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 17 July 2025

CLAIMANTS

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

represented by: Frédéric Chevallier (McDermott Will & Emery).

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 (Taylor Wessing)

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).

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).

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

R.105.5 RoP following interim conference of 17 July 2025.

POINTS RAISED DURING THE INTERIM CONFERENCE

1) The EPO BoA has not yet uploaded the written reasoned decision following the oral hearing on 2–4 June 2025, in which the patent was upheld as granted. The parties have no information regarding when this might happen. The defendants have expressed a desire to comment on the written reasons within three weeks of their availability. Sanofi will comment within the brief due on 8 August 2025, if possible.

2) Sanofi explains that the French first-instance decisions invalidating the French part of the European patent are under appeal. The appeal court has not yet scheduled a hearing.

3) The JR explained that the panel intends to assess the issues raised by the counterclaims independently, bearing in mind both the EPO and the French decisions. One question seems to be of the utmost importance for the assessment of obviousness: what information would a person working in the industry at the priority date have derived from the Phase III TROPIC study and the time that has passed since it started? Was there a reasonable expectation of success? The JR asked the parties if they had named any experts on this issue who would be available for hot tubbing at the oral hearing. This is a means of educating the panel on the factual circumstances and considerations relevant to deciding the legal question of obviousness. Sanofi referred to [redacted] Accord referred to [redacted] Stada and Reddy referred to their written evidence. The relevant parties are invited to inform their respective experts that they may be called to testify in October 2025. The final decision will be made following the last interim conference.

The JR explained that the final interim conference, scheduled for 12 September 2025, will discuss the detailed plan for the oral hearing, which is scheduled for 14–17 October 2025. Parties are invited to suggest topics to be discussed by 1 September 2025.

4) Sanofi's application for the relevant version of the order of 8 May 2025 to be the 'version of the order of 8 May 2025 tailored to the respective defendant group', and Reddy's application (ORD_22246/2025) to reject this request and order that non-confidential elements of the interim damages calculations, including overall damages figures and the court's rationale, be made available to all parties in all related proceedings with reasonable redactions limited to specific commercial data. The application also requests that any redactions be applied narrowly and proportionately, in a manner that preserves the rights of all defendants to effectively understand and challenge Sanofi’s claims. The other defendants have not filed comments on this question. The JR informs the parties that their wish to double-check Sanofi's calculation seems to justify an application under R. 262.3 RoP. Therefore, to avoid unnecessary work for the parties and the court, it is suggested that the original version of the Order of 8 May 2025 be circulated within the respective confidentiality clubs. All parties agree or do not raise objections.

5) Accord raises concerns about the way in which Sanofi drafts its briefs. As Sanofi's briefs appear to be identical for all four defendant groups, individual defendants have difficulty

identifying whether a statement is in response to their own pleadings or those of other defendants.

Furthermore, it was noted that 'the defendants' had been blamed collectively without justification. The JR informed the parties that the briefs that had already been filed would remain as they were, and that Sanofi would highlight any passages not directed to all defendants in its future brief(s) addressing the defendants collectively.

ORDER

1. The final interim conference is confirmed for 12 September 2025 at 10:00 via videoconference.
2. Parties are invited to submit suggestions for topics to be discussed at the interim conference via a Rule 9 workflow by 1 September 2025. They are also invited to highlight any relevant pleadings and exhibits relating to the issue mentioned in item 3) above.
3. The dates for the oral hearing (14–17 October 2025, 09:00) are confirmed.
4. Sanofi and Defendants may comment on the written reasoned decision by the EPO BoA via a Rule-9 workflow once it is available, within three weeks. If possible, Sanofi will provide comments already in the next brief, which is due on 8 August 2025. If this order results in the parties` time limit expiring after 11 September 2025, a new order will be issued. To this end, parties are invited to inform the court of the availability of the reasons via email as soon as possible.
5. Sanofi may file consolidated briefs addressing all four defendants. In any future briefs addressing the defendants collectively, Sanofi shall highlight any passages not directed to all defendants.

INFORMATION ABOUT REVIEW BY THE 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).

Matthias ZIGANN

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von Matthias ZIGANN
Datum: 2025.07.17
15:08:08 +02'00'

Dr. Zigann
Presiding Judge

DETAILS OF THE ORDER

Order no. ORD_22245/2025 in ACTION NUMBER: ACT_16112/2024
UPC number: UPC_CFI_145/2024
Action type: Infringement Action
Related proceeding no. Application No.: 55583/2024
Application Type: APPLICATION_ROP262A

Order no. ORD_22246/2025 in ACTION NUMBER: ACT_16119/2024
UPC number: UPC_CFI_147/2024
Action type: Infringement Action
Related proceeding no. Application No.: 57838/2024
Application Type: APPLICATION_ROP262A

Order no. ORD_22248/2025 in ACTION NUMBER: ACT_16120/2024
UPC number: UPC_CFI_148/2024
Action type: Infringement Action
Related proceeding no. Application No.: 57840/2024
Application Type: APPLICATION_ROP262A

Order no. ORD_33148/2025 in ACTION NUMBER: ACT_16116/2024
UPC number: UPC_CFI_146/2024
Action type: Infringement Action
Related proceeding no. Application No.: 22247/2025
Application Type: Procedural Order