Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Local Division Munich
UPC_CFI_145/2024 - UPC_CFI_463/2024
UPC_CFI_146/2024 - UPC_CFI_496/2024
UPC_CFI_147/2024 - UPC_CFI_374/2024
UPC_CFI_148/2024 - UPC_CFI_503/2024

Procedural Order

of the Court of First Instance of the Unified Patent Court
Local Division Munich
issued on 8 May 2025
(unredacted)

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 - UPC_CFI_463/2024

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 - UPC_CFI_496/2024

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

represented by: Daniel Hoppe (Bonabry).

DEFENDANTS – UPC_CFI_147/2024 - UPC_CFI_374/2024

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 - UPC_CFI_503/2024

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 Presiding Judge Dr. Matthias Zigann acting as judge-rapporteur.

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Patent infringement – various applications

APPLICATIONS BY THE PARTIES

Following the Rule 105.5-order by the judge-rapporteur dated 22 January 2025 Sanofi filed a brief dated 29 January 2025 and the defendants filed briefs dated 12 February 2025.

Sanofi requests:

In ACT_16112/2024 and CC_44999/2024 (Accord)

I. Dismiss all the requests of the Defendants

II. Dismiss the revocation counterclaim

III. Sanofi SA as successor for Sanofi Mature IP (the patentee) (Claimant 1) requests that

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Austria) (Defendant 2) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Austria, from, in the territory of the UPC Member State Austria,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare BV (Belgium) (Defendant 3) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Belgium, from, in the territory of the UPC Member State Belgium,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Germany) (Defendant 4) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Germany, from, in the territory of the UPC Member State Germany,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare Italia Srl (Italy) (Defendant 5) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Italy, from, in the territory of the UPC Member State Italy,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare B.V. (The Netherlands) (Defendant 6) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in The Netherlands, from, in the territory of the UPC Member State The Netherlands,

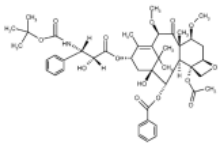
Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare, Unipessoal Lda. (Portugal) (Defendant 7) are ordered to cease and desist until European patent

No. 2 493 466 is irrevocably revoked or has expired in Portugal, from, in the territory of the UPC Member State Portugal,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare AB (Sweden) (Defendant 8) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Sweden, from, in the territory of the UPC Member State Sweden,

1. offering, placing on the market, using, importing or storing for those purposes a

    a. compound of formula

    which may be in base form or in the form of a hydrate or a solvate,

    in combination with prednisone or prednisolone,

    for use in treating prostate cancer,

    in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment;

    (direct infringement of claim 1)

    and/or

    b. compound for use according to III.1.a., where the prostate cancer is an advanced metastatic disease;

    (direct infringement of claim 2)

    and/or

    c. compound for use according to any one of claims III.1.a. to III.1.b. administered at a dose of between 15 and 25 mg/m2 , the prednisone or prednisolone being administered at a dose of 10 mg/day;

    (direct infringement of claim 5)

and/or

d. compound for use according to III.1.c. administered at a dose of 25 mg/m2 ;

(direct infringement of claim 6)

and/or

e. compound for use according to any one of III.1.a. to III.1.d, comprising repeating the administration of such compound as a new cycle every 3 weeks;

(direct infringement of claim 7)

and/or

f. compound for use according to any one of III.1.a. to III.1.e., in combination with prednisone;

(direct infringement of claim 8)

and/or

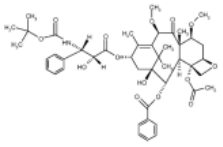
g. compound for use according to any one of III.1.a. to III.1.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(direct infringement of claim 9)

as auxiliary request

2. supplying or offering to supply in the aforementioned territory for use in the aforementioned territory

a. a compound of formula



which may be in base form or in the form of a hydrate or a solvate,

to be combined with prednisone or prednisolone,

for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment,

(indirect infringement of claim 1)

and/or

b. compound for use according to III.2.a., where the prostate cancer is an advanced metastatic disease;

(indirect infringement of claim 2)

and/or

c. compound for use according to any one of claims III.2.a. to III.2.b. administered at a dose of between 15 and 25 mg/m2 , the prednisone or prednisolone being administered at a dose of 10 mg/day;

(indirect infringement of claim 5)

and/or

d. compound for use according to III.2.c. administered at a dose of 25 mg/m2 ;

(indirect infringement of claim 6)

and/or

e. compound for use according to any one of III.2..a. to III.2.d, comprising repeating the administration of such compound as a new cycle every 3 weeks;

(indirect infringement of claim 7)

and/or

f. compound for use according to any one of III.2.a. to III.2.e., in combination with prednisone;

(indirect infringement of claim 8)

and/or

g. compound for use according to any one of III.2.a. to III.2.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(indirect infringement of claim 9)

IV. The patent has been infringed by

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Austria) (Defendant 2)'s sales of CABAZITAXEL ACCORD in Austria,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare BV (Belgium) (Defendant 3)'s sales of CABAZITAXEL ACCORD in Belgium,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Germany) (Defendant 4)'s sales of CABAZITAXEL ACCORD in Germany,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare Italia Srl (Italy) (Defendant 5)'s sales of CABAZITAXEL ACCORD in Italy,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare B.V. (The Netherlands) (Defendant 6)'s sales of CABAZITAXEL ACCORD in The Netherlands,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare, Unipessoal Lda. (Portugal) (Defendant 7)'s sales of CABAZITAXEL ACCORD in Portugal,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare AB (Sweden) (Defendant 8)'s sales of CABAZITAXEL ACCORD in Sweden.

V. Sanofi SA (Claimant 1) requests that the Defendants are ordered at their own expense to recall the products referred to above under clauses III.1 or III.2 from the channels of commerce in the respective countries as specified in formal request IV., to definitely remove the products from the channels of commerce in such country, and to destroy the products concerned from the territory above in clause III.

VI. The Defendants in clause III. are ordered to provide the Claimants in clause VIII. with information in writing and in electronic form on the extent to which each respective Defendant in clause III. has committed the acts described above under clauses III.1 or III.2 since 10 March 2021, stating

a) the origin and distribution channels of the infringing products;

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products;

c) the identity of any third person involved in the production or distribution of the infringing products or in the use of the infringing process.

VII. The Defendants in clause III. are ordered to provide the Claimants in clause VIII. with information in writing and in electronic form on the extent to which each respective Defendant has committed the acts described above under clauses III.1 or III.2 since 10 March 2021, stating

a) the individual deliveries, itemised according to delivery quantities, times and prices as well as type designations and the names and addresses of the customers;

b) the individual offers, itemised according to offer quantities, times, prices, type designation and the names and addresses of the commercial offerees;

c) the prime costs broken down by the individual cost factors and the profit realised.

VIII. It is hereby established that

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Austria) (Defendant 2) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis GmbH (Austria) (Claimant 3) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare BV (Belgium) (Defendant 3) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi Belgium (Claimant 4) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Germany) (Defendant 4) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 5) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare Italia Srl (Italy) (Defendant 5) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi S.r.l. (Claimant 6) for all damage that these Claimants have suffered and will suffer as a result of the acts

referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare B.V. (The Netherlands) (Defendant 6) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi B.V. (Claimant 7) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare, Unipessoal Lda. (Portugal) (Defendant 7) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi – Produtos Farmaceuticos Lda (Claimant 8) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare AB (Sweden) (Defendant 8) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi AB (Claimant 9) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021.

IX. As an interim award of damages,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Austria) (Defendant 2) are jointly and severally ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis GmbH (Claimant 3) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Austria.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare BV (Belgium) (Defendant 3) are jointly and severally ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi Belgium (Claimant 4) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Belgium.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Germany) (Defendant 4) are jointly and severally ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 5) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Germany.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare Italia Srl (Italy) (Defendant 5) are jointly and severally ordered to pay Sanofi SA (Claimant 1),

Sanofi Winthrop Industrie (Claimant 2), and Sanofi S.r.l. (Claimant 6) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Italy.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare B.V. (The Netherlands) (Defendant 6) are jointly and severally ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi B.V. (Claimant 7) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in The Netherlands.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare, Unipessoal Lda. (Portugal) (Defendant 7) are jointly and severally ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi – Produtos Farmaceuticos Lda (Claimant 8) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Portugal.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare AB (Sweden) (Defendant 8) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi AB (Claimant 9) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Sweden.

X. The Defendants are to bear the legal costs of proceedings and are jointly and severally liable for them, for the costs of the infringement claim (court costs and costs of representation by lawyers) to all Claimants with an interim amount of €144,000 and for the costs of the revocation counterclaim (court costs and costs of representation by lawyers) to Claimant 1 with an interim amount of €75,000.

XI. The above orders are immediately enforceable without security.

In ACT_16116/2024 and CC_48036/2024 (STADA)

I. Dismiss all the requests of the Defendants

II. Dismiss the revocation counterclaim

III. Sanofi SA as successor for Sanofi Mature IP (the patentee) (Claimant 1) requests that

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Denmark, from, in the territory of the UPC Member State Denmark,

STADAPHARM GmbH (Defendant 1) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Germany, from, in the territory of the UPC Member State Germany,

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Sweden, from, in the territory of the UPC Member State Sweden,

1. offering, placing on the market, using, importing or storing for those purposes […]

as auxiliary request

2. supplying or offering to supply in the aforementioned territory for use in the aforementioned territory […]

IV. The patent has been infringed by
STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3)'s sales of CABAZITAXEL STADA in Denmark,

STADAPHARM GmbH (Defendant 1)'s sales of CABAZITAXEL STADA in Germany,

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3)'s sales of CABAZITAXEL STADA in Sweden.

V. Sanofi SA (Claimant 1) requests that the Defendants are ordered at their own expense to recall the products referred to above under clauses III.1 or III.2 from the channels of commerce in the respective countries as specified in formal request IV., to definitely remove the products from the channels of commerce in such country, and to destroy the products concerned from the territory above in clause III.

VI. The Defendants in clause III. are ordered to provide the Claimants in clause VIII. with information in writing and in electronic form on the extent to which FRA01/30591670_3 23 each respective Defendant in clause III. has committed the acts described above under clauses III.1 or III.2 since 10 March 2021, stating

a) the origin and distribution channels of the infringing products;

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products;

c) the identity of any third person involved in the production or distribution of the infringing products or in the use of the infringing process.

VII. The Defendants in clause III. are ordered to provide the Claimants in clause VIII. with information in writing and in electronic form on the extent to which each respective Defendant has committed the acts described above under clauses III.1 or III.2 since 10 March 2021, stating

a) the individual deliveries, itemised according to delivery quantities, times and prices as well as type designations and the names and addresses of the customers;

b) the individual offers, itemised according to offer quantities, times, prices, type designation and the names and addresses of the commercial offerees;

c) the prime costs broken down by the individual cost factors and the profit realised.

VIII. It is hereby established that

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi A/S (Claimant 11) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021,

STADAPHARM GmbH (Defendant 1) are liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 6) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021,

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi AB (Claimant 10) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021.

IX. As an interim award of damages

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are jointly and severally ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi A/S (Claimant 11) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Denmark.

STADAPHARM GmbH (Defendant 1) is ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 6) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Germany.

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are jointly and severally ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi AB (Claimant 10) the amount of € --- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Sweden.

