinal product, i.e. Novartis' medicinal product Tasigna;
b) ZENTIVA and ACCORD have made identical carve-outs in the SmPCs of their respective products.
c) such carve-outs were made because of the existence of the same patent, i.e. Novartis patent EP 384;
d) NOVARTIS would be the defendant also in a (prospective) declaration of non-infringement proceedings that Zentiva may file as regards to whether or not Nilotinib Zentiva infringes EP 384.
e) The Nilotinib market is small compared to other pharmaceuticals: consequently, it would make no economic sense for ZENTIVA to incur important legal fees on a revocation action against EP'384; furthermore, the non-infringement position based on the carve-out of its SmPC would be the only sustainable defense with economic rationale.
f) The intervention in the Proceedings of ZENTIVA would be the only possibility to present its defense;
g) The forthcoming decision in this case would directly impact ZENTIVA'S rights regarding Nilotinib Zentiva since the new seized Court would be bound by the grounds and the order of the judgment issued in these proceedings (some national procedural laws -points out the applicant - provide an indication on which part of the judgment issued by the Court constitutes the decision, and thus, as *res judicata*).
h) A decision issued in these proceedings without letting ZENTIVA intervene would therefore infringe the principle of equal treatment and non-discrimination provided by Articles 20 and 21 of the Charter of Fundamental Rights of the European Union, and as recalled by the Court of Justice of the European Union (*Akzo Nobel Chemicals and Akcros Chemicals v. Commission, CJEU, 14 September 2010, Case C-550-07 P*):

12. According to Zentiva such alleged identity of *"factual and legal elements"* would create a legal interest to intervene in the Proceedings pursuant to Rule 313.1 RoP as interpreted by the case-law of the Court, such as to justify Zentiva's intervention.

13. Zentiva specified that the UPC Courts already acknowledged an interest to intervene:

a) in the right to be heard of a manufacturer of a product subject to infringement proceedings against the distributor of the product: *Swarco v. Strabag, UPC (Court of First Instance, Vienna), Judgment of 30 July 2024, Case No. UPC_CFI_33-2024*);

b) in the exclusive right of a non-exclusive licensee in a claim to revoke the patent subject to the license: *Seoul Viosys v. Expert e-Commerce, UPC (Court of First Instance, Düsseldorf), Judgment of 22 April 2024, Case No. UPC_CFI_363-2023 and No.31, NEC v. TCL, UPC (Court of First Instance, Munich), Order of 2 October 2024, Case No. UPC_CFI_487-2023*);

c) In the contractual commitment of a prospective intervener to manage the patent pool to which the plaintiff has contributed the patent in suit, and the FRAND obligation deriving from it: *Dolby v. HP Deutschland, UPC (Court of First Instance, Düsseldorf), Judgment of 26 June 2024, Case No. UPC_CFI_457-2023*); and

d) in the right of a manufacturer to keep confidential information confidential: *MediaTek v. Daedalus Prime LLC, UPC (Court of Appeal), Order of 8 January 2025, Case No. UPC_CoA_621-2024*).

14. Novartis replied on 17.03.2025 with written arguments, opposing the intervention.

15. Novartis maintained that a request for intervention is allowable only if the intervener is immediately and directly affected by the very ruling of the proceedings, to the extent that the same will directly alter the intervener's legal position; instead, a purely factual interest, merely relating to the grounds for the action, the pleas in law or the outcome of the legal dispute, as these may be influential for other similar cases, is not a sufficient ground for allowing an application to intervene.

16. Novartis further pointed out that ZENTIVA'S request was grounded on a purely factual interest, not a legal one. A decision between NOVARTIS and ACCORD would not directly affect ZENTIVA'S ability to market Nilotinib Zentiva. The "guiding effect" (as coined by the CoA in *Ocado v. Autostore)* of the case-law created in the present matter might only give rise for ZENTIVA to an indirect interest, which would be however insufficient to invoke Rule 313 RoP.

