



Local Division Munich
UPC_CFI_145/2024
UPC_CFI_146/2024
UPC_CFI_147/2024
UPC_CFI_148/2024

Procedural Order
of the Court of First Instance of the Unified Patent Court
Local Division Munich
issued on 7 January 2025

CLAIMANTS

- 1) Sanofi Mature IP**
- 2) Sanofi Winthrop Industrie**
- 3) Sanofi-Aventis France** (not in UPC_CFI 145/2024)
- 4) Sanofi-Aventis GmbH**
- 5) Sanofi Belgium**
- 6) Sanofi-Aventis Deutschland GmbH**
- 7) Sanofi S.r.l.**
- 8) Sanofi B.V.**
- 9) Sanofi - Produtos Farmaceuticos Lda**
- 10) Sanofi AB**
- 11) Sanofi A/S**

represented by: Frédéric Chevallier (Herbert Smith Freehills).

DEFENDANTS – UPC CFI 145/2024

- 1) Accord Healthcare S.L.U.**
- 2) Accord Healthcare GmbH (AT)**
- 3) Accord Healthcare BV**
- 4) Accord Healthcare GmbH (DE)**
- 5) Accord Healthcare Italia Srl**
- 6) Accord Healthcare B.V.**
- 7) Accord Healthcare, Unipessoal Lda.**
- 8) Accord Healthcare AB**

represented by: Jules Fabre, Arjan Reijns, Louise Millot (Pinsent Mason).

DEFENDANTS – UPC CFI 146/2024

- 1) STADAPHARM GmbH**
- 2) STADA Arzneimittel AG**
- 3) STADA Nordic ApS**

represented by: Daniel Hoppe (Bonabry).

DEFENDANTS – UPC CFI 147/2024

- 1) Reddy Pharma SAS**
- 2) betapharm Arzneimittel GmbH**
- 3) Dr Reddy's Srl**

represented by: Dr. Christian Meyer (Maiwald)
Dr. Andreas Ledl (Maiwald).

DEFENDANTS – UPC CFI 148/2024

- 1) Zentiva France**
- 2) Zentiva Pharma GmbH**
- 3) Zentiva, k.s.**

represented by: Dr. Anja Lunze (Taylor Wessing)
Dr. Elisabeth Greiner (df-mp).

PATENT AT ISSUE

European patent n° 2 493 466

PANEL/DIVISION

Panel 1 of the Local Division Munich

DECIDING JUDGE/S

This order has been issued by the Presiding Judge Dr. Matthias Zigann acting as judge-rapporteur.

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Patent infringement – R 305 RoP regarding Sanofi-Aventis France in UPC_CFI_146/2024, UPC_CFI_147/2024 and UPC_CFI_148/2024

REQUESTS BY THE PARTIES

Sanofi requests in App_54972/2024 UPC_CFI_146/2024, App_54976/2024 UPC_CFI_147/2024 and App_54979/2024 UPC_CFI_148/2024

- *Order that Sanofi-Aventis France be substituted by Sanofi Winthrop Industrie in the present action and all related proceedings;*
- *Order that Sanofi Winthrop Industrie is already a party and a claimant in such action;*
- *Order that this substitution of parties has no consequence on the proceedings within the meaning of Rules 306 and 310 RoP, as Sanofi Winthrop Industrie resumes all rights and obligations of Sanofi-Aventis France which has ceased to exist.*

Stada did not comment on the request.

Reddy requests:

1. *To dismiss the request for substitution on the ground that the original action involving Sanofi-Aventis France was inadmissible.*
2. *To order Sanofi to pay 1/11 of the costs of the proceedings on account of the procedural irregularity resulting from the improper inclusion of Sanofi-Aventis France in the statement of claims.*

Zentiva requests:

- I. *The Dismissal of the Claimants' requests under indents 2 and 3 of para. 7 of Claimants Application under R. 305 RoP of 10 October 2024.*
- II. *The stay the infringement action under R. 310 RoP until Claimant 3. is replaced by its successor, Claimant 2.*
- III. *The dismissal of all requests by Claimant 3. pursuant to para. 49 et seqq. Statement of Claim of 14 May 2024 as inadmissible and unfounded.*
- IV. *Claimant 2. as Claimants 3.'s legal successor shall bear*
 1. *28.4%, alternatively 9.5%, in the further alternative 9.1% of the total Court fees and total costs, whereby, in the further alternative, the decision on the allocation of Court fees and costs is left to the discretion of the LD Munich;*

and

2. *the additional costs incurred as a result of the change of party on the Claimants' side, including, but not limited to, all costs without limitation incurred by the Defendants in consequence of this proceeding under R. 310, 305 RoP brought by Claimants;*

whereby these Court fees and costs under 1. and 2. shall not be subject to any ceilings of recoverable costs in accordance with the regulations and guidelines of the UPC.

