



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 22 January 2025

CLAIMANTS

- 1) Sanofi SA as successor of Sanofi Mature IP**
- 2) Sanofi Winthrop Industrie**
- 3) Sanofi Winthrop Industrie as successor of Sanofi-Aventis France**
(not a party 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 - order following an oral argument hearing (“preliminary interim conference”) - R 105.5 RoP

PARTICIPANTS TO THE ORAL ARGUMENT HEARING (“PRELIMINARY INTERIM CONFERENCE”) VIA VIDEOCONFERENCE OF 15 JANUARY 2025

Court

- Dr. Zigann, Presiding Judge and Judge-rapporteur
- Wagner, Technically Qualified Judge

Sanofi

Herbert Smith Freehills LLP

- Frédéric Chevallier, UPC Representative
- Alice Hemery, UPC Representative
- Ina vom Feld, UPC Representative

Sanofi (in-house)

- [REDACTED] Sanofi in-house team
- [REDACTED] Sanofi in-house team
- [REDACTED] Sanofi in-house team

Accord

Pinsent Masons

- Jules Fabre (UPC representative, Paris)
- Arjan Reijns (UPC representative, Amsterdam)
- Marina Jonon (UPC representative, Paris)
- Louise Millot (UPC representative, Paris)
- Eleonore Salles (trainee, Paris)
- Yaren Altun (trainee, Paris)

Accord (in-house)

- [REDACTED]

Stada

Bonabry

- Daniel Hoppe, attorney at law, UPC Representative
- Konstantin Schallmoser, LL.M., attorney at law, UPC Representative
- Carl-Alexander Dinges, attorney at law, UPC Representative
- Dr. Sarah Salaschek, attorney at law

Hamm & Wittkopp

- Dr. Alexander Wittkopp, patent attorney, UPC Representative

STADA (in-house)

- [REDACTED]
- [REDACTED]

Reddy

- Dr. Christian Meyer (Maiwald, Düsseldorf)
- Tobias Matschke (Maiwald, Munich)

Zentiva

Taylor Wessing

- Dr. Anja Lunze, LL.M., attorney at law, UPC Representative
- Dr. Aurel-Damian Roscher, attorney at law, UPC Representative

Df-mp

- Dr. Elisabeth Greiner, patent attorney, UPC Representative
- Dr. Simon Geiger, patent attorney, UPC Representative

Zentiva (in-house)

- [REDACTED]
- [REDACTED]

REQUESTS FILED BY THE PARTIES

Accord requests in APP_36781/2024 (R 19) and App_38125/2024 (R 334 h, 361, 363 and APP_55895/2024 (R 9):

A. Dismiss the current proceedings in the main action and claims brought by the Claimants in their entirety (Rule 19 RoP).

Alternatively, should the Court decide to proceed with the current proceedings in the main action initiated by the Claimants despite the request for dismissal, it is requested to:

B. Decide that the claims brought by the Claimants are to be dismissed due to a lack of compliance with Rule 13 RoP and/or because they have no prospect of succeeding (Rule 334(h) RoP) and/or are bound to fail (Rule 361 RoP); and in any event

C. Decide that Claimants 2 to 10 do not have standing and therefore dismiss any and all claims made by them.

More alternatively, should the Court decide to proceed with all or part of the claims made in the current proceedings in the main action despite these requests for dismissal, it is requested to:

D. Align the terms for submission of the Statement of Defence and Counterclaim by the Defendants to 3 September 2024 (Rule 334(a) RoP); and/or to

E. Order that the damages claim be handled in separate proceedings, which are to start after a final decision on the merits in the main action of the current proceedings has been rendered (Rule 334(d) RoP) in case the Claimants prevail on both its

assertions of infringement and on validity of EP 466 in a counterclaim, when such claim is filed by the Defendants.

On invitation by the Judge-rapporteur Accord clarified:

The requests for dismissal for lack of jurisdiction or competence under Rule 19 RoP (Section 2 of the written submissions filed by the Defendants on 1 July 2024) are to be attributed to the Preliminary Objections (workflow 36781/2024).

The requests for dismissal under Rules 13, 334(h), 361 and 363 RoP and for lack of standing of Claimants 2 to 10 (Sections 3 and 4 of the written submissions filed by the Defendants on 1 July 2024) and the case management requests under Rule 334 RoP (Section 5 of the written submissions filed by the Defendants on 1 July 2024) are to be attributed to the General Procedural Application (workflow 38125/2024).

The Defendants will confirm the orders and requests they are seeking under workflow 38125/2024 once they will be given an opportunity to provide their comments to Sanofi's Reply to the Generic Procedural Application. For the information of the Court, the Defendants intend to maintain all of their requests made in workflow 38125/2024, with the exception of the request for alignment of the deadlines for filing the SoD and CfR, which has now become obsolete. The Defendants will also request that a decision is made on all such requests immediately and that an oral hearing is held in accordance with Rule 334(d) RoP, preferably together with the oral hearing on the Preliminary Objections.

