



Central Division (Section Munich)

UPC_CFI_1/2023

and

UPC_CFI_14/2023

Order

**of the Court of First Instance of the Unified Patent Court
delivered on 27/02/2024**

RELEVANT PROCEEDING PARTIES IN CASE 1/2023 (ACT 459505/2023)

- | | | |
|----|--|---|
| 1) | Sanofi-Aventis Deutschland GmbH
(Claimant) - Brüningstrasse 50 - 65926 -
Frankfurt - DE | Represented by Agathe Michel-de
Cazotte, Daniel Wise (Carpmeals &
Ransford) |
| 2) | Sanofi-Aventis Groupe
(Claimant) - 82 Avenue Raspail - 94250 -
Gentilly - FR | Represented by Agathe Michel-de
Cazotte, Daniel Wise (Carpmeals &
Ransford) |

3) **Sanofi Winthrop Industrie S.A.** Represented by Agathe Michel-de
(Claimant) - 82 Avenue Raspail - 94250 - Cazotte, Daniel Wise (Carpmeals &
Gentilly - FR Ransford)

4) **Amgen, Inc.** Represented by Koen Bijvank
(Defendant) - One Amgen Center Drive - CA (Brinkhof)
91320-1799 - Thousand Oaks - US

RELEVANT PROCEEDING PARTIES IN CASE 14/2023 (CC 586764/2023)

1) **Regeneron Pharmaceuticals Inc.** Represented by Niels Hölder
(Claimant) - 81 Columbia Turnpike 12144 (Hoffmann Eitle), Agathe Michel-de
Rensselaer US Cazotte, Daniel Wise (Carpmeals &
Ransford)

2) **Amgen, Inc.** Represented by Koen Bijvank
(Defendant) - One Amgen Center Drive - CA (Brinkhof)
91320-1799 - Thousand Oaks - US

Claimants 1 to 3 in action ACT_459505/2023 are jointly referred to as "Sanofi Claimants". Together with the claimant in action CC_586764/2023, "Regeneron", they are collectively referred to as "Claimants". The defendant is referred to as "Amgen" or "Defendant".

PATENT AT ISSUE

Patent no. *Proprietor/s*

EP3666797

Amgen, Inc.

PANEL/DIVISION

Panel 1 of the Central Division (Section Munich).

DECIDING JUDGE

This Order is an order of the judge-rapporteur András Kupecz.

LANGUAGE OF PROCEEDINGS:

English.

SUBJECT-MATTER OF THE PROCEEDINGS

Revocation action and counterclaim for revocation.

FACTS, BACKGROUND AND REQUESTS

The Sanofi Claimants brought a revocation action against European Patent 3 666 797 B1 (“the Patent”) in the Central Division (Section Munich) of the Unified Patent Court (ACT_459505/2023 UPC_CFI_1/2023, “the Revocation action”). The written procedure in case 1/2023 was closed on 6 February 2024.

Defendant in the revocation action (‘Defendant’) brought an infringement action to the Munich Local Division against the Sanofi Claimants and Regeneron relating to the same patent (ACT_459916/2023). In that action, the Statement of Defence by Regeneron included a counterclaim for revocation of the Patent (CC_586764/2023, “the Counterclaim”). In the Counterclaim Amgen lodged its Defence to the counterclaim for revocation on 24 January 2024.

By order dated 2 February 2024 (ORD_392/2024), the Local Division Munich, with the agreement of the parties, referred the Counterclaim of Regeneron to the Central Division.

By way of procedural applications App_6308/2024 and App_6331/2024 in case 1/2023 lodged on 5 February 2024 by Amgen and the Sanofi Claimants (also on behalf of Regeneron), respectively, all parties made clear that they wished to have the cases dealt with together by the Central Division, keeping the hearing date that was already fixed in the Revocation action.

In Application 6308/2024, Amgen additionally requested to hold an interim conference and to admit, before closure of the written procedure, two documents into the proceedings that had been referred to in Amgen's Rejoinder but were invertedly omitted when the Rejoinder was filed.