LEGAL ISSUES

Aventis argues:

On 1st July 2024, the Sanofi group reorganized its group of companies, and Sanofi-Aventis France has been merged into Sanofi Winthrop Industrie. Sanofi Winthrop Industrie thus substitutes Sanofi-Aventis France in all its rights and obligations. The universal transfer of assets from Sanofi-Aventis France to Sanofi Winthrop Industrie has been completed on 1st July 2024 with retroactive effect set on 1st January 2024. As a consequence, on the basis of Rule 305(1) RoP, the Claimants request from the Court that Sanofi-Aventis France be substituted by Sanofi Winthrop Industrie in the present action and all related proceedings. Sanofi Winthrop Industrie is already a party and a claimant in such action. This substitution of parties has no consequence on the proceedings within the meaning of Rules 306 and 310 RoP, as Sanofi Winthrop Industrie resumes all rights and obligations of Sanofi-Aventis France which has ceased to exist as a consequence of its dissolution without liquidation upon merger completion date on 1st July 2024.

Reddy argues:

As highlighted in the merger documents, the general transfer of assets from Sanofi-Aventis France to Sanofi Winthrop Industrie allegedly took effect retroactively as of 1 January 2024 (i.e. prior to the filing of the present action). This retroactive date would mean that, as of the beginning of that year, Sanofi-Aventis France no longer had any independent rights or obligations with respect to EP466, as these had been transferred in their entirety to Sanofi Winthrop Industrie. Therefore, any actions brought by or in relation to Sanofi-Aventis France in this litigation were effectively moot, as the company was not the relevant entity to assert rights or fulfil obligations (after 1 January 2024) under the patent. The dissolution of Sanofi-Aventis France on 1 July 2024, with retroactive transfer of assets, would mean that Sanofi-Aventis France no longer has legal standing or independent claims in these proceedings. Since Sanofi-Aventis France had no rights to assert from the outset of these proceedings, the substitution cannot retroactively remedy this procedural defect. This is also clear from the documents that were submitted by the Claimants themselves. For example, it is stated in Exhibit A.2.1., p. 30/31:

“...correspondingly, the results of all operation carried out by SAP from the Effective Date until the Completion Date (the „Interim Period“ will be exclusively, as the case may be, for the benefit or expense of SWI, such operations being deemed to have been completed by SWI since January 1, 2024.”

The Claimants argue that the substitution has “no consequence on the proceedings.” However, given the inadmissibility of claims asserted on behalf of Sanofi-Aventis France due to its lack of standing from 1 January 2024, the substitution significantly alters the procedural stance.

It would also mean that the Claimants could remedy the formal defects of the Statement of Claim as originally filed (see para. 38 of our Statement of Defense, where we set out several deficiencies in the standing of Claimants 2-11). In our view, to proceed with Sanofi Winthrop Industrie as if the claims were valid from the beginning misrepresents the admissibility of the action. In view of the procedural errors in the original statement of claim and the need for substitution, it would be equitable for Sanofi to bear at least 1/11 of the costs of the proceedings, given that the initial inclusion of Sanofi-Aventis France as applicant 3) was incorrect and that this misstep has led to additional procedural considerations for the Court and the Defendant’s.

First, the Defendants respectfully request that the Court dismiss the request for substitution on the ground that the original action involving Sanofi-Aventis France was inadmissible. Second, the Defendants respectfully request that the Court order Sanofi to pay 1/11 of the

costs of the proceedings on account of the procedural irregularity resulting from the improper inclusion of Sanofi-Aventis France in the statement of claims.

