

Procedural Order of the Court of First Instance of the Unified Patent Court Local Division Munich issued on 26 March 2025

CLAIMANTS - UPC CFI 146/2024

- 1) Sanofi Mature IP
- 2) Sanofi Winthrop Industrie
- 3) Sanofi-Aventis France
- 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 146/2024

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

represented by: Daniel Hoppe (Preu Bohlig).

APPLICANT - UPC CFI 146/2024

Medac Gesellschaft für klinische Spezialpräparate m.b.H.

represented by: Alexander Eisenführ (Uexkull + Stolberg)

PATENT AT ISSUE

European patent n° 2 493 466

PANEL/DIVISION

Panel 1 of the Local Division Munich

DECIDING JUDGE/S

The order was made by the presiding judge, Dr Matthias Zigann, acting as judge-rapporteur, the legally qualified judges Alima Zana and Tobias Pichlmaier and the technically qualified judge Carola Wagner.

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Application RoP262.1(b) - App_34720/2024 Application for leave to withdraw an action (RoP265) dated 21 October 2024 - App_11680/2025

PROCEDURAL HISTORY

By brief dated 26 June 2024, Medac filed a RoP262.1(b) application. A letter from Sanofi to Medac dated 3 June 2024 was uploaded in unredacted form as "Exhibit 2". No applications under Rule 262.2 or 262A RoP had been made by Medac. The letter had originally been sent by e-mail marked "privileged and confidential":

De: FR	
Envoyé: lundi 3 juin 2024 14:09	
À: @medac.de>	
Objet :	Confidential and Without Prejudice
Importance : Haute	
Critère de diffusion : Confidentiel	
Privileged and Confidential	

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Sanofi objected to the granting of access to file and argued that Exhibit 2 should not have been uploaded at all.

By briefs dated 21 October 2024 (App_34720/2024) and 10 March 2025 (App_11680/2025), Medac withdrew the RoP262.1(b) application.

REQUESTS BY THE PARTIES

Medac requests:

- the request under Rule 262.1(b) RoP is hereby withdrawn
- withdraws from the proceedings Applicant's "Exhibit 2" as being privileged and confidential as requested by Sanofi
- does not order any measures against Applicant's representative in request for access APP 34702/2024, and
- does not issue an order as to costs with regard to the withdrawn request for access APP_34720/2024.

Sanofi requests:

- withdraw from the proceedings the Applicant's "Exhibit 2" as being privileged and confidential, and enjoin the Applicant, the Defendants in the main action and their respective representatives from ever invoking, relying on or submitting such document in any circumstances, under penalty of €10,000,000 per reference to such document;
- order any measures it deems relevant against the Applicant's representative;
- in any case, <u>acknowledge the Applicant's withdrawal of the present request</u> dismiss the Applicant's request for access as being unfounded and meritless;

In the alternative:

Only allow access to the Statement of claim with the redaction detailed above by Sanofi, and to the Exhibits except Exhibits Nos. B.1.1, B.1.1.1, B.1.1.2, D.2, and D.2.1;

in any case:

- the Applicant has to bear the costs of the application;
- grant leave to appeal to Sanofi if any of its requests were dismissed.

GROUNDS

- 1. Medac and Sanofi requested that Exhibit 2 be withdrawn, arguing that it should not have been submitted in the first place due to its privileged and confidential nature. The application to withdraw the Rule 262.1(b) application and exhibit 2 must be granted, as no party to the proceedings has raised any concerns. The withdrawal of Exhibit 2 can be based on Rule 262A.1 RoP. Paragraph 1 provides that a party may apply to the Court for an order prohibiting the use of evidence in the proceedings.
- 2. In order to ensure that neither Medac nor Stada makes use of Exhibit 2 or discloses it to third parties, a periodic penalty payment must be ordered (Rule 354.3 RoP). The amount will be determined in the event of a culpable breach of the court order.

- 3. The CMS does not provide a tool for users to withdraw uploaded files. Therefore, a ticket must be opened with the current CMS service provider. The current CMS service provider charges an additional fee for tickets that are not related to a malfunction of the CMS, as is the case here. According to Art. 69(3) UPCA, a party should bear any unnecessary costs it has caused the court or another party. In this case, Medac is causing unnecessary costs to the court by requiring an exhibit previously uploaded to the CMS by Medac to be deleted. To ensure that these costs are reimbursed, the opening of a ticket is subject to a prior deposit. The deposit may also be paid by another party.
- 4. With regard to Sanofi's requests for a decision on costs, reference is made to the order of the Central Division Paris Seat, of 8 January 2025 (APP_56782/2024 UPC_CFI_189/2024). Consequently, an application under Rule 262(1)(b) of the Rules of Procedure or its withdrawal does not justify an award of costs.
- 5. As regards Sanofi's request that the Court orders such measures as it considers appropriate against Medac's representative, the Court expresses its disapproval of the negligent conduct of Medac's representative and issues a warning:
- a. Sanofi submits that, by communicating to the Court and to STADA Exhibit 2, which is a privileged and confidential document, Medac's representative breached his duties to the Court under Rule 290.2 of the Rules of Procedure and Rule 2.1 of the Code of Conduct for Representatives. Sanofi also considers that Medac's conduct violated German civil and criminal law and French criminal law.
- b. Medac's representative and Medac responded as follows