X. The Defendants are to bear the legal costs of proceedings and are jointly and severally liable for them, for the costs of the infringement claim (court costs and costs of representation by lawyers) to all Claimants with an interim amount of €336,000 and for the costs of the revocation counterclaim (court costs and costs of representation by lawyers) to Claimant 1 with an interim amount of €75,000.

XI. The above orders are immediately enforceable without security.

In ACT_16119/2024 and CC_39391/2024 (Reddy)

I. Dismiss all the requests of the Defendants

II. Dismiss the revocation counterclaim

III. Sanofi SA as successor for Sanofi Mature IP (the patentee) (Claimant 1) requests that

Reddy Pharma SAS (Defendant 1) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in France, from, in the territory of the UPC Member State France

betapharm Arzneimittel GmbH (Defendant 2) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Germany, from, in the territory of the UPC Member State Germany

Dr Reddy's Srl (Defendant 3) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Italy, from, in the territory of the UPC Member State Italy

1. offering, placing on the market, using, importing or storing for those purposes […]

as auxiliary request

2. supplying or offering to supply in the aforementioned territory for use in the aforementioned territory […]

IV. The patent has been infringed by Reddy Pharma SAS (Defendant 1)'s sales of CABAZITAXEL REDDY PHARMA in France,

betapharm Arzneimittel GmbH (Defendant 2)'s sales of CABAZITAXEL BETA in Germany,

Dr Reddy's Srl (Defendant 3)'s sales of CABAZITAXEL DR. REDDY'S in Italy.

V. Sanofi SA (Claimant 1) requests that the Defendants are ordered at their own expense to recall the products referred to above under clauses III.1 or III.2 from the channels of commerce in the respective countries as specified in formal request IV., to definitely remove the products from the channels of commerce in such country, and to destroy the products concerned from the territory above in clause III.

VI. The Defendants in clause III. are ordered to provide the Claimants in clause VIII. with information in writing and in electronic form on the extent to which each respective Defendant in clause III. has committed the acts described above under clauses III.1 or III.2 since 10 March 2021, stating

a) the origin and distribution channels of the infringing products;

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products;

c) the identity of any third person involved in the production or distribution of the infringing products or in the use of the infringing process.

VII. The Defendants in clause III. are ordered to provide the Claimants in clause VIII. with information in writing and in electronic form on the extent to which each respective Defendant has committed the acts described above under clauses III.1 or III.2 since 10 March 2021, stating

a) the individual deliveries, itemised according to delivery quantities, times and prices as well as type designations and the names and addresses of the customers;

b) the individual offers, itemised according to offer quantities, times, prices, type designation and the names and addresses of the commercial offerees;

c) the prime costs broken down by the individual cost factors and the profit realised.

VIII. It is hereby established that

Reddy Pharma SAS (Defendant 1) are liable to compensate Sanofi SA (Claimant 1) and Sanofi Winthrop Industrie (Claimants 2 and 3) for all damage that these

Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021.

betapharm Arzneimittel GmbH (Defendant 2) are liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and SanofiAventis Deutschland GmbH (Claimant 6) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021.

Dr Reddy's Srl (Defendant 3) are liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi S.r.l. (Claimant 7) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021.

IX. As an interim award of damages

Reddy Pharma SAS (Defendant 1) is ordered to pay Sanofi SA (Claimant 1) and Sanofi Winthrop Industrie (Claimants 2 and 3) the amount of € --- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in France.

betapharm Arzneimittel GmbH (Defendant 2) is ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 6) the amount of € --- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Germany.

Dr Reddy's Srl (Defendant 3) is ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi S.r.l. (Claimant 7) the amount of € --- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Italy.

X. The Defendants are to bear the legal costs of proceedings and are jointly and severally liable for them, for the costs of the infringement claim (court costs and costs of representation by lawyers) to all Claimants with an interim amount of €186,000 and for the costs of the revocation counterclaim (court costs and costs of representation by lawyers) to Claimant 1 with an interim amount of €75,000.

XI. The above orders are immediately enforceable without security.

In ACT_16120/2024 and CC_49716/2024 (Zentiva)

I. Dismiss all the requests of the Defendants

II. Dismiss the revocation counterclaim

III. Sanofi SA as successor for Sanofi Mature IP (the patentee) (Claimant 1) requests that

Zentiva France (Defendant 1) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in France, from, in the territory of the UPC Member State France

Zentiva Pharma GmbH (Defendant 2) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Germany, from, in the territory of the UPC Member State Germany

1. offering, placing on the market, using, importing or storing for those purposes […]

as auxiliary request

2. supplying or offering to supply in the aforementioned territory for use in the aforementioned territory […]

IV. The patent has been infringed by

Zentiva France (Defendant 1)'s sales of CABAZITAXEL ZENTIVA in France,

Zentiva Pharma GmbH (Defendant 2)'s sales of CABAZITAXEL ZENTIVA in Germany.

V. Sanofi SA (Claimant 1) requests that the Defendants are ordered at their own expense to recall the products referred to above under clauses III.1 or III.2 from the channels of commerce in the respective countries as specified in formal request IV., to definitely remove the products from the channels of commerce in such country, and to destroy the products concerned from the territory above in clause III.

VI. The Defendants in clause III. are ordered to provide the Claimants in clause VIII. with information in writing and in electronic form on the extent to which each respective Defendant in clause III. has committed the acts described above under clauses III.1 or III.2 since 10 March 2021, stating

a) the origin and distribution channels of the infringing products;

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products;

c) the identity of any third person involved in the production or distribution of the infringing products or in the use of the infringing process.

VII. The Defendants in clause III. are ordered to provide the Claimants in clause VIII. with information in writing and in electronic form on the extent to which each respective Defendant has committed the acts described above under clauses III.1 or III.2 since 10 March 2021, stating

a) the individual deliveries, itemised according to delivery quantities, times and prices as well as type designations and the names and addresses of the customers;

b) the individual offers, itemised according to offer quantities, times, prices, type designation and the names and addresses of the commercial offerees;
c) the prime costs broken down by the individual cost factors and the profit realised.

VIII. It is hereby established that

Zentiva France (Defendant 1) are liable to compensate Sanofi SA (Claimant 1) and Sanofi Winthrop Industrie (Claimants 2 and 3) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021.

Zentiva Pharma GmbH (Defendant 2) are liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 6) for all damage that these Claimants have FRA01/30591670_3 34 suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) committed since 10 March 2021.

IX. As an interim award of damages

Zentiva France (Defendant 1) is ordered to pay Sanofi SA (Claimant 1) and Sanofi Winthrop Industrie (Claimants 2 and 3) the amount of € --- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in France.

Zentiva Pharma GmbH (Defendant 2) is ordered to pay Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 6) the amount of €--- for the acts referred to in III.1 (as an auxiliary request in III.2) committed in Germany.

X. The Defendants are to bear the legal costs of proceedings and are jointly and severally liable for them, for the costs of the infringement claim (court costs and

costs of representation by lawyers) to all Claimants with an interim amount of €186,000 and for the costs of the revocation counterclaim (court costs and costs of representation by lawyers) to Claimant 1 with an interim amount of €75,000.

XI. The above orders are immediately enforceable without security.

Accord requests in ORD_3577/2025 UPC_CFI_145/2024:

A. Dismiss the Claimants' application for leave to amend their claims entirely;

B. In the alternative, dismiss the Claimants' application for leave to amend their claims in so far as Claimants' requests III.2, IV, V, VI, VII, VIII, IX, X and XI are concerned;

C. Order that the new infringement arguments developed by the Claimants in their Comments on the Application to Amend Requests under Rule 263 RoP of 29 January 2025 are disregarded;

D. Order that the Defendants have satisfied the request to separate the costs for the infringement action and for the counterclaim for revocation and grant leave for amended requests as set out in Section 8.

Accord requests in relation to workflow 38125/2024

Dismiss the action and all claims brought by Claimants 1 to 10 in their entirety under Rule 19 RoP.

Accord requests in relation to workflow 38125/2024

A. Dismiss the action and all claims brought by Claimants 1 to 10, due to 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

B. Dismiss the action and all claims brought by the Claimants 2 to 10 due to a lack of standing.

Accord requests in relation to the action ACT_16112/2024 and the counterclaim CC_44999/2024:

1. Dismiss the action and all of the claims brought by the Claimants 1 to 10;

2. Order the revocation of all claims of European patent EP 2 493 466 for all its national designations which are UPC Contracting Member States, namely: Austria, Belgium, Germany, Denmark, France, Italy, Malta, the Netherlands, Portugal and Sweden;

~~In the alternative, should the Court dismiss the Defendants' Preliminary Objection for lack of jurisdiction and issue an injunction and the other orders sought by the Claimants covering~~

~~"national designations of States in which the UPCA shall enter into force", order the revocation of all claims of European patent EP 2 493 466 B1 for all its national designations, namely: Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, Greece, Italy, Liechtenstein, Malta, the Netherlands, Poland, Portugal and Sweden;~~

3. Order the Registry to send a copy of the decision to the European Patent Office and to each of the relevant national patent offices;

In the alternative, should the Court decide to grant any of the orders sought by the Claimants 1 to 10

4. Order that any such orders

(i) shall not have immediate effect pending appeal and

(ii) shall be under the condition subsequent that

> (x) the European Patent Office does not hold European patent EP 2 493 466 to be wholly or partially invalid and
>
> (y) the Unified Patent Court or any national court (or other competent national body) in the territory covered by the order(s) does not hold European patent EP 2 493 466 to be wholly or partially invalid and/or does not dismiss a request for an injunction in a parallel case against a generic cabazitaxel product sought on the basis of European patent EP 2 493 466, in a final or appealable decision;

5. And, should the Court decide to grant the orders sought by the Claimants 1 to 10 under Article 67 UPCA, order that the information must be communicated under appropriate confidentiality restrictions pursuant to Rules 262A, 191 and 190(1) RoP;

And in any event

6. Order that Claimants 1 to 10 shall jointly bear the costs of the ~~proceedings in both the~~ infringement action ~~and the counterclaim for revocation~~;

7. Order Claimants 1 to 10 to jointly pay Defendants 1 to 8 the amount of 150,000 euros as an interim award of cost <u>for the infringement</u> action, with penalty payments of 10,000 euros per day payable to the Court in the event that they fail to comply with such order within 15 days of the date of service of this decision;

<u>8. Order that Claimant 1 shall bear the costs of the counterclaim for revocation;</u>

9. <u>Order Claimant 1 to pay Defendants 1 to 8 the amount of 100,000 euros as an interim award of costs for the counterclaim for revocation</u>, with penalty payments of 10,000 euros per day payable to the Court in the event that it fails to comply with such order within 15 days of the date of service of this decision.

STADA requests in ORD_3580/2025 UPC_CFI_146/2024:

Declare the proceedings closed with regards to the Claimants Sanofi Belgium, Sanofi S.r.l., Sanofi B.V., Sanofi - Produtos Farmaceuticos Lda, SanofiAventis France and Sanofi-Aventis GmbH and, insofar, order these Claimants to bear the costs of the proceedings;

Declare the proceedings closed with regards to the request mentioned under mn. 6 as far as they have been withdrawn and, insofar, order the remaining Claimants to bear the cost of the proceedings;

Dismiss the Claimants' application for leave to amend their claims;

In the alternative:

Dismiss the Claimants' application for leave to amend their claims as far as they are based on the allegation of indirect infringement;

Dismiss the Claimants' application for leave to amend their claims as far as a second request for information is made;

Dismiss the Claimants' application for leave to amend their claims as far as a finding of liability for damages is sought;

Dismiss the Claimants' application for leave to amend their claims as far as an interim damages award is sought.