Zentiva argues:

The change in parties requested by Claimants is not governed by R. 305 RoP, but by R. 310 RoP, since R. 305 RoP only constitutes a fall-back provision while R. 310 RoP constitutes the prevailing specific provision in this case. Contrary to para. 6 of Claimant's Application under R. 305 RoP of 10 October 2024, this infringement action must be stayed, since R. 310 RoP provides for no discretionary power, whereby the order terminating the stay can be combined with the stay order in a single order (Tilmann/Plassmann/Plassmann/Dorn, 1. Aufl. 2024, EPGVerfO § Regel310 Rn. 3, 9). The infringement action brought by Claimant 3. was inadmissible and/or unfounded pursuant Art. 47 UPCA from the outset for all requests made. In the alternative, Defendants maintain their position on the question of standing to sue under Art. 47 UPCA and refer to Statement of Defense/Counterclaim for revocation (SoD/CC) dated September 2, 2024, para. 50 et seqq. In this infringement action, all requests filed by Claimant 3. are inadmissible and without merit:

- Request for declaration of infringement and injunctive relief (para. 49 and 59 Statement of Claim (SC))*
- Request for damages (para. 50 and 59 SC)*
- Request for an order regarding the production of documents and information by the Defendants pursuant to Art. 59 and 67 UPCA (para. 50, 56, 59 SC)*
- Request for order of publication of the decision (para. 59 SC)*
- Request for recall and removal from the channels of commerce or destruction (para. 50, 55 SC)*

Claimant 3. shall therefore bear the Court fees and costs in relation to these requests without a ceiling:

First, the Court fees and costs shall not be subject to any ceilings of recoverable costs in accordance with the regulations and guidelines of the UPC: These ceilings are based on considerations of appropriateness, which are based on the cost-by-cause principle. The unsuccessful party in the proceedings, being the party that caused the proceedings and therefore the Court fees and costs, has to bear Court fees and costs, whereby certain ceilings apply for reason of appropriateness. However, this general rule may not apply in the case of additional costs incurred by a party as a result of an act of the opposing party to the proceedings which is unrelated to the proceedings and thus beyond the sphere of influence of the other party. The merger on the part of the Claimants incurs additional costs for the Defendants, which are to be borne in their entirety and unrestrictedly by the Claimants.

Based on the Claimants' requests to the LD Munich, it is evident that Claimants do not operate on the basis of joint creditors but assert their requests on their own behalf: Art. 47.2 and 47.3 UPCA is based on the consideration that the material risk on the part of the Defendants and the material benefit on the part of the Claimants must not be increased by several claimants asserting one claim November 12, 2024 (Tilmann/Plassmann/W. Tilmann, 1. Aufl. 2024, EPGÜ Art. 47 Rn. 12 et seqq.). Therefore, there is an inevitable consequence that the Claimants' requests to the LD Munich must be phrased in such a way that a joint creditor relationship must be recognizable for the Defendants. Since the Claimants did not clarify their requests to the LD Munich accordingly, it must be assumed that each Claimant is asserting the requests on its own behalf. In the infringement action at hand, the Claimants phrased their requests clearly as individual, not as joint creditors. Therefore, the Court fees and costs to be borne by Claimant 2. as Claimant 3.'s legal successor must be calculated on

the basis of its share in all requests of the infringement action. The share of the request for damages can serve as the governing standard since the other requests either precede or follow this claim for payment. When deciding on Court fees and costs, it should be noted that Claimants have substantiated their claims for damages only for Germany and France, with France accounting for 28.4% of the total damages claimed in the amount of EUR 7,779,506 as indicated by Claimants for the infringement action. As a result, Claimant 2., as the legal successor to Claimant 3., shall bear 28.4% of the total Court fees and total costs of the infringement action. Alternatively, Claimant 2. shall bear 1/3 of 28.4%, i.e. 9.5%, of the total Court fees and total costs if the LD Munich finds that in addition to Claimant 3., Claimant 1. and Claimant 2. are also entitled to enforce EP 466 in relation to the territory of France. In the further alternative, Claimant 2. shall bear 1/11, i.e. 9.1% of the total Court fees and total costs, since Claimant 3. is one of 11 Claimants. In the further alternative, the decision on the Court fees and costs is left to the discretion of the LD Munich.

GROUNDS

The application is successful. Sanofi-Aventis France is replaced by Sanofi Winthrop Industrie in the present action and all related proceedings. As Sanofi Winthrop Industrie is already party to the proceedings this replacement has no consequence on proceedings. Sanofi Winthrop Industrie is bound by the proceedings as now constituted.