In Application 6331/2024, the Sanofi Claimants furthermore requested to be allowed to use demonstratives at the main oral hearing that do not introduce any new substance, in particular models and a set number of slides and that in its Rule 103 RoP order the Court order a schedule of deadlines to exchange demonstratives before said oral hearing. The Sanofi Claimants also requested to be allowed to produce a case summary (pursuant to Rule 104(e) RoP) that does not introduce any new arguments, evidence or facts into the case, is limited to a certain length, does not include additional annexes/exhibits, and is to be provided to the panel on a fixed date before the oral hearing.

In view of the developments and requests as set out above, the judge-rapporteur considered that it would be most efficient to discuss with all parties how to proceed with the Counterclaim and Revocation actions, also taking the opportunity to hear the parties in relation to the requests made in their respective procedural applications before making any order.

A hearing was held by videoconference on Thursday 22 February at 13.00 CET. At the hearing before the judge-rapporteur:

- The Sanofi Claimants and Regeneron were represented by their representatives mentioned above. Also present were Mike Gruber and Michael Pfeifer, both representatives from Hoffmann Eitle, ... (Senior Patent Counsel) and ... (Head of Global Patent Litigation), both of Sanofi, ... (Senior Director Dispute Resolution) and ... (Director Dispute Resolution), both of Regeneron.
- Defendant Amgen was represented by its representative mentioned above. Also present were Johannes Heselberger (Bardehle), Ulrich Dörries (df-mp), both representatives, and ... , senior IP counsel of Amgen.

DECISIONS TAKEN AND GROUNDS

In relation to combining the actions

The judge-rapporteur discussed with the parties their (essentially identical) requests to deal with the Revocation action that was already pending before the Central Division and the Counterclaim in relation to the Patent that was referred by the Local Division Munich together.

The judge-rapporteur informed the parties that the Central Division was in principle prepared to deal with the cases jointly and to hear both cases at the oral hearing date already fixed in the Revocation action (4 June 2024, 5 June as a reserve date), with the proviso that it should be made clear that all parties are "on the same page" where it concerns the grounds for revocation, arguments, facts and evidence, such that the Court (and the parties) would be able to prepare for and deal with both cases together on the time path originally envisaged for the Revocation action, the latter being considerably further advanced compared to the referred Counterclaim.

This was discussed with the parties and at the hearing, the parties and the judge-rapporteur agreed on the following way forward:

- All facts, grounds, arguments and evidence exchanged are known to all parties and are accepted as submitted by the Claimants in both cases. Those brought forward by the Sanofi Claimants in the Revocation action are deemed to have been submitted by Regeneron in the Counterclaim and vice-versa. All Defences raised by Amgen are deemed to have been raised in both actions against all Claimants.
- This means that all pleadings and applications (including the application to amend/auxiliary requests) are also deemed to have been submitted in both actions. Those submitted by the Sanofi Claimants are deemed to have been submitted by Regeneron (and vice versa) and Amgen's pleadings and applications are deemed to have been submitted in both actions.
- All exhibits (and evidence) are deemed to have been filed in and are part of both actions.
- Going forward, the Claimants agree to make identical submissions in both cases. Amgen agrees and also agrees to make identical submissions in both cases.
- (Only) costs may be dealt with separately.
- Regeneron may submit a short and succinct submission replying to any (in its view) new points of substance raised in Amgen's Defence to the counterclaim for revocation (to be lodged by **March 7, 2024, 17.00 CET**). For the sake of completeness, from the above, it follows that this reply will also be deemed to have been submitted by the Sanofi Claimants in the Revocation action. Amgen is granted two weeks to submit a similar length "rejoinder", replying only to points raised in Regeneron's submission (to be lodged by **March 21, 2024, 17.00 CET**). Likewise, to confirm for the sake of completeness, as per the above, this submission will thus also be part of the Revocation action against the Sanofi Claimants. These submissions may not contain/refer to any new (expert) evidence or exhibits.

The Claimants' further requests

In relation to the further requests made by the Sanofi Claimants, the parties and the judge-rapporteur agreed that they are allowed to use a number of slides (but not models) as demonstratives at the hearing which may not introduce any new facts or substance to the case. These slides are to be submitted by all parties by **7 May 2024, 17.00 CET** at the latest. The Claimants are to inform the judge-rapporteur by e-mail (always copying the Defendant's representative) on **23 April 2024** at the latest how many slides they intend to use (this should be a reasonable number) and the Defendant may use the same number of slides. Both parties are to include with the slides a table indicating exactly where in the pleadings/evidence already on file the contents of the slides can be found.