Reddy requests in ORD_3582/2025 UPC_CFI_147/2024 with regard to the infringement action ACT_16119/2024:

1. To dismiss the Claimants' requests to rule that their amended requests comply with Art. 76 UPCA and Rule 263 RoP as inadmissible and procedurally unjustified.

2. To dismiss all requests by the Claimants as inadmissible and/or unfounded, namely the request

> a. To order a cease and desist declaration pursuant to Amended Request no. III.1 (direct infringement) or no. III.2 (indirect infringement);
>
> b. To issue a decision that the patent has been infringed by the Defendants pursuant to Amended Request no. IV.;
>
> c. To order the Defendants to recall, remove and destroy the products pursuant to Amended Request no. V.;

d. To order the Defendants to provide the information pursuant to the Amended Requests no. VI. and VII.;

e. To establish that the Defendants are liable to compensate certain Claimants for damages pursuant to Amended Request no. VIII.;

f. To order interim awards of damages pursuant to the Amended Request no. IX.;

g. To order the Defendants to bear the legal costs of the proceedings and to pay interim amounts pursuant to Amended Request no. X.

3. To order the Claimants to bear the legal costs of the proceedings (Infringement Action).

4. To make the enforcement of the decision subject to the prior provision of a security by the Claimants of at least EUR 3,000,000, corresponding to the Defendants legal costs and expenses as well as compensation for any damage incurred or likely to be incurred by the other party if the decisions and orders are enforced and subsequently be revoked (Rules 352.1, 354.2 RoP), which can be provided by a written, irrevocable, unconditional and unlimited guarantee from a credit institution authorized to do business in the territory of a member state of the UPC.

5. To permit the Defendants to avert enforcement of the decision by providing security, which can be made by way of a written, irrevocable, unconditional, and indefinite guarantee of a financial institution in the territory of a member state of the UPC authorized to conduct business in the territory of a member state of the UPC,
irrespective of a provision of security by the Claimants (Rule 9.1 RoP).

Reddy request in ORD_3582/2025 UPC_CFI_147/2024 with regard to the counterclaim CC_39391/2024:

6. To revoke EP 2 493 466 with effect for all UPC Contracting Member States in which the patent has effect, namely: Austria, Belgium, Germany, Denmark, France, Italy, the Netherlands, Portugal and Sweden.

7. To order the Defendant of the Counterclaim for Revocation (Sanofi SA) to bear the legal costs of the proceedings (Counterclaim for Revocation).

8. (#39) Sanofi shall bear the costs of the partial withdrawal of its claims in respect of Claimants 3, 5, 8, 9, 10 and 11. The Defendants hereby consent to the withdrawal. The Court is asked to give a decision closing the proceedings in respect of these entities and to make an order as to costs.

9. (#47) These significant amendments of the request for injunctive relief should be dismissed as being belated. At the very least, as stated above, Sanofi should bear the costs of the partial withdrawal/limitation of its requests.

10. (#104) The Defendants request the Court to dismiss Sanofi's claims for interim damages as premature and to require Sanofi to provide extensive financial evidence before any decision on damages can be made.

Reddy provides clarification as to the counterclaim CC_39391/2024:

1. To revoke EP 2 493 466 with effect for all UPC Contracting Member States in which the patent has effect, namely: Austria, Belgium, Germany, Denmark, France, Italy, the Netherlands, Portugal and Sweden.

2. To order the Defendant of the Counterclaim for Revocation (Sanofi SA) to bear the legal costs of the proceedings (Counterclaim for Revocation).

Zentiva requests in ORD_3586/2025 and App_7356/2025 UPC_CFI_148/2024:

A. In reply to Claimants' comments and (potential) application under R. 263 RoP:

I. the dismissal of the request of the Claimants under R. 263 RoP.

II. the dismissal and disregard of the facts, evidence, arguments and requests filed by Claimants in violation of R. 263 RoP in the Claimants' Statement of Claim dated May 14, 2024, the Claimants' Reply to the Statement of Defence dated November 1, 2024, and the Claimants' Comments dated January 29, 2025.

III. the Claimants to jointly and severally bear Court fees, costs and other expenses incurred by Defendants and in favor of the Defendants as joint and several creditors with regard to the proceedings under R. 263 RoP, whereby these Court fees and costs shall not be subject to any ceilings of recoverable costs in accordance with the regulations and guidelines of the UPC.

B. In reply to Claimants' amendment under Art. 76 UPCA:

I. the dismissal and disregard of the facts, evidence, arguments and requests filed by Claimants in violation of Art. 76 UPCA in the Claimants' Statement of Claim dated May 14, 2024, the Claimants' Reply to the Statement of Defence dated November 1, 2024, and the Claimants' Comments dated January 29, 2025.

II. the Claimants to jointly and severally bear Court fees, costs and other expenses incurred by Defendants and in favor of the Defendants as joint and several creditors with regard to the proceedings under Art. 76 UPCA, whereby these Court fees and costs shall not be subject to any ceilings of recoverable costs in accordance with the regulations and guidelines of the UPC.

C. In Defendants' application under R. 263 RoP (amendments highlighted in red):

In the Counterclaim for revocation:

I. to grant the request of the Defendants under R. 263 RoP to amend request III. of Defendants' Counterclaim for revocation of September 2, 2024 as follows:

> Claimant 1. ~~Claimants~~ to ~~jointly and severally~~ bear reasonable and proportionate costs and other expenses incurred by Defendants and in favor of the Defendants as joint and several creditors in these proceedings and order, insofar such costs are to be determined in separate proceedings for the determination of such costs, that Claimant 1. ~~Claimants jointly and severally~~ pays to the Defendants as joint and several creditors by means of an interim award of costs an amount of EUR 100,000.00 within 14 days after service of the judgment in this matter (Art. 69 UPCA, R. 118.5, 150.2 RoP);

II. Claimant 1. to bear Court fees, costs and other expenses incurred by Defendants and in favor of the Defendants as joint and several creditors with regard to the proceedings under R. 263 RoP.

In the Infringement action:

III. to grant the request of the Defendants under R. 263 RoP to amend request II. of Defendants' Statement of Defence of September 2, 2024, in the Infringement action of as follows:

> Claimants to jointly and severally bear
>
> 1. reasonable and proportionate costs and other expenses incurred by Defendants and in favor of the Defendants as joint and several creditors in these proceedings and order, insofar such costs are to be determined in separate proceedings for the determination of such costs, that the Claimants jointly and severally pay to the Defendants as joint and several creditors by means of an interim award of costs an amount of EUR 100,000.00 within 14 days after service of the judgment in this matter (Art. 69 UPCA, R. 118.5, 150.2 RoP);
>
> 2. Court fees, costs and other expenses incurred by Defendants and in favor of the Defendants as joint and several creditors with regard to the following workstreams:
>
> • Preliminary Objection (initiated by App 39370/2024, maintained by ORD 3586/2025)
> • Change of parties (initiated by App 54979/2024, replaced by ORD 610/2025)
> • Protection of confidential information (initiated by App 57840/2024, replaced by ORD 59838/2024)
> • Extension of deadline (initiated by App 65226/2024, replaced by ORD 67267/2024)

• Application to amend requests (initiated by App_57845/2024)
• Change of parties (initiated by App_1193/2025, replaced by ORD_2039/2025) February 12, 2025 Page 7
• Change of parties (initiated by App_1197/2025, replaced by ORD_2040/2025)
• Application to amend requests (announced in response to ORD_3586/2025, not initiated yet)

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

With order dated 27 February 2025 the judge-rapporteur gave some further guidance and invited the parties to submit further observations:

"Sanofi did not quite manage to remedy the formal shortcomings set out in the 105.5 order. Therefore, another round of comments is necessary. It should also be noted that some of the defendants amended their respective formal pleadings. This necessitates granting Sanofi the right to be heard.

To provide guidance to the parties and to streamline the forthcoming rounds of written submissions, the Judge-Rapporteur informs the parties as follows:

1. If the changes made by both parties fall under Rules 263 and/or 265 of the RoP, a dedicated workflow should have been used. However, in view of the order of the Judge-Rapporteur inviting both parties to remedy formal deficiencies, no blame can be laid at the parties' door, and the amendments will therefore be deemed to have been duly lodged.

2. The introduction of claims relating to indirect infringement does not seem to fall under Rule 263 RoP as it involves the same patent, the same attacked embodiment and the same patent claims. Reference is made to UPC_CoA_456/2024 APL_44633/2024 and App_53768/2024 UPC_CFI_114/2024.

3. The introduction of a request for an interim award of damages and costs might be allowable given the special circumstances of this case. Some of the defendants also filed amendments to their respective formal pleadings.

4. Corrections of deficiencies made after the court has invited the party concerned to do so under Rule 9.1 RoP can never be too late. Such corrections are not covered by Rule 16 RoP. That provision relates to deficiencies which the Sub-Registry is able to identify. The deficiencies which are the subject of the Rule 105.5-order go beyond that.

5. Rule 9.1 RoP vests the court with the power to grant more than one round to remedy deficiencies. A reason for granting another round might be that the party concerned has tried hard to remedy the situation in the first attempt, but has still accidentally failed to do so completely. This seems to be the case here:

    a. In no. IV (the patent has been infringed) it is unclear who the claimant is, what claims of the patent are addressed (all claims or just a subset?) and if it is a direct or indirect infringement.

b. In no. V (recall) the reference to "product referred to above under clauses III.1 or III.2" is unclear as clauses III.1 or III.2 do not mention a product but refer to acts of infringement described by using the claim language.
c. In no. VI and VII (information) it is unclear if all claimants ask for information or only the respective claimants. Further it is unclear what the "or" in "clauses III.1 or III.2" means as a reference to the auxiliary character is missing. In VI.c) it is unclear what "infringing process" means. Until now a direct or indirect infringement of a product claim was subject of the proceedings.
d. In no. VIII (declaration) the territory is missing. Further it is unclear which claimants ask for this finding. Are the claimants mentioned asking for this finding?
e. Amended Request no. IX. fails to clarify whether the Claimants referenced in this request shall be entitled as joint or as separate creditors. Besides that, it is incomprehensible why a plurality of Claimants should be entitled to one interim award: According to the Exhibits filed by Sanofi, Sanofi claims separate lost profits for each Sanofi entity. However, Amended Request no. IX, para. 1 now (e.g.) claims a payment to Claimants without differentiating between the alleged lost profits of each of said Claimants.
f. A combination of a declaration and an order to pay as formulated in no. X is unfortunate. Further it is unclear if "all Claimants" refers to all claimants as listed in the statement of claim or just the claimants mentioned in the latest version of the formal pleadings.
g. Sanofi will also have to rectify the deficiencies laid out in Zentiva's statement e.g. at mn. 92.

6. As far as the requests by the defendants are concerned the following observations are to be made:

a. Accord:

A penalty payment in the case an interim cost award is not paid in time amounts to interest to be paid to the court. As interest to be paid to the creditor is not owned a penalty payment might be the only remedy to encourage payment in time. However, the amount should be reasonable. A penalty payment of 10.000 € per day for 100.000 € owed would amount to an annual interest rate of 3650 percent.

b. STADA and Reddy

At present, the judge-rapporteur does not consider there to be sufficient benefit in declaring the proceedings closed with regard to the claimants not mentioned in the latest set of formal pleadings. On the contrary, it would be extremely burdensome to make a partial cost decision.