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17. Rule 313.1 RoP stipulates that an intervention in the proceedings is admissible if it is established that the intervener has a "*legal interest in the result of an action submitted to the Court*".

18. The intervener must proof an interest justifying the support to the reasons of one of the parties and, specifically, not a mere factual interest, but a legally qualified interest, determined by the need to prevent the direct impact, in its own domain, of any harmful consequences deriving from the judgement.

19. This principle was set out in Ocado vs. Autostore case (UPC_CoA_404/2023), where the Court of Appeal explained that "*An interest in the result of the action within the meaning of R.313.1 RoP means a direct and present interest in the grant by the Court of the order or decision as sought by the party, whom the prospective intervener wishes to support and not an interest in relation to the pleas in law put forward. It is necessary to distinguish between prospective interveners establishing a direct interest in the ruling on the specific request sought by the supported party, and those who can establish only an indirect interest in the result of the case by reason of similarities between their situation and that of one of the parties. A similarity between two cases is not sufficient*".

20. The same views have been expressed in the orders issued by the CD Milan and the LD Milan in the parallel cases Insulet v. Eoflow and Insulet v. Menarini.

21. This CD Milan in Insulet v. Menarini (UPC_CFI_380/2024 Order no. ORD_52068/2024 1 October 2024 Related Proceedings Application No. 39640/2024) stated that: "*pursuant to Art. 313 RoP intervention is allowed to a third party having its own interest not merely factual but legal. The third party must therefore present itself as the owner of a legal relationship connected with the one brought in litigation by the counterpart or dependent on it and the connection must entail a total or partial impairment of the right of which the third party claims to be the owner in the event the original party loses the case; that is to say, it is necessary to be the owner of a substantial situation connected with the relationship brought in litigation, such as to expose the third party to the reflexive effects of the judgement*".

22. In the present case, the similarities between the claim of ACCORD and the interests of ZENTIVA are not in doubt. However, as the CoA stated in the Ocado/Autostore case (reference above) parallelism alone do not allow to affirm that the outcome of the present judgment has a direct impact on the ZENTIVA such as to establish a legal interest to participation.

23. Zentiva maintains that a final judgment between ACCORD and NOVARTIS would have a direct impact on any action it might propose in the immediate future in breach of its right to be heard and would also entail the necessary suspension of the present proceedings to avoid conflicting judgments.

24. This Court disagrees and observes that the *res judicata* occurs only between the parties who participate in the proceedings. A decision in the present proceedings would not be *res judicata* in any proceedings brought by ZENTIVA against anyone. Consequently, it appears there is no infringement of the principle of right of defense o equal treatment whatsoever.

25. ZENTIVA points out that in some legal systems, to identify the scope of the judgment, reference is made not only to the order but also to the grounds, a circumstance which might lead to

repercussions on the decision to-be-issued. The court would feel obliged not to deviate from the precedent.

26. This fear is baseless. Such an interpretation of the *res judicata* is confirmed by the ECJ rulings *(i.e. ECJ, judgment of 15 November 2012, C-456/11 para. 40)*, however, this does not mean that the *res judicata* extends beyond the parties involved in the proceedings (Article 322 of German Code of Civil Procedure, art. 1355 French Code Civil, art. 2909 Italian Civil Code), nor that a judgment given between different parties is binding in another dispute where the parties were/are/have been not present. Of course, the reasoning adopted by the Court might be adopted also in similar cases (law enforcement predictability) but not necessarily and automatically; each case has its own features, which may lead to different results also in presence of evident similarities. Different outcomes might depend on different legal strategies and factual allegation (right to defence).