I. The law on a change in parties is as follows:

Rule 310 RoP:

- 1. If a party dies or ceases to exist during proceedings, the proceedings shall be stayed until such party is replaced by his successor. The Court may specify a period in this respect.*
- 2. If there are more than two parties to the proceedings, the Court may decide that:
(a) proceedings between the remaining parties be continued separately; and
(b) the stay shall only concern the proceedings regarding the party that no longer exists.*
- 3. If the successor of the party that died or ceased to exist does not continue the proceedings of his own motion, within a period specified by the Court, any other party may apply to have the successor added to or substituted for a party.*
- 4. The Court shall decide who shall be added or substituted as a party pursuant to Rule 305 and 306 shall apply mutatis mutandis.*

Rule 305 RoP:

- 1. The Court may, on application by a party, order a person to:
(a) be added as a party;
(b) cease to be a party;
(c) be substituted for a party.*
- 2. The Court shall invite other parties to the proceedings to comment on the application, as soon as practicable after service of the application.*
- 3. When ordering that a person shall become a party or shall cease to be a party, the Court may make appropriate orders as to payment of court fees and costs as regards such party.*

Rule 306 RoP:

- 1. Where the Court orders that a party be added, removed or substituted under Rule 305.1, it shall give directions to regulate the consequences as to case management.*
- 2. The Court shall also determine the extent to which a new party is bound by the proceedings as then constituted.*

II. This means that if a party ceases to exist during the proceedings, the proceedings shall be stayed until such party is replaced. In this case, Sanofi-Aventis France ceased to exist on 1 July 2024. The action was brought on 14 May 2025. The retroactive effect of the provisions relating to the transfer of assets is not relevant in this respect. These provisions could not be taken into account at the time the action was filed. Since it is undisputed that Sanofi Winthrop Industrie succeeded Sanofi-Aventis France from the moment Sanofi-Aventis France ceased to exist, there is no need to order a formal stay. It is sufficient to order that Sanofi-Aventis France be replaced by Sanofi-Aventis France. Since this decision may be reversed, Claimant No 2 shall be designated "Sanofi Winthrop Industrie as successor to Sanofi-Aventis France" in addition to Claimant No 2, which remains "Sanofi Winthrop Industrie".

This substitution of parties has no effect on the proceedings within the meaning of Rules 306 and 310 of the Rules of Procedure. Sanofi Winthrop Industrie as successor to Sanofi-Aventis France is bound by the proceedings as now constituted. Therefore, it is not necessary to decide now on the defendants' arguments that Sanofi-Aventis France had no right to bring the action. Sanofi Winthrop Industrie is the successor to Sanofi-Aventis France, nothing more and nothing less. The transfer of rights and obligations does not alter those rights and obligations.

III. A decision on costs is not justified now. A decision on costs will be taken in the final decision.

ORDER

1. Sanofi-Aventis France is replaced by Sanofi Winthrop Industrie in the present action and all related proceedings (UPC_CFI_146/2024, UPC_CFI_147/2024 and UPC_CFI_148/2024).
2. Claimant No. 3 shall be designated "Sanofi Winthrop Industrie as successor of Sanofi-Aventis France".
3. The name of Claimant No. 2 shall stay "Sanofi Winthrop Industrie".
4. This replacement of parties has no consequence on the proceedings within the meaning of Rules 306 and 310 RoP. Sanofi Winthrop Industrie as successor of Sanofi-Aventis France is bound by the proceedings as now constituted.
5. All further requests are dismissed.

INFORMATION ABOUT REVIEW BY PANEL

Any party may request that this Order be referred to the panel for a review pursuant to R. 333 RoP. Pending review, the Order shall be effective (R. 102.2 RoP).

INSTRUCTIONS TO THE PARTIES AND THE REGISTRY

1. Claimant No. 3 shall be designated “Sanofi Winthrop Industrie as successor of Sanofi-Aventis France”.
2. The name of Claimant No. 2 shall stay “Sanofi Winthrop Industrie”.
3. It may be impossible to implement this change in the old CMS. However, this order takes precedence.

DETAILS OF THE ORDER

Order no. ORD_59770/2024 in ACTION NUMBER: ACT_16116/2024
UPC number: UPC_CFI_146/2024
Action type: Infringement Action
Related proceeding no. Application No.: 54972/2024
Application Type: Application for a change in parties

Order no. ORD_59768/2024 in ACTION NUMBER: ACT_16119/2024
UPC number: UPC_CFI_147/2024
Action type: Infringement Action
Related proceeding no. Application No.: 54976/2024
Application Type: Application for a change in parties

Order no. ORD_610/2025 in ACTION NUMBER: ACT_16120/2024
UPC number: UPC_CFI_148/2024
Action type: Infringement Action
Related proceeding no. Application No.: 54979/2024
Application Type: Application for a change in parties

Dr. Zigann
Presiding Judge