7. The correction of formal deficiencies in the pleadings does not affect the substance of the case. However, the following observations are prompted by the discussion between the parties.

a. Without assignment agreements, which can bundle all claims for damages in one person, each of the Claimants can only seek damages for the harm suffered personally in its respective role as patent owner, exclusive licensee and non-exclusive licensee.

Therefore, it is insufficient to calculate an ask for a single amount of damages. Furthermore, these individual damages must be attributable to specific acts of infringement, in the sense that they relate to a specific act in a specific territory at a specific time.

b. If less than actual damages are claimed, the difference must be attributed to specific acts of infringement as explained above. It is not permissible to make a general deduction based on an arbitrary quotation.
c. These statements must be made in writing in the pleadings and for each and every claimant, territory, time interval and defendant. It is not permissible to provide the Court with an algorithm and instructions or an example for self-calculation.
d. This is also the case when calculating an interim award of damages.
e. For an interim award of costs, these costs must be explained if the other party disputes the amount.
f. Dismissal of the other claimants' action for lack of standing is unlikely as the patentee has joined the action from the outset.
g. The preliminary objections might be dealt with in the main proceedings (Rule 20.2. RoP).
h. The applications pursuant to Rules 334.h, 361, 363 RoP might be dealt with in the main proceedings.

8. Parties are again encouraged to inform the court of any developments at the EPO`s BoA."

In reaction parties filed further briefs and requests.

Sanofi now requests in ORD_10064/2025 UPC_CFI_145/2024 (Accord)

I. Dismiss all the requests of the Defendants

II. Dismiss the revocation counterclaim

III. Sanofi SA as successor for Sanofi Mature IP (the patentee) (Claimant 1) requests that

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Austria) (Defendant 2) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Austria, from, in the territory of the UPC Member State Austria,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare BV (Belgium) (Defendant 3) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Belgium, from, in the territory of the UPC Member State Belgium,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Germany) (Defendant 4) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Germany, from, in the territory of the UPC Member State Germany,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare Italia Srl (Italy) (Defendant 5) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Italy, from, in the territory of the UPC Member State Italy,

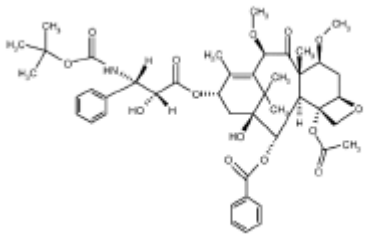
Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare B.V. (The Netherlands) (Defendant 6) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in The Netherlands, from, in the territory of the UPC Member State The Netherlands,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare, Unipessoal Lda. (Portugal) (Defendant 7) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Portugal, from, in the territory of the UPC Member State Portugal,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare AB (Sweden) (Defendant 8) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Sweden, from, in the territory of the UPC Member State Sweden,

1. offering, placing on the market, using, importing or storing for those purposes a

a. compound of formula



which may be in base form or in the form of a hydrate or a solvate,
in combination with prednisone or prednisolone,
for use in treating prostate cancer,
in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment;

(direct infringement of claim 1)

and/or

b. compound for use according to III.1.a., where the prostate cancer is an advanced metastatic disease;

(direct infringement of claim 2)

and/or

c. compound for use according to any one of claims III.1.a. to III.1.b. administered at a dose of between 15 and 25 mg/m2, the prednisone or prednisolone being administered at a dose of 10 mg/day;

(direct infringement of claim 5)

and/or

d. compound for use according to III.1.c. administered at a dose of 25 mg/m2;

(direct infringement of claim 6)

and/or

e. compound for use according to any one of III.1.a. to III.1.d, comprising repeating the administration of such compound as a new cycle every 3 weeks;

(direct infringement of claim 7)

and/or

f. compound for use according to any one of III.1.a. to III.1.e., in combination with prednisone;

(direct infringement of claim 8)

and/or

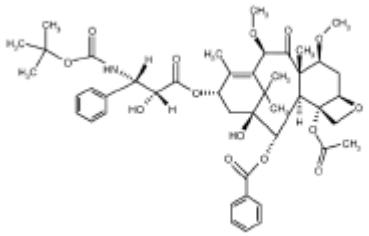
g. compound for use according to any one of III.1.a. to III.1.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(direct infringement of claim 9)

as auxiliary request

2. supplying or offering to supply in the aforementioned territory for use in the aforementioned territory

a. a compound of formula



which may be in base form or in the form of a hydrate or a solvate,
to be combined with prednisone or prednisolone,
for use in treating prostate cancer,
in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment,

(indirect infringement of claim 1)

and/or

b. compound for use according to III.2.a., where the prostate cancer is an advanced metastatic disease;

(indirect infringement of claim 2)

and/or

c. compound for use according to any one of claims III.2.a. to III.2.b. administered at a dose of between 15 and 25 mg/m2, the prednisone or prednisolone being administered at a dose of 10 mg/day;

(indirect infringement of claim 5)

and/or

d. compound for use according to III.2.c. administered at a dose of 25 mg/m2;

(indirect infringement of claim 6)

and/or
e. compound for use according to any one of III.2..a. to III.2.d, comprising repeating the administration of such compound as a new cycle every 3 weeks;

(indirect infringement of claim 7)

and/or
f. compound for use according to any one of III.2.a. to III.2.e., in combination with prednisone;

(indirect infringement of claim 8)

and/or

g. compound for use according to any one of III.2.a. to III.2.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(indirect infringement of claim 9)

IV. With respect to the acts described above under clauses III.1 and auxiliary request III.2, the rights conferred respectively by the Austrian, Belgian, German, Italian, Dutch, Portuguese, and Swedish national designations of European patent No. 2 493 466 to

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis GmbH (Claimant 3) with respect to Austria,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi Belgium (Claimant 4) with respect to Belgium,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 5) with respect to Germany,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi S.r.l. (Claimant 6) with respect to Italy,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi B.V. (Claimant 7) with respect to The Netherlands,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi – Produtos Farmaceuticos Lda (Claimant 8) with respect to Portugal,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi AB (Claimant 9) with respect to Sweden,

Have been infringed by

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Austria) (Defendant 2)'s sales of CABAZITAXEL ACCORD in Austria,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare BV (Belgium) (Defendant 3)'s sales of CABAZITAXEL ACCORD in Belgium,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Germany) (Defendant 4)'s sales of CABAZITAXEL ACCORD in Germany,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare Italia Srl (Italy) (Defendant 5)'s sales of CABAZITAXEL ACCORD in Italy,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare B.V. (The Netherlands) (Defendant 6)'s sales of CABAZITAXEL ACCORD in The Netherlands,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare, Unipessoal Lda. (Portugal) (Defendant 7)'s sales of CABAZITAXEL ACCORD in Portugal,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare AB (Sweden) (Defendant 8)'s sales of CABAZITAXEL ACCORD in Sweden.

V. Sanofi SA (Claimant 1) requests that the Defendants are ordered at their own expense to recall the products CABAZITAXEL ACCORD referred to above under clause IV. from the channels of commerce in the respective countries as specified in formal request IV., to definitely remove the products CABAZITAXEL ACCORD from the channels of commerce in such country, and to destroy the products CABAZITAXEL ACCORD present in such country.

VI. The respective claimants under formal request IV. request that the respective defendants in formal request IV. are ordered to provide the respective claimants under formal request IV. with information in writing and in electronic form on the extent to which each of these respective defendants has committed the acts described above under clauses III.1 and auxiliary request III.2 since 10 March 2021, stating:

a) the origin and distribution channels of the infringing products;

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products;

c) the identity of any third person involved in the production or distribution of the infringing products referred to in formal request IV.

VII. The respective claimants under formal request IV. request that the respective defendants in formal request IV. are ordered to provide the respective claimants under formal request IV. with information in writing and in electronic form on the extent to which each of these respective defendants has committed the acts described above under clauses III.1 and auxiliary request III.2 since 10 March 2021, stating

a) the individual deliveries, itemised according to delivery quantities, times and prices as well as type designations and the names and addresses of the customers;

b) the individual offers, itemised according to offer quantities, times, prices, type designation and the names and addresses of the commercial offerees;

c) the prime costs broken down by the individual cost factors and the profit realised.

VIII. The respective claimants with respect to the respective territories request an order that:

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Austria) (Defendant 2) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis GmbH (Austria) (Claimant 3) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Austria since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare BV (Belgium) (Defendant 3) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi Belgium (Claimant 4) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Belgium since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Germany) (Defendant 4) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 5) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Germany since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare Italia Srl (Italy) (Defendant 5) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi S.r.l. (Claimant 6) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Italy since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare B.V. (The Netherlands) (Defendant 6) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi B.V. (Claimant 7) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Netherlands since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare, Unipessoal Lda. (Portugal) (Defendant 7) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi – Produtos Farmaceuticos Lda (Claimant 8) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Portugal since 10 March 2021,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare AB (Sweden) (Defendant 8) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi AB (Claimant 9) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Sweden since 10 March 2021.

IX. As an interim award of damages with respect to the products referred to in IV.,

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Austria) (Defendant 2) are jointly and severally ordered to pay separately to Sanofi SA (Claimant 1) the amount of €--- and Sanofi Winthrop Industrie (Claimant 2) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Austria since 10 March 2021.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare BV (Belgium) (Defendant 3) are jointly and severally ordered to pay separately to Sanofi SA (Claimant 1) the amount of €--- and Sanofi Winthrop Industrie (Claimant 2) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Belgium since 10 March 2021.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare GmbH (Germany) (Defendant 4) are jointly and severally ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, Sanofi Winthrop Industrie (Claimant 2) the amount of €---, and Sanofi-Aventis Deutschland GmbH (Claimant 5) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Germany since 10 March 2021.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare Italia Srl (Italy) (Defendant 5) are jointly and severally ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, Sanofi Winthrop Industrie (Claimant 2) the amount of €---, and Sanofi S.r.l. (Claimant 6) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Italy since 10 March 2021.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare B.V. (The Netherlands) (Defendant 6) are jointly and severally ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, Sanofi Winthrop Industrie (Claimant 2) the amount of €---, and Sanofi B.V. (Claimant 7) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in The Netherlands since 10 March 2021.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare, Unipessoal Lda. (Portugal) (Defendant 7) are jointly and severally ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, Sanofi Winthrop Industrie (Claimant 2) the amount of €---, and Sanofi – Produtos Farmaceuticos Lda (Claimant 8) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Portugal since 10 March 2021.

Accord Healthcare S.L.U. (Defendant 1) and Accord Healthcare AB (Sweden) (Defendant 8) are jointly and severally ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, Sanofi Winthrop Industrie (Claimant 2) the amount of €---, and Sanofi AB (Claimant 9) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Sweden since 10 March 2021.
committed in Austria since 10 March 2021.

X. All Defendants are jointly and severally ordered to pay the costs of the infringement claim (court costs and costs of representation by lawyers) to all Claimants 1 to 10 with an interim amount of €144,000 and for the costs of the revocation counterclaim (court costs and costs of representation by lawyers) to Claimant 1 with an interim amount of €75,000.