Accord now request the Court in 36781/2024 to

A. Deal with and decide immediately on the Preliminary Objections in accordance with Rule 20(1) RoP;

B. Reject as inadmissible under Rule 263 RoP the changes to their claims and the amendments to their case made by the Claimants in their comments to the Preliminary Objections filed on 14 July 2024;

C. Dismiss the infringement action and all claims brought by the Claimants altogether due to a lack of jurisdiction or competence in accordance with Rule 19 RoP; and

D. Dismiss any and all requests made by the Claimants in relation workflow 36781/2024.

E. Grant leave to appeal to the Defendants if any of its requests were dismissed.

Stada requests in App_38526/2024 (R 19) and App_37537/2024 (R 19):

I. grant the preliminary objection to the extent requested and declare the action partially inadmissible and exclude those parts of the claimants' requests which relate to the territories of Ireland, Poland, Czech Republic, Slovakia, Hungary, Romania, Spain, Croatia, Greece and Cyprus;

II. grant the preliminary objection to the extent requested and declare the action partially inadmissible and exclude those parts of the claimants' requests which relate to acts committed before the entry into force of the UPC;

III. decide on the objection in an interlocutory decision pursuant to Rule 20.1 of the Rules of Procedure;

IV. in the event that the claimants fail to act within the time limit provided for in the Rules of Procedure or set by the Local Division or fails to appear at an oral hearing after being duly summoned, to issue a default judgment against the claimants.

Reddy requests in App_36747/2024 (R 19):

1. the partial dismissal of the infringement action No. ACT_16119/2024 UPC_CFI_147/2024 for lack of jurisdiction of the Unified Patent Court (Rule 19.1(a) RoP) in respect of

a. all claims, in particular

- claims for damages (paragraph 52 et seq. of the Statement of Claim),*
- claims for corrective measures (paragraph 57 of the Statement of Claim), and*
- request for information (paragraph 58) of the Statement of Claim,*

asserted by the plaintiffs which relate to a period prior to the entry into force of the UPC on 1 June 2023, and

b. all claims asserted by the plaintiffs for countries which are not yet Contracting States to the Agreement on a Unified Patent Court;

2. the plaintiffs to bear the costs of the proceedings in so far as they relate to the lack of jurisdiction of the Unified Patent Court; and;

3. to rule on the Preliminary Objection by way of interlocutory decision pursuant to Rule 20.1 of the RoP.

Zentiva requests in App_39370/2024 (R 19):

I. the partial dismissal of all Claimants' requests of the infringement action ACT_16120/2024 UPC_CFI_148/2024 for lack of territorial jurisdiction of the UPC pursuant R. 19.1(a) UPC-RoP in states which are not Contracting Member States of the Agreement on a Unified Patent Court (2013/C 175/01), in particular the partial dismissal of Claimants' requests for injunction (paragraphs 49, 59), damages (paragraphs 50, 59), corrective measures (paragraphs 55, 59), information (paragraphs 56, 59) and publication of the decision (paragraph 59). Date 2 July 2024 Page 5

II. the partial dismissal of all Claimants' requests of the infringement action ACT_16120/2024 UPC_CFI_148/2024 for lack of retroactive temporal jurisdiction of the UPC pursuant R. 19.1(a) UPC-RoP, in particular the partial dismissal of Claimants' requests for damages (paragraphs 50, 59), corrective measures (paragraphs 55, 59), information (paragraphs 56, 59) relating to a period prior to entry into force of the UPC and on 1 June 2023.

III. the dismissal of all Claimants' requests of the infringement action ACT_16120/2024 UPC_CFI_148/2024 for inadmissibility of the offer of evidence for Claimants' standing to sue in the language of the proceedings pursuant to Art. 53, 49 UPCA and R. 19.1(c) UPC-RoP.

IV. the Claimants to bear the costs of the proceedings in so far as they relate to the lack of jurisdiction of the UPC and lack of admissible language of the proceedings pursuant to Art. 69(1) UPCA.

and to rule on the Preliminary Objection by way of interlocutory decision pursuant to R. 20.1 UPC-RoP.

Sanofi`s requests:

- Order that the Preliminary objections be dealt with in the main proceedings;

In the alternative:

- Dismiss the preliminary objections regarding the alleged lack of jurisdiction of the Court;

- Dismiss the requests under Rules 13, 334, 361 and 363 RoP;

- Dismiss the request that all Claimants except Sanofi Mature IP would not have standing to sue;

In any case:

- The Defendants have to bear the costs of the preliminary objections;

- Grant leave to appeal to the Claimants if any of its requests were dismissed.

Together with the reply to the statement of defence Sanofi filed applications pursuant to Rule 263 RoP (App_57841/2024, App_57844/2024, App_57842/2024, App_57845/2024).