27. These understandings are in the interest of the regular functioning of justice. On the one hand, law '*must be accessible to those facing trial and predictable as to its effects*' (ECHR 27.1.2017, Paradiso and Campanelli v. Italy, in case no. 25358/12, § 169), so that it is rational to expect from the Courts similar results at the outcome of similar cases; it is also consistent with the European principles that 'national bodies' (which obviously include supranational judicial bodies such as the UPC) should 'have stable guidelines', and exercise their powers over time in such a way as not to unpredictably damage subjective legal situations and relationships (EU Court of Justice, 15 February 1986, Duff, in case C-63/93; in the same judgement, and in the same sense, see in particular the significant conclusions of the Advocate General Georgios Cosmas). On the other hand, courts must always consider the features of the very case and start from the facts and defenses presented by the parties. From this point of view ZENTIVA's concerns about any prejudice of this Court in a future action filed by ZENTIVA based on the factual finding in these proceedings are unsubstantiated.

28. This said, regarding the difficulties ZENTIVA would face in protecting its present/future rights outside these proceedings, so that the two proceedings should necessarily be joined, it should be noted that Article 33 of the UPCA itself regulates numerous hypotheses of case connections on the same patent, providing for separate adjudications (bifurcation) as well as the stay of proceedings or joint decisions. These solutions are all part of UPC legal system and are not prejudicial to the right to defense. As a matter of fact, joint treatment of two proceedings is just one the possibilities of dealing with a case and does not constitute a prerequisite for the intervention of a party, since the intervention of a party in a proceeding is not left to an case-by-case assessment at the judge's

discretion, but must be based on a right that is endangered/compromised by the failure of the party to intervene. Therefore, the simple convenience for the party to enter a process already initiated by virtue of savings on processing costs cannot be placed at the basis of an intervention.

29. Moreover, as established by the Paris LD in UPC_CFI_440/2023 on 06.05.2024, the intervention can never go beyond the support of the party to the intervention is made for. Therefore, an intervention is not allowed when the party aims to pursue its own interest even if in line with one of the parties '*A ce titre la partie intervenante dispose des droits attachés à la qualité de partie et participe à la procédure, sous réserve néanmoins, conformément à la règle 313.2 RdP, que l'intervention soit « faite au soutien en tout ou partie d'une demande », ce qui signifie que l'intervenant ne peut développer des prétentions contraires à la partie qu'il soutient et ne peut développer de manière autonome des demandes et selon des modalités procédurales distinctes de celles offertes à la partie qu'il soutient'.* In this case clearly ZENTIVA's intervention is not entirely dependent on ACCORD winning the case (being functional to support a ruling that could serve as a deterrent for the patent owner) but it could also diverge on the merits during the proceedings.

30. This point deserves further analysis as to the relationship between intervener and supported party. In fact, the procedural rules of the UPC do not clearly define the role of the intervener; they do not distinguish between a type of intervention exclusively in support of one of the parties, where the intervener is fully aligned with the supported party and may support (if the case) only a portion of the claims (RoP 313.2 reads "*in whole or <u>in part</u> of a claim, order or remedy*") and where he is bound to accept the procedural situation prior to the intervention, from a different type of intervention in which the intervener, although on the same side as the supported party, may seek a legal remedy which is not entirely the one sought by the supported party (again RoP 313.2 reads "*in support, in whole or <u>in part</u>, of a claim, order or remedy*").

31. The wording of Rule 312.2 'in whole or in part' seems ambiguous as it is not clear whether it refers to partiality by containment or by partial overlap.

32. Rule 313 RoP seems to straddle the two figures, because, on the one hand, there is no obligation for the intervener to accept the process as it stands and intervention can take place at any stage of the proceedings (even after closure of the written procedure by order of the Court), and, on the other hand, it provides for the need to intervene in 'support of a party'. There is a provision of non-contradiction between the legal remedies sought by the parties but not as to the strategy of defense, though. And yet the intervener, having become a party (Rule 315.4), could not be excluded from the proceedings, even though, once admitted, he put forward a defence which would not not exactly the same as that of the supported party (rule 315.1 letter B provides for a

statement of intervention which might be also different in content from the grounds laid down in the application to intervene).