XI. The above orders are immediately enforceable without security.

Sanofi now requests in ORD_10065/2025 UPC_CFI_146/2024 (STADA)

I. Dismiss all the requests of the Defendants

II. Dismiss the revocation counterclaim

III. Sanofi SA as successor for Sanofi Mature IP (the patentee) (Claimant 1) requests that

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Denmark, from, in the territory of the UPC Member State Denmark,

STADAPHARM GmbH (Defendant 1) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Germany, from, in the territory of the UPC Member State Germany,

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Sweden, from, in the territory of the UPC Member State Sweden,

1. offering, placing on the market, using, importing or storing for those purposes a

a. compound of formula […]

which may be in base form or in the form of a hydrate or a solvate, in combination with prednisone or prednisolone, for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment;

(direct infringement of claim 1)

and/or

b. compound for use according to III.1.a., where the prostate cancer is an advanced metastatic disease;

(direct infringement of claim 2)

and/or

c. compound for use according to any one of claims III.1.a. to III.1.b. administered at a dose of between 15 and 25 mg/m2 , the prednisone or prednisolone being administered at a dose of 10 mg/day; (direct infringement of claim 5) and/or d. compound for use according to III.1.c. administered at a dose of 25 mg/m2 ;

(direct infringement of claim 6)

and/or
e. compound for use according to any one of III.1.a. to III.1.d, comprising repeating the administration of such compound as a new cycle every 3 weeks; (direct infringement of claim 7) and/or f. compound for use according to any one of III.1.a. to III.1.e., in combination with prednisone;

(direct infringement of claim 8)

and/or

g. compound for use according to any one of III.1.a. to III.1.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(direct infringement of claim 9)

as auxiliary request

2. supplying or offering to supply in the aforementioned territory for use in the aforementioned territory

a. a compound of formula […]

which may be in base form or in the form of a hydrate or a solvate, to be combined with prednisone or prednisolone, for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment,

(indirect infringement of claim 1)

and/or

b. compound for use according to III.2.a., where the prostate cancer is an advanced metastatic disease;

(indirect infringement of claim 2)

and/or

c. compound for use according to any one of claims III.2.a. to III.2.b. administered at a dose of between 15 and 25 mg/m2 , the prednisone or prednisolone being administered at a dose of 10 mg/day;

(indirect infringement of claim 5)

and/or

d. compound for use according to III.2.c. administered at a dose of 25 mg/m2 ; (indirect infringement of claim 6) and/or e. compound for use according to any one of III.2..a. to III.2.d, comprising repeating the administration of such compound as a new cycle every 3 weeks;
(indirect infringement of claim 7)

and/or

f. compound for use according to any one of III.2.a. to III.2.e., in combination with prednisone;

(indirect infringement of claim 8)

and/or

g. compound for use according to any one of III.2.a. to III.2.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(indirect infringement of claim 9)

IV. With respect to the acts described above under clauses III.1 and auxiliary request III.2, the rights conferred respectively by the Danish, German, and Swedish national designations of European patent No. 2 493 466 to

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi A/S (Claimant 11) with respect to Denmark,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 6) with respect to Germany,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi AB (Claimant 10) with respect to Sweden,

Have been infringed by STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3)'s sales of CABAZITAXEL STADA in Denmark,

STADAPHARM GmbH (Defendant 1)'s sales of CABAZITAXEL STADA in Germany,

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3)'s sales of CABAZITAXEL STADA in Sweden.

V. Sanofi SA (Claimant 1) requests that the Defendants are ordered at their own expense to recall the products CABAZITAXEL STADA referred to above under clause IV. from the channels of commerce in the respective countries as specified in formal request IV., to definitely remove the products CABAZITAXEL STADA from the channels of commerce in such country, and to destroy the products CABAZITAXEL STADA present in such country.

VI. The respective claimants under formal request IV. request that the respective defendants in formal request IV. are ordered to provide the respective claimants under formal request IV. with information in writing and in electronic form on the extent to which each of these respective defendants has committed the acts described above under clauses III.1 and auxiliary request III.2 since 10 March 2021, stating

a) the origin and distribution channels of the infringing products;

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products;

c) the identity of any third person involved in the production or distribution of the infringing products referred to in formal request IV.

VII. The respective claimants under formal request IV. request that the respective defendants in formal request IV. are ordered to provide the respective claimants under formal request IV. with information in writing and in electronic form on the extent to which each of these respective defendants has committed the acts described above under clauses III.1 and auxiliary request III.2 since 10 March 2021, stating

a) the individual deliveries, itemised according to delivery quantities, times and prices as well as type designations and the names and addresses of the customers;

b) the individual offers, itemised according to offer quantities, times, prices, type designation and the names and addresses of the commercial offerees;

c) the prime costs broken down by the individual cost factors and the profit realised.

VIII. The respective claimants with respect to the respective territories request an order that

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi A/S (Claimant 11) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Denmark since 10 March 2021,

STADAPHARM GmbH (Defendant 1) are liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 6) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Germany since 10 March 2021,

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are jointly and severally liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi AB (Claimant 10) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Sweden since 10 March 2021.

IX. As an interim award of damages with respect to the products referred to in IV.,

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are jointly and severally ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, and Sanofi Winthrop Industrie (Claimant 2) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Denmark since 10 March 2021.

STADAPHARM GmbH (Defendant 1) is ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, Sanofi Winthrop Industrie (Claimant 2) the amount of €---, and Sanofi-Aventis Deutschland GmbH (Claimant 6) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Germany since 10 March 2021.

STADA Arzneimittel AG (Defendant 2) and STADA Nordic ApS (Defendant 3) are jointly and severally ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, Sanofi Winthrop Industrie (Claimant 2) the amount of €---, and Sanofi AB (Claimant 10) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Sweden since 10 March 2021.

X. All Defendants are jointly and severally ordered to pay the costs of the infringement claim (court costs and costs of representation by lawyers) to all Claimants 1 to 11 with an interim amount of €336,000 and for the costs of the revocation counterclaim (court costs and costs of representation by lawyers) to Claimant 1 with an interim amount of €75,000.

XI. The above orders are immediately enforceable without security.

Sanofi now requests in ORD_10067/2025 UPC_CFI_147/2024 (Reddy)

I. Dismiss all the requests of the Defendants

II. Dismiss the revocation counterclaim

III. Sanofi SA as successor for Sanofi Mature IP (the patentee) (Claimant 1) requests that

Reddy Pharma SAS (Defendant 1) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in France, from, in the territory of the UPC Member State France

betapharm Arzneimittel GmbH (Defendant 2) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Germany, from, in the territory of the UPC Member State Germany

Dr Reddy's Srl (Defendant 3) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Italy, from, in the territory of the UPC Member State Italy

1. offering, placing on the market, using, importing or storing for those purposes

a. a compound of formula […]

which may be in base form or in the form of a hydrate or a solvate, in combination with prednisone or prednisolone, for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment;

(direct infringement of claim 1)

and/or

b. compound for use according to III.1.a., where the prostate cancer is an advanced metastatic disease;

(direct infringement of claim 2)

and/or

c. compound for use according to any one of claims III.1.a. to III.1.b. administered at a dose of between 15 and 25 mg/m2 , the prednisone or prednisolone being administered at a dose of 10 mg/day;

(direct infringement of claim 5)

and/or

d. compound for use according to III.1.c. administered at a dose of 25 mg/m2 ;

(direct infringement of claim 6)

and/or

e. compound for use according to any one of III.1.a. to III.1.d, comprising repeating the administration of such compound as a new cycle every 3 weeks;

(direct infringement of claim 7)

and/or

f. compound for use according to any one of III.1.a. to III.1.e., in combination with prednisone;

(direct infringement of claim 8)

and/or
g. compound for use according to any one of III.1.a. to III.1.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(direct infringement of claim 9)

as auxiliary request

2. supplying or offering to supply in the aforementioned territory for use in the aforementioned territory

a. a compound of formula […]

which may be in base form or in the form of a hydrate or a solvate, to be combined with prednisone or prednisolone, for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment,

(indirect infringement of claim 1)

and/or

b. compound for use according to III.2.a., where the prostate cancer is an advanced metastatic disease;

(indirect infringement of claim 2)

and/or

c. compound for use according to any one of claims III.2.a. to III.2.b. administered at a dose of between 15 and 25 mg/m2 , the prednisone or prednisolone being administered at a dose of 10 mg/day;

(indirect infringement of claim 5)

and/or

d. compound for use according to III.2.c. administered at a dose of 25 mg/m2 ;

(indirect infringement of claim 6)

and/or

e. compound for use according to any one of III.2..a. to III.2.d, comprising repeating the administration of such compound as a new cycle every 3 weeks;

(indirect infringement of claim 7)

and/or f. compound for use according to any one of III.2.a. to III.2.e., in combination with prednisone;

(indirect infringement of claim 8)

and/or

g. compound for use according to any one of III.2.a. to III.2.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(indirect infringement of claim 9)

IV. With respect to the acts described above under clauses III.1 and auxiliary request III.2, the rights conferred respectively by the French, German, and Italian national designations of European patent No. 2 493 466 to

Sanofi SA (Claimant 1) and Sanofi Winthrop Industrie (Claimants 2 and 3) with respect to France,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 6) with respect to Germany,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi S.r.l. (Claimant 7) with respect to Italy,

Have been infringed by Reddy Pharma SAS (Defendant 1)'s sales of CABAZITAXEL REDDY PHARMA in France,

betapharm Arzneimittel GmbH (Defendant 2)'s sales of CABAZITAXEL BETA in Germany,

Dr Reddy's Srl (Defendant 3)'s sales of CABAZITAXEL DR. REDDY'S in Italy.

V. Sanofi SA (Claimant 1) requests that the Defendants are ordered at their own expense to recall the products CABAZITAXEL REDDY PHARMA, CABAZITAXEL BETA, and CABAZITAXEL DR. REDDY'S referred to above under clause IV. from the channels of commerce in the respective countries as specified in formal request IV., to definitely remove the products CABAZITAXEL REDDY PHARMA, CABAZITAXEL BETA, and CABAZITAXEL DR. REDDY'S from the channels of commerce in such country, and to destroy the products CABAZITAXEL REDDY PHARMA, CABAZITAXEL BETA, and CABAZITAXEL DR. REDDY'S present in such country.

VI. The respective claimants under formal request IV. request that the respective defendants in formal request IV. are ordered to provide the respective claimants under formal request IV. with information in writing and in electronic form on the extent to which each of these respective defendants has committed the acts described above under clauses III.1 and auxiliary request III.2 since 10 March 2021, stating

a) the origin and distribution channels of the infringing products;

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products;

c) the identity of any third person involved in the production or distribution of the infringing products referred to in formal request IV.

VII. The respective claimants under formal request IV. request that the respective defendants in formal request IV. are ordered to provide the respective claimants under formal request IV. with information in writing and in electronic form on the extent to which each of these respective defendants has committed the acts described above under clauses III.1 and auxiliary request III.2 since 10 March 2021, stating

a) the individual deliveries, itemised according to delivery quantities, times and prices as well as type designations and the names and addresses of the customers;

b) the individual offers, itemised according to offer quantities, times, prices, type designation and the names and addresses of the commercial offerees;

c) the prime costs broken down by the individual cost factors and the profit realised.

VIII. The respective claimants with respect to the respective territories request an order that

Reddy Pharma SAS (Defendant 1) are liable to compensate Sanofi SA (Claimant 1) and Sanofi Winthrop Industrie (Claimants 2 and 3) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in France since 10 March 2021.

betapharm Arzneimittel GmbH (Defendant 2) are liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and SanofiAventis Deutschland GmbH (Claimant

6) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Germany since 10 March 2021.

Dr Reddy's Srl (Defendant 3) are liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi S.r.l. (Claimant 7) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Italy since 10 March 2021.