Sanofi additionally requests in App_57841/2024 UPC_CFI_145/2024 (ACCORD):

- Rule that the requests and amended requests comply with Article 76 UPCA and Rule 263 RoP;

- Proceed with both the action for infringement and with the counterclaim for revocation; - Dismiss all the requests of the Defendants;

- Dismiss the revocation counterclaim lodged by the Defendants; - Rule that European patent No. 2 493 466 is valid in all UPC Contracting Member States in which the patent has effect;

- Rule that Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB commit acts of infringement of at least claims 1, 2, 5, 6, 7, 8 and 9 European patent No. 2 493 466 in Austria, Belgium, Germany, Italy, The Netherlands, Portugal, and Sweden;

o Alternatively, rule that Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB commit acts of infringement of claims 1, 2, 5, 6, 7, 8 and 9 European patent No. 2 493 466 in Austria, Belgium, Germany, Italy, The Netherlands, Portugal, and Sweden;

- Order a permanent injunction against Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB, their affiliates and any third parties acting pursuant to any agreement with them, to commit acts of infringement of European patent No. 2 493 466 until its expiry, in all Unified Patent Court Member States where the national designations of such patent are in force, with the exception of France, including for national designations of States in which the Agreement on a Unified Patent Court shall enter into force; FRA01/30313549_9 165

o Alternatively, order a permanent injunction against Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB to commit acts of infringement of European patent No. 2 493 466 until its expiry, in all Unified Patent Court Member States where acts of infringement have been committed;

- Order Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare,

Unipessoal Lda., and Accord Healthcare AB to pay jointly to Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S €4,142,256 as damages subject to further assessment;

o Alternatively, order Accord Healthcare S.L.U. to pay to Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S €4,142,256 as damages subject to further assessment;

- Order Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB to publish the following declaration of infringement on their respective website's homepages during 1 month after the present order has been issued:

The Unified Patent Court has issued a first instance decision ruling that Accord Healthcare has committed acts of infringement of Sanofi's patent rights on Jevtana® and cabazitaxel. An appeal can be lodged against the decision of the Unified Patent Court available at the following link: [insert link towards the full decision].

- Order Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB, their affiliates and any third parties acting pursuant to any agreement with them, at their own expense, to recall the infringing products from the channels of commerce, to definitively remove the products from the channels of commerce, and to destroy the products concerned from the territories of all Unified Patent Court Member States where the national designations of European patent No. 2 493 466 are in force, with the exception of France, including for the territories in which the Agreement on a Unified Patent Court shall enter into force;

o Alternatively, order Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia FRA01/30313549_9 166 Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB, at their own expense, to recall the infringing products from the channels of commerce, to definitively remove the products from the channels of commerce, and to destroy the products concerned from the territories of all Unified Patent Court Member States where acts of infringement have been committed;

- Order Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB to communicate within 1 month of the order to be issued, the information listed in Article 67 of the Unified Patent Court in relation to all designations of EP 466 covered by the exclusive competence of the Unified Patent Court where EP 466 is in force, including for national designations of States in which the UPCA shall enter into force, with the exception of the French designation of EP 466 and the French territory, such that Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S can make a final calculation of damages;

o Alternatively, order Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB to communicate within 1 month of the order to be issued, the information listed in Article 67 of the Unified Patent Court in relation to all designations of EP 466 covered by the exclusive competence of the Unified Patent Court where acts of infringement have been committed, such that Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi

S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S can make a final calculation of damages;

- Order the award of legal costs to Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S set at the ceiling corresponding to the court fees paid by these entities to start the present action;

- Order the enforceability of the measures requested by Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S notwithstanding an appeal that may be lodged by Accord Healthcare S.L.U., Accord Healthcare GmbH, Accord Healthcare BV, Accord Healthcare GmbH, Accord Healthcare Italia Srl, Accord Healthcare B.V., Accord Healthcare, Unipessoal Lda., and Accord Healthcare AB;

- Reserve Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., FRA01/30313549_9 167 Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S's right to lodge further pleadings and written evidence;

- Allow Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S to provide detailed information on its lost margins on the reference product JEVTANA® in order to demonstrate the damages calculation, requesting that Confidential Information be protected accordingly.

Sanofi additionally requests in App 57844/2024 UPC CFI 146/2024 (STADA):

- Rule that the requests and amended requests comply with Article 76 UPCA and Rule 263 RoP;

- Proceed with both the action for infringement and with the counterclaim for revocation; - Dismiss all the requests of the Defendants;

- Dismiss the revocation counterclaim lodged by the Defendants;

- Rule that European patent No. 2 493 466 is valid in all UPC Contracting Member States in which the patent has effect;

- Rule that STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS commit acts of infringement of at least claims 1, 2, 5, 6, 7, 8 and 9 European patent No. 2 493 466 in Germany, Denmark, and Sweden;

o Alternatively, rule that STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS commit acts of infringement of claims 1, 2, 5, 6, 7, 8 and 9 European patent No. 2 493 466 in Germany, Denmark, and Sweden; FRA01/30313202_5 162