33. It is legitimate to ask to what extent this principle of non-contradiction might correspond to what is laid down in some continental legal systems which provide for non-contradiction between the defense of the main party and that of the intervener (i.e. Art. 67 ZPO or Art. 105.2 Italian Code of Civil Procedure) and whether RoP 313.2 might be read in accordance with this view.

34. If so, and if the principle of non-contradiction were therefore to apply strictly to RoP 313, which is the conclusion reached by this Court (because it does not appear to be 'fair and equitable' to allow an intervener to enter a case, even at an advanced stage, and to let him bring arguments only partially in line with those of the other parties), intervention should be limited to the sole event that the intervener expresses a right depending from the right at issue (i.e. license or distribution agreement).

35. As a further theoretical consideration, if admitted into the proceedings, the bearer of an autonomous and parallel right would even be restricted of his defence rights in the proceedings, since he would be bound to the pleas of the supported party and nevertheless, he would be exposed to the *res judicata* at the outcome of the proceedings.

36. As Zentiva has correctly argued in its observations, what is relevant in the Rule 313 RoP is the right to be heard in the procedure, but if the party has a parallel legal interest in the procedure, the rule is that it should present its defence in a parallel procedure.

37. To summarize, (see UPC_CFI_380/2024 Order no. ORD_52068/2024 CD Milan and in UPC_CFI_153/24 CD Munich) a distinction must be made between prospective interveners who have a direct interest in the outcome of the specific form of order sought by the party they are supporting, and those who have only an indirect and parallel interest in the outcome of the case by virtue of factual similarity between their situation and that of one of the parties.

38. In the present case, there is no need for ZENTIVA to be heard in the non-infringement proceedings because the decision in these proceedings shall have no direct effect on it. Whatever is decided between ACCORD and NOVARTIS will always and in any case remain *res inter alios acta* for ZENTIVA. The application is therefore unfounded.

39. As to the request filed by NOVARTIS to have compensation for the legal costs incurred in preparing the defense in these proceedings, it must be noted (see CD Milan Order no. ORD_59988/2024 in UPC_CFI_380/2024 Application No. 39640/2024) that intervention pursuant to Art. 313 RoP is a sub-proceeding governed by rule of law in accordance with the adversarial principle. Applicant and respondent in the intervention proceedings must be considered as parties

for the purpose of Art. 150 RoP. Moreover, “Successful party” pursuant to Rule 151 is to be considered every winning party at the outcome of said sub-proceeding. Therefore, the party gaining access to the proceedings or successfully preventing the access of a third party into the proceedings are entitled to ask for legal cost compensation pursuant to Art. 69 UPC.

40. Consequently, ZENTIVA shall bear the costs of this sub-proceedings. Since there was no indication of the value of the dispute and the dispute only entailed the drafting of a written submission, the lowest ceiling must be indicated.

ORDER

The application to intervene is dismissed.

Applicant shall bear the costs of this sub-proceedings.

Milan 27.03.2025

Judge rapporteur and presiding judge

Andrea Postiglione

ANDREA POSTIGLIONE

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Legally qualified judge

Marije Knijff

Marije Knijff

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Technically qualified judge

Oliver Werner

Oliver Manfred Werner

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INFORMATION ABOUT APPEAL

Leave to appeal is not granted (RoP 317: ‘There shall be no appeal against an order refusing an Application to intervene’).

INFORMATION ABOUT COSTS AND DAMAGES

NOVARTIS is entitled to ask for legal cost compensation related to these proceedings. Cost ceiling is set at 38.000 euro.

ORDER DETAILS

Order no. ORD_10348/2025 in ACTION NUMBER: ACT_61148/2024
UPC number: UPC_CFI_698/2024
Action type: Declaration of Non-Infringement
Related proceeding no. Application No.: 9038/2025
Application Type: APPLICATION_ROP313

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