IX. As an interim award of damages with respect to the products referred to in IV.,

Reddy Pharma SAS (Defendant 1) is ordered to pay separately to Sanofi SA (Claimant 1) the amount of €--- and Sanofi Winthrop Industrie (Claimants 2 and 3) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in France since 10 March 2021.

betapharm Arzneimittel GmbH (Defendant 2) is ordered to pay separately to Sanofi SA (Claimant 1) the amount of €--- and Sanofi Winthrop Industrie (Claimant 2) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Germany since 10 March 2021.

Dr Reddy's Srl (Defendant 3) is ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, Sanofi Winthrop Industrie (Claimant 2) the amount of €---, and Sanofi S.r.l. (Claimant 7) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Italy since 10 March 2021.

X. All Defendants are jointly and severally ordered to pay the costs of the infringement claim (court costs and costs of representation by lawyers) to all Claimants 1 to 11 with an interim amount of €186,000 and for the costs of the revocation counterclaim (court costs and costs of representation by lawyers) to Claimant 1 with an interim amount of €75,000.

XI. The above orders are immediately enforceable without security.

Sanofi now requests in ORD_10069/2025 UPC_CFI_148/2024 (Zentiva)

I. Dismiss all the requests of the Defendants I

I. Dismiss the revocation counterclaim

III. Sanofi SA as successor for Sanofi Mature IP (the patentee) (Claimant 1) requests that

Zentiva France (Defendant 1) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in France, from, in the territory of the UPC Member State France

Zentiva Pharma GmbH (Defendant 2) are ordered to cease and desist until European patent No. 2 493 466 is irrevocably revoked or has expired in Germany, from, in the territory of the UPC Member State Germany

1. offering, placing on the market, using, importing or storing for those purposes a

a. compound of formula […]

which may be in base form or in the form of a hydrate or a solvate, in combination with prednisone or prednisolone, for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment;

(direct infringement of claim 1)

and/or

b. compound for use according to III.1.a., where the prostate cancer is an advanced metastatic disease;

(direct infringement of claim 2)

and/or

c. compound for use according to any one of claims III.1.a. to III.1.b. administered at a dose of between 15 and 25 mg/m2 , the prednisone or prednisolone being administered at a dose of 10 mg/day;

(direct infringement of claim 5)

and/or

d. compound for use according to III.1.c. administered at a dose of 25 mg/m2 ;

(direct infringement of claim 6)

and/or

e. compound for use according to any one of III.1.a. to III.1.d, comprising repeating the administration of such compound as a new cycle every 3 weeks;

(direct infringement of claim 7) and/or f. compound for use according to any one of III.1.a. to III.1.e., in combination with prednisone;

(direct infringement of claim 8)

and/or

g. compound for use according to any one of III.1.a. to III.1.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(direct infringement of claim 9)

as auxiliary request

2. supplying or offering to supply in the aforementioned territory for use in the aforementioned territory

a. a compound of formula […]

which may be in base form or in the form of a hydrate or a solvate, to be combined with prednisone or prednisolone, for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer who have been previously treated with docetaxel based regimen and have prostate cancer that progressed during or after said treatment,

(indirect infringement of claim 1)

and/or

b. compound for use according to III.2.a., where the prostate cancer is an advanced metastatic disease;

(indirect infringement of claim 2)

and/or

c. compound for use according to any one of claims III.2.a. to III.2.b. administered at a dose of between 15 and 25 mg/m2 , the prednisone or prednisolone being administered at a dose of 10 mg/day;

(indirect infringement of claim 5)

and/or

d. compound for use according to III.2.c. administered at a dose of 25 mg/m2 ;

(indirect infringement of claim 6)

and/or

e. compound for use according to any one of III.2..a. to III.2.d, comprising repeating the administration of such compound as a new cycle every 3 weeks;

(indirect infringement of claim 7)

and/or

f. compound for use according to any one of III.2.a. to III.2.e., in combination with prednisone;

(indirect infringement of claim 8)

and/or

g. compound for use according to any one of III.2.a. to III.2.f., wherein said patients have been previously treated with at least 225 mg/m2 cumulative dose of docetaxel;

(indirect infringement of claim 9)

IV. With respect to the acts described above under clauses III.1 and auxiliary request III.2, the rights conferred respectively by the French and German national designations of European patent No. 2 493 466 to

Sanofi SA (Claimant 1) and Sanofi Winthrop Industrie (Claimants 2 and 3)
with respect to France,

Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and SanofiAventis Deutschland GmbH (Claimant 6) with respect to Germany,

Have been infringed by Zentiva France (Defendant 1)'s sales of CABAZITAXEL ZENTIVA in France,

Zentiva Pharma GmbH (Defendant 2)'s sales of CABAZITAXEL ZENTIVA in Germany.

V. Sanofi SA (Claimant 1) requests that the Defendants are ordered at their own expense to recall the products CABAZITAXEL ZENTIVA referred to above under clause IV. from the channels of commerce in the respective countries as specified in formal request IV., to definitely remove the products CABAZITAXEL ZENTIVA from the channels of commerce in such country, and to destroy the products CABAZITAXEL ZENTIVA present in such country.

VI. The respective claimants under formal request IV. request that the respective defendants in formal request IV. are ordered to provide the respective claimants under formal request IV. with information in writing and in electronic form on the extent to which each of these respective defendants has committed the acts described above under clauses III.1 and auxiliary request III.2 since 10 March 2021, stating

a) the origin and distribution channels of the infringing products;

b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products;

c) the identity of any third person involved in the production or distribution of the infringing products referred to in formal request IV.

VII. The respective claimants under formal request IV. request that the respective defendants in formal request IV. are ordered to provide the respective claimants under formal request IV. with information in writing and in electronic form on the extent to which each of these respective defendants has committed the acts described above under clauses III.1 and auxiliary request III.2 since 10 March 2021, stating

a) the individual deliveries, itemised according to delivery quantities, times and prices as well as type designations and the names and addresses of the customers;

b) the individual offers, itemised according to offer quantities, times, prices, type designation and the names and addresses of the commercial offerees;

c) the prime costs broken down by the individual cost factors and the profit realised.

VIII. The respective claimants with respect to the respective territories request an order that

Zentiva France (Defendant 1) are liable to compensate Sanofi SA (Claimant 1) and Sanofi Winthrop Industrie (Claimants 2 and 3) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in France since 10 March 2021.

Zentiva Pharma GmbH (Defendant 2) are liable to compensate Sanofi SA (Claimant 1), Sanofi Winthrop Industrie (Claimant 2), and Sanofi-Aventis Deutschland GmbH (Claimant 6) for all damage that these Claimants have suffered and will suffer as a result of the acts referred to in III.1 (and as an auxiliary request in III.2) and IV. committed in Germany since 10 March 2021.

IX. As an interim award of damages with respect to the products referred to in IV.

Zentiva France (Defendant 1) is ordered to pay separately to Sanofi SA (Claimant 1) the amount of €--- and Sanofi Winthrop Industrie (Claimants 2 and 3) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in France since 10 March 2021.

Zentiva Pharma GmbH (Defendant 2) is ordered to pay separately to Sanofi SA (Claimant 1) the amount of €---, Sanofi Winthrop Industrie (Claimant 2) the amount of €---, and Sanofi-Aventis Deutschland GmbH (Claimant 6) the amount of €--- for the acts of placing on the market referred to in III.1 (or supplying referred to as an auxiliary request in III.2) committed in Germany since 10 March 2021.

X. All Defendants are jointly and severally ordered to pay the costs of the infringement claim (court costs and costs of representation by lawyers) to all Claimants 1 to 11 with an interim amount of €186,000 and for the costs of the revocation counterclaim (court costs and costs of representation by lawyers) to Claimant 1 with an interim amount of €75,000.

XI. The above orders are immediately enforceable without security

Accord now requests in ORD_10064/2025 UPC_CFI_145/2024 (Accord)

The Defendants maintain all of their objections and challenges and the list of orders included in their comments filed on 12 February 2025.

STADA now requests in App_17291/2025 UPC_CFI_146/2024 (STADA)

STADA maintains all requests as previously filed.

Reddy now requests in ORD_10067/2025 UPC_CFI_147/2024 (Reddy)

In addition to the motions set out in the Statement of Defence and the Counterclaim for Revocation filed on 29 August 2024 as well as our Comments on the Courts procedural Order of 22 January 2025 (ORD_3582/2025) filed on 12 February 2025, we ask the Court to rule as follows, with regard to the infringement action:

8. To dismiss the infringement action in respect of the French part of EP466.

9. To order the Claimants to bear all costs incurred in connection with the defence against the assertion of the French part of EP466.

Zentiva now requests in ORD_10069/2025 UPC_CFI_148/2024 (Zentiva)

In the Counterclaim for revocation:

I. to grant the request of the Defendants under R. 263 RoP to amend request I. of Defendants' Counterclaim for revocation of September 2, 2024 as follows:

on the Defendants' Counterclaim for revocation, to revoke EP 2 493 466 B1 in its entirety (claims 1-9) for all Contracting Member States in which EP 2 493 466 B1 is in force, namely: Austria, Belgium, Germany, Denmark, France, Italy, ~~Malta~~, Netherlands, Portugal and Sweden; and

II. Claimant 1. to bear Court fees, costs and other expenses incurred by Defendants

and in favor of the Defendants as joint and several creditors with regard to the proceedings under R. 263 RoP.

ARGUMENTS BROUGHT FORWARD BY THE PARTIES

Accord argues - among other things - summarized as follows:

- The Court lacks jurisdiction as Claimants are, pursuant to Art. 34 UPCA, not permitted to carve out France. Further it lacks jurisdiction for countries for which the Claimants have not claimed that (one of) the Defendants have carried out allegedly infringing acts: Denmark and Malta. Further the UPC lacks jurisdiction for States in which the UPC shall enter into force. The Court further lacks jurisdiction to issue a decision against unspecified third parties. And finally, the Court lacks jurisdiction in relation to infringing acts which took place prior to 1 June 2023.

- The statement of claim lacks proper substantiation and evidence to support the claims and shows formal deficiencies. Sanofi therefore failed to comply with Rule 13 RoP, in particular with Rule 13 (k) RoP. This failure cannot be corrected.

- Claimants 2-10 lack standing to sue as the formal requirements set out in Art. 47 (2-3) UPCA have not been fulfilled.

- The claims have no prospect of succeeding and/or are bound to fail. Accord does not directly infringe the compound claims as the attacked product does not include prednisone or prednisolone.

- The request to amend the action, including the request to add claims for indirect infringement and the replacement of the claim for damages with a request for an interim award of damages and a damage-declaration, must be rejected as late filed.

- New arguments in respect to the calculation of damages / provisional damages are late filed and must be disregarded.

- New Requests I, II, IV, IX, X and XI still do not specify at all who is making the request (Requests IX and X do mention to which Claimants the payments shall be made however they still do not mention which Claimants are requesting these orders); requests VI and VII now say “The respective claimants under formal request IV, request that (…)”, however as stated above Request IV does not state who is making the request; request VIII now says “The respective claimants with respect to the respective territories request (…)”, however it is not clear what “the respective claimants” means, not what “the respective territories” are, particularly for Claimants 1 and 2.

- It is now unclear whether Claimant 10 (Sanofi’s affiliate in Denmark) is making any request at all.

- Request IV still does not specify which claims have allegedly been infringed.

- It is still unclear why Request V (recall, removal and destruction) is made against "the Defendants".