- Order a permanent injunction against STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS, their affiliates and any third parties acting pursuant to any agreement with them, to commit acts of infringement of European patent No. 2 493 466 until its expiry, in all Unified Patent Court Member States where the national designations of such patent are in force, including for national designations of States in which the Agreement on a Unified Patent Court shall enter into force;

o Alternatively, order a permanent injunction against STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS to commit acts of infringement of European patent No. 2 493 466 until its expiry, in all Unified Patent Court Member States where acts of infringement have been committed;

- Order STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS to pay jointly to Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S €15,777,587 as damages subject to further assessment;

o Alternatively:

♣ order STADA Arzneimittel AG and STADA Nordic ApS to pay to Sanofi Mature IP, Sanofi Winthrop Industrie and Sanofi A/S €642,171 as damages subject to further assessment;

♣ order STADAPHARM GmbH to pay to Sanofi Mature IP, Sanofi Winthrop Industrie and Sanofi-Aventis Deutschland GmbH €12,082,554 as damages subject to further assessment;

♣ order STADA Arzneimittel AG and STADA Nordic ApS to pay to Sanofi Mature IP, Sanofi Winthrop Industrie and Sanofi AB €3,052,862 as damages subject to further assessment;

- Order STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS to publish the following declaration of infringement on their respective website's homepages during 1 month after the present order has been issued:

The Unified Patent Court has issued a first instance decision ruling that STADA has committed acts of infringement of Sanofi's patent rights on Jevtana® and cabazitaxel. An appeal can be lodged against the decision of the Unified Patent Court available at the following link: [insert link towards the full decision].

- Order STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS, their affiliates and any third parties acting pursuant to any agreement with them, at their own expense, to recall the infringing products from the channels of commerce, to definitively remove the products from the channels of commerce, and to destroy the products concerned from the territories of all Unified Patent Court Member States where the national designations of European patent No. 2 493 466 are in force, including for the territories in which the Agreement on a Unified Patent Court shall enter into force;

o Alternatively, order STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS, at their own expense, to recall the infringing products from the channels of commerce, to definitively remove the products from the channels of commerce, and to destroy the products concerned from the territories of all Unified Patent Court Member States where acts of infringement have been committed;

- Order STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS to communicate within 1 month of the order to be issued, the information listed in Article 67 of the Unified Patent Court in relation to all designations of EP 466 covered by the exclusive competence of the Unified Patent Court where EP 466 is in force, including for national designations of States in which the UPCA shall enter into force, such that Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S can make a final calculation of damages;

o Alternatively, order STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS to communicate within 1 month of the order to be issued, the information listed in Article 67 of the Unified Patent Court in relation to all designations of EP 466 covered by the exclusive competence of the Unified Patent Court where acts of infringement have been committed, such that Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis Deutschland GmbH, Sanofi AB, and Sanofi A/S can make a final calculation of damages;

- Order the award of legal costs to Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S set at the ceiling corresponding to the court fees paid by these entities to start the present action;

- Order the enforceability of the measures requested by Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis-France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S notwithstanding an appeal that may be lodged by STADAPHARM GmbH, STADA Arzneimittel AG, and STADA Nordic ApS;

- Reserve Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis-France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, FRA01/30313202_5 164 Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S's right to lodge further pleadings and written evidence;

- Allow Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis-France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S to provide detailed information on its lost margins on the reference product JEVTANA® in order to demonstrate the damages calculation, requesting that Confidential Information be protected accordingly.

Sanofi additionally requests in App 57842/2024 UPC CFI 147/2024 (REDDY):

- Rule that the requests and amended requests comply with Article 76 UPCA and Rule 263 RoP;

- Proceed with both the action for infringement and with the counterclaim for revocation;

- Dismiss all the requests of the Defendants;

- Dismiss the revocation counterclaim lodged by the Defendants;

- Rule that European patent No. 2 493 466 is valid in all UPC Contracting Member States in which the patent has effect;

- Rule that Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl commit acts of infringement of at least claims 1, 2, 5, 6, 7, 8 and 9 European patent No. 2 493 466 in Germany, France, and Italy;

o Alternatively, rule that Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl commit acts of infringement of claims 1, 2, 5, 6, 7, 8 and 9 European patent No. 2 493 466 in Germany, France, and Italy;

- Order a permanent injunction against Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl, their affiliates and any third parties acting pursuant to any agreement with them, to commit acts of infringement of European patent No. 2 493 466 until its expiry, in all Unified Patent Court Member States where the national designations of such patent are in force, including for national designations of States in which the Agreement on a Unified Patent Court shall enter into force;

o Alternatively, order a permanent injunction against Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl to commit acts of infringement of European patent No. 2 493 466 until its expiry, in all Unified Patent Court Member States where acts of infringement have been committed;

- Order Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl to pay jointly to Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis-France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S €8,050,148 as damages subject to further assessment;

o Alternatively:

♣ order Reddy Pharma SAS to pay to Sanofi Mature IP and Sanofi Winthrop Industrie €60,987 as damages subject to further assessment; FRA01/30275559_6 164

♣ order betapharm Arzneimittel GmbH to pay to Sanofi Mature IP, Sanofi Winthrop Industrie and Sanofi-Aventis Deutschland GmbH €1,444,176 as damages subject to further assessment;

♣ order Dr Reddy's Srl to pay to Sanofi Mature IP, Sanofi Winthrop Industrie and Sanofi S.r.l. €6,544,985 as damages subject to further assessment;

- Order Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl to publish the following declaration of infringement on their respective website's homepages during 1 month after the present order has been issued:

The Unified Patent Court has issued a first instance decision ruling that Dr Reddy's has committed acts of infringement of Sanofi's patent rights on Jevtana® and cabazitaxel. An appeal can be lodged against the decision of the Unified Patent Court available at the following link: [insert link towards the full decision].

- Order Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl, their affiliates and any third parties acting pursuant to any agreement with them, at their own expense, to recall the infringing products from the channels of commerce, to definitively remove the products from the channels of commerce, and to destroy the products concerned from the territories of all Unified Patent Court Member States where the national designations of European patent No. 2 493 466 are in force, including for the territories in which the Agreement on a Unified Patent Court shall enter into force;

o Alternatively, order Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl, at their own expense, to recall the infringing products from the channels of commerce, to definitively remove the products from the channels of commerce, and to destroy the products concerned from the territories of all Unified Patent Court Member States where acts of infringement have been committed;

- Order Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl to communicate within 1 month of the order to be issued, the information listed in Article 67 of the Unified Patent Court in relation to all designations of EP 466 covered by the exclusive competence of the Unified Patent Court where EP 466 is in force, including for national designations of States in which the UPCA shall enter into force, such that Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S can make a final calculation of damages;

o Alternatively, order Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl to communicate within 1 month of the order to be issued, the information listed in Article 67 of the Unified Patent Court in relation to all designations of EP 466 covered by the exclusive competence of the FRA01/30275559_6 165 Unified Patent Court where acts of infringement have been committed, such that Sanofi Mature IP, Sanofi Winthrop Industrie, Sanofi-Aventis Deutschland GmbH, and Sanofi S.r.l. can make a final calculation of damages;

- Order the award of legal costs to Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S set at the ceiling corresponding to the court fees paid by these entities to start the present action;

- Order the enforceability of the measures requested by Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S notwithstanding an appeal that may be lodged by Reddy Pharma SAS, betapharm Arzneimittel GmbH, and Dr Reddy's Srl;

- Reserve Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S's right to lodge further pleadings and written evidence;

- Allow Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S to provide detailed information on its lost margins on the reference product JEVTANA® in order to demonstrate the damages calculation, requesting that Confidential Information be protected accordingly.

Sanofi additionally requests in App 57845/2024 UPC CFI 148/2024 (ZENTIVA):

- Rule that the requests and amended requests comply with Article 76 UPCA and Rule 263 RoP;

- Proceed with both the action for infringement and with the counterclaim for revocation;

- Dismiss all the requests of the Defendants;

- Dismiss the revocation counterclaim lodged by the Defendants;

- Rule that European patent No. 2 493 466 is valid in all UPC Contracting Member States in which the patent has effect;

- Rule that Zentiva France, Zentiva k.s. and Zentiva Pharma GmbH commit acts of infringement of at least claims 1, 2, 5, 6, 7, 8 and 9 European patent No. 2 493 466 in Germany and France;

o Alternatively, rule that Zentiva France and Zentiva Pharma GmbH commit acts of infringement of claims 1, 2, 5, 6, 7, 8 and 9 European patent No. 2 493 466 in Germany and France; FRA01/30311597_6 161

- Order a permanent injunction against Zentiva France, Zentiva k.s. and Zentiva Pharma GmbH, their affiliates and any third parties acting pursuant to any agreement with them, to commit acts of infringement of European patent No. 2 493 466 until its expiry, in all Unified Patent Court Member States where the national designations of such patent are in force, including for national designations of States in which the Agreement on a Unified Patent Court shall enter into force;

o Alternatively, order a permanent injunction against Zentiva France and Zentiva Pharma GmbH to commit acts of infringement of European patent No. 2 493 466 until its expiry, in all Unified Patent Court Member States where acts of infringement have been committed;

- Order Zentiva France, Zentiva k.s. and Zentiva Pharma GmbH to pay jointly to Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S €7,779,506 as damages subject to further assessment;

o Alternatively:

♣ order Zentiva France to pay to Sanofi Mature IP and Sanofi Winthrop Industrie €1,719,540 as damages subject to further assessment;

♣ order Zentiva Pharma GmbH to pay to Sanofi Mature IP, Sanofi Winthrop Industrie and Sanofi-Aventis Deutschland GmbH €6,059,966 as damages subject to further assessment;

- Order Zentiva France, Zentiva k.s. and Zentiva Pharma GmbH to publish the following declaration of infringement on their respective website's homepages during 1 month after the present order has been issued:

The Unified Patent Court has issued a first instance decision ruling that Zentiva has committed acts of infringement of Sanofi's patent rights on Jevtana® and cabazitaxel. An appeal can be lodged against the decision of the Unified Patent Court available at the following link: [insert link towards the full decision].