"It is believed that the accusations against the applicant and its representative raised in the claimant's submission dated 25 July 2024 are unfounded. At the time of filing the subject request, neither the applicant nor its representative had any reasons to assume that the document submitted as Exhibit 2 would have to be treated as confidential. Moreover, the subject request has meanwhile become moot because the claimant's statement of claim in parallel proceedings against Accord (ACT_16112/2024 UPC_CFI_145/2024) has become public as part of the EPO's public file for EP 2 493 466, thereby providing the applicant with the information which it sought to obtain through the present request. On this background, the request under Rule 262.1(b) RoP is hereby withdrawn. It is believed that there is no need for an order for costs."

c. The Court finds that Sanofi has sufficiently demonstrated that Exhibit 2 has always been privileged and confidential and that Medac and Medac's representative have always been aware of the privileged and confidential nature of Exhibit 2. As regards any civil or criminal consequences, the Court considers that these should be dealt with by Sanofi as the injured party. As regards the UPC's Code of Conduct for Representatives, the Court finds that Medac's representative culpably breached the Code of Conduct in that Exhibit 2 should not have been uploaded at all, or at least not in an unredacted version, and thus made available to Stada, without an application pursuant to Rules 262.2 or 262A RoP. As the proceedings regarding the RoP 262.1(b) application have been concluded, an exclusion from the proceedings pursuant to

Rule 291.1. RoP would be pointless. However, the court expresses its disapproval of the negligent conduct of Medac's representative and issues a warning.

Order

- 1. The withdrawal of the RoP262.1(b)-application is permitted.
- 2. The proceedings on the RoP262.1(b)-application are closed.
- 3. This decision shall be entered on the Register.
- 4. Medac's "Exhibit 2" filed on 26 June 2024 in App_34720/2024 UPC_CFI_146/2024 is withdrawn from the proceedings.
- 5. Exhibit 2 shall, as far as possible, be removed from the CMS and replaced by this order.
- 6. Medac shall pay the costs incurred by the Court in this connection.
- 7. The execution of paragraph 5 is subject to a prior deposit of costs of EUR 600,00.
- 8. Medac and Stada and their UPC representatives shall not use Annex 2 or disclose it to third parties, subject to payment of a recurring penalty to the Court.
- 9. All further requests are rejected.
- 10. Leave to appeal is granted.

INFORMATION ABOUT APPEAL IN CASE OF AN ORDER FALLING UNDER ART. 73(2)(B) UPCA:

The present order may either - be the subject of an appeal by any party which has been unsuccessful, in whole or in part, in its submissions together with the appeal against the final decision of the Court of First Instance in the main proceedings, or - be appealed by any party which has been unsuccessful, in whole or in part, in its submissions at the Court of Appeal with the leave of the Court of First Instance within 15 days of service of the Court of First Instance's decision to that effect (Art. 73(2)(b) UPCA, R. 220.2, 224.1(b) RoP)

INSTRUCTIONS TO THE PARTIES

The deposit is to be transferred to a bank account of the UPC. The details of which will be communicated by the Sub-Registry on request.

Instructions to the Registry

After the deposit has been received a ticket with the CMS service provided shall be opened to deleted exhibit 2 from the CMS and to replaced it by this order.

DETAILS OF THE ORDER

Order no. ORD 13509/2025 in ACTION NUMBER: ACT 16116/2024

UPC number: UPC_CFI_146/2024 Action type: Infringement Action

Related proceeding no. Application No.: 11680/2025

Application Type: Application for leave to withdraw an action (RoP265)

Order no. ORD 41504/2024 in ACTION NUMBER: ACT 16116/2024

UPC number: UPC CFI 146/2024

UPC_CFI_146/2024

Action type: Infringement Action

Related proceeding no. Application No.: 34720/2024

Application Type: APPLICATION_ROP262_1_b

Dr. Zigann Presiding Judge	
Zana Legally Qualified Judge	
Pichlmaier Legally Qualified Judge	
Wagner Technically Qualified Judge	