- It is still unclear in Requests VI and VII (requests for the communications of information under Article 67 UPCA) who are the "respective defendants in formal request IV" and whether there should be any joint or separate liability.

- Requests VI and VII also contain requirements (e.g. "in writing and in electronic form" or "since 10 March 2021") that were not included in the requests as filed with the Statement of Claim and why the time limitation ("within 1 month of the order") has been removed. The Claimants have also still not given reasons to explain why the starting point in time should be 10 March 2021.

- In addition, with the further amendments filed on 20 March 2025, the requests now refer to "the acts described above under clauses III.1 **and** auxiliary request III.2 since 10 March 2021" (amendments in redline). Given that Request III.2 is an auxiliary request, there cannot be an infringement under both Request III.1 (direct) and Request III.2 (indirect), it can only be one or the other (or none).

- Similarly, it is unclear why Request VI.c) now refers to "the infringing products referred to in formal request IV" whereas Requests VI.a) and VI.b) have not been amended in a similar way and still refer more generally to "the infringing products".

- In addition, it is also still the case that: the information requested in Request VII goes beyond the initial claim which referred to "information listed in Article 67", as the information requested in Request VII is not listed in Article 67 UPCA; the information requested under Request VI refers to "the quantities produced, manufactured (…)", whereas production and manufacturing are not covered by Requests III.1 and III.2; as highlighted by the Judge Rapporteur during the preliminary interim conference of 15 January 2025, as well as in the procedural order issued on 22 January 2025, these requests for information should have been submitted through a separate, dedicated, workflow and properly justified, including as to why their necessary and proportionate. The Claimants still have failed to do so.

- Furthermore, the Claimants have made a number of further amendments to Request IX which are not prompted or justified by any of the comments made by the Judge Rapporteur on their order and that are creating more confusion and/or are inconsistent with the content of the Claimant's own comments: The local Sanofi affiliates in Austria (Claimant 3) and Belgium (Claimant 4) are not requesting any damages anymore (whereas for each other country a separate amount is now claimed by the local affiliate). No explanation whatsoever are provided for this. It is unclear whether this is another inadvertent error by the Claimants or whether Claimants 3 and 4 have unconditionally surrendered their damages claim. If one adds up the total amounts of damages now claimed in respect of each country, these are not the same as the amounts previously claimed in Request IX as filed on 29 January 2025 for the corresponding country, for each country but the Netherlands. For example, the total amounts of damages claimed respectively for Austria and Belgium are significantly higher and the total

amount claimed for Portugal is significantly lower. There is again no explanation whatsoever for these changes. The total amount of damages claimed in Request IX in respect of Portugal by Claimant 8 is significantly different from the total amount as per the calculations included in the content of the Claimants' comments at para. 14. There is no explanation whatsoever for this and the amount now claimed by Claimant 8 in Request IX seems totally random. Claimant 8 has ignored the request made by the Judge Rapporteur to explain the difference and attribute it to specific acts of infringement (para. 7(b) of the order dated on 27 February 2025). In addition to the above, if one adds up the total amount of damages now claimed in Request IX for all countries combined, the amount is slightly lower than the amount initially claimed in the Statement of Claim. Therefore, the Claimants' statement at the end of para. 14 of their comments filed on 20 March 2025 that they have limited the request to the total amount initially claimed is not true. Again, there is no explanation for this.

STADA argues - among other things - summarized as follows:

- The jurisdiction and competence of the Court does not extend to non-contracting Member States of the UPCA. In addition, claims arising before 1 June 2023, the date of entry into force of the UPCA, cannot be considered by the Court due to the lack of a legal basis.

- Formal request III.1. (injunctive relief based on direct infringement) has become obscure in view of the Claimants' arguments under para. 40 of their brief. According to the Claimants' most recent pleading, it has been demonstrated that the Defendants had the possibility to place their products on the market at any time in any Member State where have not yet placed their products on the market. Therefore, there was no reason to close the proceedings with regards to any Claimants or Defendants. Against this background, it is unclear whether the Claimants Sanofi-Aventis GmbH, Sanofi-Belgium, Sanofi S.r.l., Sanofi B.V., Sanofi – Produtos Farmaceuticos Lda und Sanofi AB are requesting the ordering of injunctive relief or not.

- Formal request III.2. (injunctive relief based on indirect infringement) is inadmissible as introducing indirect infringement required a request to amend the claim under R. 263 RoP. We disagree with no. 2. of the Court's Order.

- Contrary to the Court's Order (no. 5.a.), formal request IV. (finding of infringement) neither makes clear who the claimant is nor which claims of the patent are addressed (all claims or just a subset?). In addition, it is unclear whether direct or indirect infringement is alleged. The request is, thus, inadmissible and must be dismissed out of hand.

- Formal request VI. (information) combines the information about direct infringement with the information about indirect infringement ("on the extent to which each of these respective defendants has committed the acts described above under clauses III.1 **and** auxiliary request III.2"), which is not possible due to the auxiliary nature of request III.2 and the mutual exclusivity of direct and indirect infringement. The request is, thus, inadmissible and must be dismissed out of hand.

- Formal request VII. (further information) concerns an amendment of the claim, as set out earlier. Neither the Court in its Court Order nor the Claimants have addressed this. We continue to submit that the requirements of R. 263 RoP are not met. The request is, thus, inadmissible and must be dismissed out of hand.

- Formal request IX. (interim award of damages) is inadmissible and must be dismissed out of hand as the Claimants have not specified which infringing actions are supposed to be covered by the damages amounts asked for.

Reddy argues - among other things - summarized as follows:

- The defendants seek the partial dismissal of the plaintiff's infringement action based on European patent EP 2 493 466 (hereinafter also referred to as "EP466" or "the patent") for lack of jurisdiction of the Unified Patent Court (Rule 19.1(a) RoP). This concerns, on the one hand, the temporal scope of all the plaintiff's claims, which relate to a period prior to the entry into force of the UPC system on 1 June 2023, and, on the other hand, the geographical scope of the claims for those countries that are not yet UPC contracting states at the time the action is brought, or until the date of the oral hearing.

- Sanofi´s amendments violate Rule 263(1) RoP because they do not merely "clarify or correct" Sanofi's original requests but instead introduce substantive changes. This also applies to the further amendments made by Sanofi in its submission of 20 March 2025.

- Claimants fail to clarify why all Claimants 1) to 11) should remain in the proceedings when, according to the Amended Requests, only Claimants 1, 2, 3, 6, and 7 have material claims against the Defendants. Sanofi latest submission also lacks any justification or explanation in this regard. Instead, the Claimants refer to “Zentiva k.s.” in para. 40 of their submission, which is clearly not a party to the present proceedings. Para. 40 of their submission does not contain any information about the present Defendants. Since Amended Requests III. (injunctive relief) and IV. (declaration of infringement) have now been limited to certain territories (Germany, Italy, France), it is also not plausible that there is an actual risk that the attacked products will be launched in other member states of the UPC (see page 18 seqq. of our Statement of Defense). The fact that the Claimants have limited their claims to the three countries mentioned above confirms this understanding. The argument raised in para. 40 of Sanofi’s last submission is therefore in clear inconsistent with the claim limitations and amendments sought by Sanofi.

- Defendants further contend that, as a result of the French court's decision to invalidate the French part of the Patent, there is currently no enforceable French part of the Patent that could be enforced against Defendants in the present proceedings. This is not altered by Sanofi's further extensive submissions in its statement of 20 March 2025 (paragraphs 25 to 38). While the registration of the nullity in the INPI register is suspended until the judgment becomes final, the judgment itself is immediately opposable to all parties, including third parties such as the present Defendants.

Zentiva argues – among other things - summarized as follows:

- The UPC has no jurisdiction over the Claimants' requests (in particular the above mentioned requests) in states which are not Contracting Member States according to Art. 2(c) UPCA. The UPC was not delegated any jurisdiction to decide on damages, production of information and corrective measures for acts that occurred before 1 June 2023. Therefore, the UPC may not exercise such non-delegated jurisdiction without the consent of the Contracting Member States. The Claimants did not admissibly submit the offer of evidence for the Claimants' standing to sue in the language of the proceedings, since the links to websites in footnotes 2, 3 and 4 on p. 4 of the Statement of claim, which apparently serve as means for offering evidence for Claimants standing to sue, refer to websites in French. This offer of evidence constitutes a violation of Art. 53, 49 UPCA and R. 14.2 (b) UPC-RoP. Therefore, the offer of evidence under footnotes 2, 3 and 4 on p. 4 of the Statement of claim may not be accepted as evidence by the Court in the infringement proceedings, which means that the Claimants failed to meet the requirement of offering evidence according to R. 171.1 UPC-RoP, Art. 53(2) UPCA. As a result, the action is to be regarded as not admissibly filed.

- The Claimants' have yet again – for the seventh time – failed to submit unambiguous formal requests. The Defendants' objections in this regard must not lead to the Claimants' action being allowed to proceed completely outside the time limits and rules of the UPC. Otherwise, the UPC would turn the role of the defence upside down: Defendants must submit their defence – otherwise Defendants would risk that the UPC would enter default judgment against them. But if Claimants are allowed to simply redraft their formal requests on an ongoing basis following the LD's increasingly detailed guidance, in response to any defence, then this also results in a de facto judgment against Defendants. Defendants again respectfully request that the LD Munich dismisses the action. The Claimants have completely crossed the line of fairness. A further opportunity for correction would completely unbalance the fairness of the proceedings to the detriment of Defendants.

- Defendants maintain their position that Defendants' introduction of new claims for indirect infringement constitutes an impermissible amendment of their original complaint. This is different from the case law of the CoA cited by the Claimants (CoA_456/2024 APL 44633/2024). That CoA decision concerned the amendment to existing unambiguous claims. Here, however, Defendants are introducing new claims based on existing ambiguous claims and new arguments for indirect infringement.

- The changes made by the Claimants do not constitute either a clarification or a limitation, but an aliud compared to the previous request.

- For example with respect to Requests VI. and VII. (Information) & Section 5.c. Procedural Order of Feb 27 – Claimants 1.-3., 6. vs. Defendants 1.-2. – it is still unclear what is the nature of the liability with respect to and among the various Claimants and Defendants. Is there, for example, joint and several liability with respect to the individual Defendants (and if so, with which ones)? And are the individual Claimants related, e.g. as joint creditors? Furthermore, it

is unclear, what are the allegedly “infringing products”, since no reference is made to infringing products in formal request IV. and III.1, III.2 which the Claimants refer to.

- It stays unclear to what extent the claimants are individual or joint creditors and the defendants joint or several debtors.

- The Paris First Instance Court explicitly states that the French part of EP 466 is not enforceable. The Claimants do not explain how this unambiguous wording of the decision can be understood in any other way than that the rights conferred by EP 466 cannot be enforced until a final decision has been made regarding the validity of EP 466. Rather, it appears, for example in paras. (34) and (38) of Claimants’ comment of March 20, 2025, that the Claimants do not distinguish between “in force” and “enforceable”. While the French part of EP 466 is “in force” until the revocation becomes final, it is not “enforceable”. Accordingly – and contrary to paras. (37) of Claimants’ comment of March 20, 2025, the patent registers can only provide information on the administrative question of “in force”, but not on the "enforceability" under civil law.

Sanofi argues - among other things - summarized as follows:

- The defendants' arguments that the French designation of EP 466 would not be currently in force or enforceable are meritless. The first instance decision of the Paris First Instance Court is not final, it has no final res judicata, and EP 466 is indisputably enforceable in France. This remains true whether or not the first instance decision has been provisionally enforced by Accord Healthcare at its own risks.