- Order Zentiva France, Zentiva k.s. and Zentiva Pharma GmbH, their affiliates and any third parties acting pursuant to any agreement with them, at their own expense, to recall the infringing products from the channels of commerce, to definitively remove the products from the channels of commerce, and to destroy the products concerned from the territories of all Unified Patent Court Member States where the national designations of European patent No. 2 493 466 are in force, including for the territories in which the Agreement on a Unified Patent Court shall enter into force;

o Alternatively, order Zentiva France and Zentiva Pharma GmbH, at their own expense, to recall the infringing products from the channels of commerce, to definitively remove the products from the channels of commerce, and to destroy the products concerned from the territories of all Unified Patent Court Member States where acts of infringement have been committed;

- Order Zentiva France, Zentiva k.s. and Zentiva Pharma GmbH to communicate within 1 month of the order to be issued, the information listed in Article 67 of the Unified Patent Court in relation to all designations of EP 466 covered by the exclusive competence of the Unified Patent Court where EP 466 is in force, including for national designations of States in which the UPCA shall enter into force, such that Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S can make a final calculation of damages;

o Alternatively, order Zentiva France and Zentiva Pharma GmbH to communicate within 1 month of the order to be issued, the information listed in Article 67 of the Unified Patent Court in relation to all designations of EP 466 covered by the exclusive competence of the Unified Patent Court where acts of infringement have been committed, such that Sanofi Mature IP, Sanofi Winthrop Industrie, and Sanofi-Aventis Deutschland GmbH can make a final calculation of damages;

- Order the award of legal costs to Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S set at the ceiling corresponding to the court fees paid by these entities to start the present action;

- Order the enforceability of the measures requested by Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S notwithstanding an appeal that may be lodged by Zentiva France, Zentiva k.s. and Zentiva Pharma GmbH;

- Reserve Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S's right to lodge further pleadings and written evidence;

- Allow Sanofi Mature IP, Sanofi Winthrop Industrie, ~~Sanofi-Aventis France~~, Sanofi-Aventis GmbH, Sanofi Belgium, Sanofi-Aventis Deutschland GmbH, Sanofi S.r.l., Sanofi B.V., Sanofi Produtos Farmaceuticos Lda, Sanofi AB, and Sanofi A/S to provide detailed information on its lost margins on the reference product JEVTANA® in order to demonstrate the damages calculation, requesting that Confidential Information be protected accordingly.

In the statement of claim in each of the four cases, Sanofi also made the following additional applications:

Pursuant to Articles 59 and 67 UPCA, and Rules 13(o), 101, 103, 104, 190 and 191 RoP, the Claimants request the Judge-rapporteur to issue an order regarding the production by the Defendants of the documents and information relating to the infringing products in suit for all designations of EP 466 covered by the exclusive competence of the Unified Patent Court where EP 466 is in force, including for national designations of States in which the UPCA shall enter into force, [in ACT_16112/2024 UPC_CFI_145/2024 with the exception of the French designation of EP 466 and the French territory], in order notably to be able to calculate the damages requested by Sanofi. Sanofi has indeed presented reasonably available and plausible evidence in support of its damages claim, but the remaining information concerning notably precise quantities, margins and third parties involved in the infringing acts lies in the control of the Defendants.

These applications have not been filed in dedicated workflows.

SUMMARY OF THE PRELIMINARY INTERIM CONFERENCE OF 15 JANUARY 2025

Substitution of Sanofi Mature IP by Sanofi SA

The defendants did not object. The Court has no objections either. Sanofi Mature IP has therefore been substituted by Sanofi SA in the present and all related proceedings by separate orders in the respective dedicated workflows.

Preliminary objections (Rule 19 RoP)

The Court found that it was possible to carve out France and that the UPC had jurisdiction for damages claims relating to periods prior to 1 June 2023. It was also noted that the remaining concerns depend on the understanding of the territories for which formal reliefs are requested. Sanofi announced that it would submit amended formal reliefs within 7 days, as requested by the Court. It was further discussed whether and why an immediate decision on the preliminary objections was necessary.

Applications by Accord under Rules 334h, 361, 363 of the Rules of Procedure

The Court questioned why the right to sue might be an issue in the present case as all relevant parties, the patent proprietor, the exclusive licensee and the non-exclusive licensees, filed the infringement actions jointly. Accord noted that even if joint filing were to be considered as implied consent, it would still not qualify as "expressly permitted" under Art. 47(3) UPCA.