GROUNDS FOR THE ORDER

In exercise of the case management powers provided for in Rule 332(d) RoP, the Judge-Rapporteur decides to refer all pending requests to the panel for decision after the main oral hearing. For the preliminary objections this means that the Judge-Rapporteur informs the parties in accordance with Rule 20.2 RoP. The reasons are as follows:

Preliminary Objections

The CoA has already ruled that there can be a carve-out of certain Contracting Member States (CMS) and that the Court has jurisdiction over acts committed before 1 June 2023. The CoA also held that Art. 34 UPCA has the effect that it is sufficient to prove an act of infringement in one CMS in order to claim infringement in all CMS. States in which the UPC will enter into force and unspecified third parties are no longer mentioned in the latest set of claims.

Validity of the patent at issue

The French designation of the patent in question was invalidated by the French court of first instance and an appeal is pending. No date has yet been announced. The OD of the EPO has upheld the patent, an appeal is also pending. The EPO Board of Appeal has rescheduled the oral proceedings for 2-4 June 2025. The oral hearing in the infringement action is scheduled for 14-17 October 2025.

The parties have different views on the legal consequences of the invalidation of the patent in France at first instance. The panel shall decide on the dispute between the parties whether or not the French denomination can currently be enforced. As a decision will not dispose of the whole case there is no benefit in deciding now.

Regardless of this dispute, this non-final invalidation raises doubts about the validity of the patent. In view of these doubts, it appears more economical to await the BoA decision and the discussion of validity and infringement at the oral hearing before the panel addresses the legal issues raised by the pending requests.

Infringement of the patent at issue

The discussion on the alleged late amendment of the indirect infringement claim will, due to the auxiliary nature of the respective requests, only come into play if the Panel dismisses the counterclaim and the infringement claim based on direct infringement, which is the subject of the main request. This assessment can't be made now. Therefore, it seems more economical to wait for the BoA decision and the discussion of validity and infringement at the oral hearing.

Rules 13, 263, 265 RoP

It should be noted that the defendants are correct in their assessment that the UPC representative for Sanofi has still not succeeded in submitting a set of claims and requests that do not raise any doubt. Reference is made to the defendants' latest observations.

It is the duty of the claimant's UPC representative to explain clearly and unambiguously the claimant's material claims ("Klagebegehren" in German), which reflect what the claimant wants from whom and why. A correct understanding of the content and scope of the statement of claim is essential for the defendants to be able to defend themselves properly. It is also crucial for the win-loss ratio and therefore for the decision on costs. The formal requests ("Klageanträge" in German) try to put the material claims into words. Ideally there should be no divergence.

Both the material claims and the formal requests can be interpreted by the court. Before the court interprets them, the party concerned should be asked to clarify any uncertainties and correct any discrepancies. If this ultimately fails, the court must interpret the material claims and formal requests. Only after such an interpretation can there be room for dismissal on formal or material grounds. In its decision, the court is bound by the material claims and not by the formal requests (Art. 76(1) UPCA).

Therefore, the defendants' criticism of the court's invitations to remedy the defects and ambiguities is unjustified.
Defects and ambiguities may be remedied upon the court's invitation.

Attention should also be drawn to Rules 9 and 332 (l) RoP. These Rules do not limit the number of such invitations. However, it appears that in this case no further opportunities for rectification are to be granted.

Against this background the Judge-Rapporteur is of the opinion that the remaining ambiguities pointed out by the defendants must and can be interpreted. This should be done by the panel. It should be noted however, that in interpreting the still unclear claims and requests, a generous view should, in the Judge-Rapporteur's view, be taken in order to achieve both that claims probably envisaged by the claimant still have to be decided on their merits and that ambiguities lead to a decision on costs to the detriment of the claimant. This could mean, for example, that the result of the interpretation is that all claimants seek a declaration of infringement, all claims are alleged to be infringed, and all defendants are subject to a specific request. The question whether these claims and requests will be successful is a question of substantive law and outside the scope of Rules 13 and 263.

Therefore, in the view of the Judge-Rapporteur, there is no possibility at this stage to dismiss the (entire) action on formal grounds.

As regards the amendments, it should be noted that, according to the CoA's case law, not every new argument constitutes an "amendment of a case" requiring a party to apply for leave under R. 263 RoP. An amendment of a case occurs when the nature or scope of the dispute changes. For example, in an infringement case, this occurs when the claimant invokes a different patent or objects to a different product (UPC_CoA_456/2024 APL_44633/2024; UPC_CoA_169/2025 APL_9191/2025).

Regarding in particular the introduction of auxiliary requests for indirect infringement and the change from a request for damages to a request for a declaration of damages and an interim award of damages, it must be noted that these do not seem to invoke a different patent or a different product and thus do not fall within the scope of Rule 263 RoP as interpreted by the CoA. The order of the Local Division Munich dated 22 September 2024 (UPC_CFI_114/2024 UPC_CFI_448/2024 APP_ 33728/2024), which has been cited by some defendants, was issued prior to the above-mentioned decisions of the CoA.

In the view of the Judge-Rapporteur, the defendants' ability to defend themselves against these new requests will not be unduly hampered. The defendants will have a further two months to prepare and file a further brief, as explained below.

The partial withdrawals are likely to be approved. This includes withdrawals by some members of the plaintiffs' group. Apart from the costs of these withdrawals, no interest of the defendants has been established not to grant approval. Some defendants have agreed to partial withdrawal subject to a partial costs order in their favour. The costs will be dealt with in the context of the final decision.

It is noted that the manner in which the UPC representative for Sanofi has conducted and is conducting the proceedings has caused and is causing enormous additional work and costs for the defendants, their UPC representatives and the Court. This may be taken into account in a final decision on costs (Art. 69(3) UPCA).

Rules 334 (h) and 361 RoP

The defendants challenge the standing to sue with respect to claimants who rely on an exclusive or non-exclusive license. As explained before the arguments based on Art. 47 (2-3) UPCA do not seem to be convincing as the patent owner, the exclusive-licensee and the non-exclusive licensees have started these actions together.

Some defendants further argue that there is no direct infringement and that the case amendment for indirect infringement must be rejected. Therefore, the action based on direct infringement can and must be dismissed right away without oral hearing. Sanofi can file another action for indirect infringement. As the amendment for requests directed to an indirect infringement are likely be admissible as explained above the panel should decide in the oral hearing whether there is an infringement of a valid patent and if so, whether it is a direct or indirect infringement. Only then the questions must be answered whether the amendment is admissible or not.

As to Sanofi`s ongoing effort to calculate (provisional) damages it must be noted that the calculation of actual damages will anyhow be performed in separate proceedings pursuant to Rule 125 RoP following the main proceedings. This is so either because the panel decides that the amendment is admissible or that – if the amendment is inadmissible – the amount of damages will be determined in separate proceedings pursuant to Rule 118 RoP. The Judge-Rapporteuer suggests deciding that way.

As regards the calculation of interim damages the court has discretion to estimate an amount probably owned by defendants pursuant to Rule 119 RoP. For this assessment which has only to be done if there is an infringement of a valid patent the court can rely on all information presented in the proceedings irrespective of the time of filing. The court will however take due account of any concerns due to inconsistencies within the figures presented.

Requests by Sanofi for information

In case Sanofi is still requesting an order for information to be issued prior to the main oral hearing it must be noted that the calculation of actual damages will be performed in separate proceedings pursuant to Rule 125 RoP following the main proceedings. Therefore, there is now no room for an order against the defendants to produce sales figures.

Further it must be kept in mind that the French designation of the patent in suit has been invalidated by the competent French first instance court (appeal is pending) and that the

panel will assess whether still a valid patent has been infringed after the main oral hearing. Therefore, considering these requests now would be premature and an order to produce information would not be proportionate.

Further requests by Zentiva

The panel shall decide on the request to strike out Malta from the formal request to revoke the patent. As a decision will not dispose of the whole counterclaim there is no benefit in deciding now.

Overall assessment

The Judge-Rapporteur does not see any possibility of disposing of the entire case immediately. Since difficult procedural and substantive issues need to be decided, it's more efficient to wait for the outcome of the oral proceedings before the EPO's BoA. Moreover, if the patent in question is upheld by the BoA, the panel should only decide on these difficult issues after an oral hearing and only if they are still decisive. The defendants are not unduly burdened. This order already gives them some guidance as to what to expect in a possible final decision. Any details of the calculation of damages will be dealt with in separate proceedings. And the defendants have the full two months to file their rejoinder to the reply to the defence, as explained below, although they have been aware of the reply to the defence since 1 November 2024.

Further schedule and deadlines

The next step in the proceedings will be for the defendants to file their rejoinder to the reply to the defence within two months from today, as required by Rule 29 (d) of the Rules of Procedure.

Sanofi will then have one month in which to file a further written statement pursuant to Rule 29 (2) of the Rules of Procedure.

No application to amend the patent has been filed.

The written procedure will then be closed on 8 August 2025.

As the Interim Conference currently scheduled for 17 July 2025 will take place within the written procedure, it will be devoted to discussing the outcome of the oral hearing before the EPO's BoA, currently scheduled for 2-4 June 2025.

A second interim conference will be held by videoconference on 12 September 2025 at 10.00.

The dates for the Oral Hearing (14-17 October 2025) are confirmed. A detailed schedule for these days will be communicated at a later date.

ORDER

1. The judge-rapporteur informs the parties that the preliminary objections will be dealt with in the main proceedings.

2. The judge-rapporteur puts the remaining pending requests to the panel for decision following the main oral hearing.

3. The defendants are invited to file the rejoinder to the reply to the defence (Rule 29 (d) RoP) within two months from today.

4. The claimants are invited to file a brief according to Rule 29 (2) RoP within one month following the filing of the rejoinder to the reply to the defence.

5. The written procedure will be closed on 8 August 2025.

6. The date for the Interim Conference scheduled for 17 July 2025 is confirmed. The IC will primarily focus on the outcome of the appeal proceedings at the BoA of the EPO.
7. Another (the main) Interim Conference is set for 12 September 2025, 10.00 a.m., via videoconference.

8. The dates for the oral hearing scheduled for 14-17 October 2025 are confirmed.

9. The parties are summoned to the above-mentioned hearings and interim conferences.

Matthias ZIGANN

Digital unterschrieben von Matthias ZIGANN
Datum: 2025.05.08 16:36:57 +02'00'

Dr. Zigann
Presiding Judge

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). - A decision by default may be given, upon request, against a party that was duly summoned but fails to appear at the oral hearing (R. 355.1 (b) RoP.

DETAILS OF THE ORDER

Order no. ORD_10064/2025 in ACTION NUMBER: ACT_16112/2024
UPC number: UPC_CFI_145/2024

Action type: Infringement Action

Order no. ORD_22027/2025 in ACTION NUMBER: ACT_16116/2024
UPC number: UPC_CFI_146/2024
Action type: Infringement Action
Related proceeding no. Application No.: 17291/2025 for ORD_10065/2025
Application Type: Generic procedural Application

Order no. ORD_10067/2025 in ACTION NUMBER: ACT_16119/2024
UPC number: UPC_CFI_147/2024
Action type: Infringement Action

Order no. ORD_10069/2025 in ACTION NUMBER: ACT_16120/2024
UPC number: UPC_CFI_148/2024
Action type: Infringement Action