Deficiencies in Sanofi's formal reliefs and applications under Rule 263 of the Rules of Procedure

The Court set out in detail the deficiencies of the formal reliefs filed (undefined Contracting Member States, no entitlement to a declaration that the patent is valid, undefined "acts of infringement", undefined attacked embodiment, lack of claim language, unclear "at least claims 1, 2, 5, 6, 7, 8 and 9"), lack of clarification as to which claimant is seeking which relief from which defendant for which territory, undefined "affiliates and third parties", undefined whether and why claimants are joint creditors and defendants are joint debtors, concerns about an order that defendants publish the judgment on their websites, lack of timeframe for some of the relief sought, "information listed in Art. 67 UPCA" is undefined, award of legal costs should be specified or formulated as a declaration that costs are owed. Sanofi

announces that it will submit amended formal requests as requested by the Court within 7 days.

Sanofi's requests under Rules 13(o), 101, 103, 104, 190, 191 of the Rules of Procedure for information on the defendant's profits

The Court noted that the calculation of damages under Art. 68 UPCA does indeed differ from national practice. According to Art. 68(3) UPCA, the court shall determine the amount of damages taking into account all appropriate aspects, such as (a) the negative economic consequences, including lost profits, incurred by the injured party, any unfair profits made by the infringer and, in appropriate cases, elements other than economic factors, such as the moral prejudice caused to the injured party by the infringement; (b) as an alternative to subparagraph (a), it may, in appropriate cases, fix the damages as a lump sum on the basis of elements such as at least the amount of royalties or fees that would have been due if the infringer had applied for authorisation to use the patent in question. In order for the court to assess damages in this way, the patent owner must meet his burden of proof. Therefore, the patentee may indeed make a preliminary claim for damages based on lost profits and request additional disclosure of the infringer's profits in the same proceedings. However, these requests must be made in the dedicated workflows and not in the statement of claim. In any event, the Court noted that when deciding on a request for disclosure in the context of ongoing proceedings, a balance must be struck between the competing interests of the parties. Data relating to the infringer's profits are by their nature particularly sensitive. Therefore, the prospects of the patentee's case must be weighed against the prospects of the defendant's case. In this context, the Court took note of the decision of the French courts of first instance invalidating the French designation of the patent in dispute, the rejection of the opposition by the Opposition Division of the EPO and the date set for the oral proceedings before the Boards of Appeal of the EPO on 1-3 April 2025. The parties informed the Court that a preliminary opinion from the Boards of Appeal is expected shortly. Consequently, no disclosure of infringers' profits will be ordered before that preliminary opinion is issued, even if those requests are subsequently filed in the dedicated workflows.

Separate proceedings for damages

Some of the defendants suggested that there should be separate proceedings for the calculation of damages. The Court noted that under Rule 118(1)(2) of the Rules of Procedure, separation is at the discretion of the Court. The claimants argued that damages should, if possible, be calculated in the main proceedings. In another context, the Claimants stated that the formal reliefs for damages should be understood as a request for an interim award of damages pursuant to Rule 119 of the Rules of Procedure. The Court noted that this was not currently reflected in the pleadings and should not be so understood until a formal amendment is made.

Requests in some of the counterclaims

In some of the counterclaims, the defendants requested that the patent in suit be declared invalid in its entirety and/or that the " claimants " be ordered to pay the costs of the proceedings. The Court held that the territorial scope of the counterclaim must be made clear by naming the territories. It should also be made clear who, on the claimant side, should bear the costs. If the requests include claimants other than the patentee, it should be explained why they should also bear the costs and, if so, whether and why they are jointly and severally liable with the patentee. In any event, the costs incurred for the infringement action and the counterclaims must be kept separate and claimed separately. The defendants concerned shall address this issue in their observations on Sanofi's next submission.

Submission of witness statement D4

The Court noted that the filing of a witness statement does not count as a pleading. If the accompanying pleading is filed in the future, it will be necessary to consider whether this could have been done earlier. All parties stated that they would not request a panel review of the confidentiality order in respect of D4.

Validity of the contested patent

The parties informed the Court that an appeal hearing in France is expected in late 2026/early 2027. The oral hearing before the BoA is scheduled for 1-3 April 2025. A preliminary opinion is expected shortly. A written decision is expected in late June/early July 2025. Sanofi informed the Court that it has not filed any request for amendment of the patent with the Court, but reserves the right to do so following a decision by the BoA. The court did not comment on whether this approach complied with the Rules of Procedure. Accord argued that the first instance invalidation decision for France had immediate effect, even for the period during which an appeal was pending. Therefore, no protection was now available for the French territory. Reddy argued that no stay of proceedings was necessary. Zentiva's lawyer said that this issue needed to be discussed with the client first.

PMAC

The Court invited the parties to consider using the PMAC. However, no agreement to do so could be reached prior to a decision by the BoA.

Values of the actions and counterclaims

Sanofi argued that the claims for damages were requests for an interim award of damages that could increase or decrease depending on further information. The defendants disagreed with this interpretation based on the wording of the formal reliefs filed. The Court noted that this was not now reflected in the pleadings and therefore should not be understood in this way until a formal amendment is made.

In any event, the claims relate to a specific amount of money to be paid and therefore the value of the claims for damages is the amount of money to be paid. The other remedies sought, such as injunctive relief, recall and destruction, add to this value. In the absence of better figures, the Court estimates that these other remedies add 100 per cent to the value.

As to the value of the counterclaims, the defendants disagreed with the Court's view that the value of each counterclaim should be the sum of all four values of the infringement actions plus 50 per cent. However, this is precisely the calculation method set out in point 2.b of the Guidelines. The value of the patent must be determined. In the absence of relevant information, the value of the counterclaim may be assumed to be equal to the value of the infringement action plus up to 50 per cent. In the case of multiple infringement actions, the values should be added together. As the parties have not provided a better method of calculation, the values shall be increased as follows:

Value of the infringement actions:

Accord:

4,13 Mio increased to 8,5 Mio. EUR

Stada

15,77 Mio. increased to 32 Mio. EUR

Reddy

8,05 Mio. increased to 16,5 Mio. EUR

Zentiva

7,779 Mio. increased to 16 Mio. EUR

Value of the counterclaims:

The value of each counterclaim is increased to 109.50 mio. EUR.

The value of the counterclaims is only relevant for the recoverable costs cap. The value of the infringement actions is also relevant for the court fees. Sanofi will have to pay an additional fee within 30 days.

Agreement on the level of recoverable costs

The Court encouraged the parties to reach an out-of-court agreement on the amount of the recoverable costs prior to any decision by the Boards of Appeal or the Court of First Instance.

Conduct of further proceedings

It was agreed that, for the purposes of further proceedings, it would be sufficient for the Court to invite only one of several claimants or defendants to submit observations in the CMS, and that it would be sufficient for only one of several claimants or defendants to file a brief in the CMS, as long as it was clear from the PDF file submitted which party or parties were intervening.

The Court has asked the parties not to repeat what has already been written and filed, and to make clear which parts of the briefs are common to all four parallel cases and all claimants and defendants, and which parts relate only to the particular circumstances of each procedural relationship. This will save reading time for both the parties and the Court.

The defendants informed the Court that there is currently no joint defence group in place and that it is unlikely that there will be one in the future.

It was discussed that, as a first step, Sanofi should address the issues with the formal relief. The defendants will be invited to comment. The Court will then give guidance on further deadlines. All other time limits, including the time limit for the rejoinder, currently due on 13 February 2025, will therefore be suspended.

ORDER

1. Sanofi is invited to remedy the deficiencies in the formal submissions and to explain within 7 days exactly who is asking what of whom in what territory and why.

2. The defendants are invited to comment on this and, if relevant, also on the concerns regarding the counterclaims within a further 14 days.

3. All other deadlines are waived.

4. The value of the infringement claims is set as follows:

Accord: 8.5 million EUR

Stada: 32 million EUR

Reddy: 16.5 million EUR

Zentiva: 16 million EUR

5. The value of each counterclaim is set at 109.50 million EUR.

6. Sanofi must pay the additional court fees for the infringement actions within 30 days.

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).

INFORMATION ABOUT DECISION BY DEFAULT

Should a party fail to comply with the present Order within the time period specified, a decision by default may be given in accordance with R. 355 RoP (R. 103.1, last subparagraph and .2 RoP).

INSTRUCTIONS TO THE REGISTRY

The value of the infringement actions and counterclaims must be adjusted in the CMS. Additional fees shall be charged for infringement actions.

INSTRUCTIONS TO THE PARTIES

The Court will announce the next deadlines for the filing of any briefs and will rule on the open applications in due course after the parties have filed their briefs as ordered. However, the parties are invited to provide the Court with any information on the French invalidity proceedings and the BoA proceedings without delay. The dates for the interim conference (17 July 2025) and the oral hearing (14-17 October 2025) are confirmed.

DETAILS OF THE ORDER

Order no. ORD_3577/2025 in ACTION NUMBER: ACT_16112/2024

UPC number: UPC_CFI_145/2024

Action type: Infringement Action

Order no. ORD_3580/2025 in ACTION NUMBER: ACT_16116/2024

UPC number: UPC_CFI_146/2024

Action type: Infringement Action

Order no. ORD_3582/2025 in ACTION NUMBER: ACT_16119/2024

UPC number: UPC_CFI_147/2024

Action type: Infringement Action

Order no. ORD_3586/2025 in ACTION NUMBER: ACT_16120/2024

UPC number: UPC_CFI_148/2024

Action type: Infringement Action

Matthias
ZIGANN

Digital unterschrieben
von Matthias ZIGANN
Datum: 2025.01.22
14:55:49 +01'00'

Dr. Zigann
Presiding Judge