In addition, the parties and the judge-rapporteur agreed that the parties are allowed to submit a case summary, provided that this does not introduce any new arguments, evidence or facts into the case. This case summary may have a maximum length of **7500 words** and is to be exchanged on **5 April 2024, 17.00 CET**.

At the occasion of submitting the case summary, together with the summary (as an exhibit, not included in the word count), the Claimants are to provide a **consolidated list of exhibits/evidence** (including a cross-referencing table of documents in both actions) submitted by all parties to allow each document to be referred to by one unique reference by the parties and the Court during the hearing.

The Defendant's further requests

The Defendant requested the admission of documents D99 and C10a into the proceedings. These documents were inadvertently omitted when submitting the Rejoinder. Claimants did not have any objection nor did the judge-rapporteur. Documents D99 and C10a were admitted accordingly.

In view of the opportunity to be heard in relation to its requests and the combining of both actions at the present hearing and with reference to the order dated 24 January 2024 in the Revocation action, the judge-rapporteur informed the parties that he did not see the need for an interim conference. To the extent that the request to hold an interim conference was maintained by the Defendant, it is rejected.

Value of the proceedings and further submissions on costs

At the hearing, the judge-rapporteur informed the parties that he intended to decide the value of the proceedings for the purpose of applying the scale of ceilings for recoverable costs.

Parties were in agreement of the value of the proceedings being set at **EUR 100,000,000** (one hundred million euro) for each action. The Court did not have any objections. The value of the proceedings is set accordingly.

In relation to costs, the Administrative Committee ('AC') has published a scale of ceilings for recoverable costs depending on the value in dispute (dated 24 April 2023, published as D-AC/10/24042023_D). According to this table, the ceiling corresponding to a value of **EUR 100,000,000** would be set at EUR 2,000,000 (two million euro).

The judge-rapporteur pointed out to the parties the scale as drawn up by the AC relates to a ceiling for recoverable costs, i.e. the maximum amount of costs recoverable. In accordance with article 69 UPCA, reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity requires otherwise (up to a ceiling set in accordance with the Rules of Procedure, see above).

In order for the parties and the Court to assess whether costs incurred are indeed reasonable and proportionate and whether or not equity requires otherwise, the Court and parties must have access to information showing at least a detailed description of the number of hours spent working on this particular case, by whom, what for and at what rate. The same applies to any expenses incurred.

To this end, the Court will allow the filing of additional exhibits relating to costs until two weeks prior to the hearing (**21 May 2024**) for all costs incurred until that date. This submission may be updated by a further submission to be lodged at the latest **noon CET** on the day before the hearing (**3 June 2024**). The last submission may include an estimate of costs incurred for the hearing itself. For the sake of clarity, separate submissions on costs should be made in both actions. The ceiling for recoverable costs applies in each action separately.

The judge-rapporteur informed the parties that the Court will, in principle, respect an agreement between the parties on the amount of costs that is deemed reasonable and proportionate.

Further submissions and party experts

The judge-rapporteur informed the parties that the Court saw no need for further written submissions or evidence other than the submissions specifically mentioned in this order. In particular, the Claimants confirmed during the hearing that their arguments in relation to competition law were not raised as a ground for revocation and do not belong in these proceedings. Therefore, these submissions/arguments are no longer considered to be part of the present proceedings. No further submissions from the parties are therefore required.

The judge-rapporteur informed the parties that the Court does not intend to hear any of the party experts. Written reports have been exchanged and the Court at this point in time does not see any added benefit in formally hearing the experts. However, the parties may bring their experts to the oral hearing, either in person or by video-link. Should the Court have a specific question for an expert, it may ask a question to a party expert.

Parties agreed to inform the Court before the hearing who of their experts will attend the hearing and in what form (in person at the hearing or by video-link). Parties are instructed to use the occasion of filing of the case summaries (**5 April 2024**) in order to **announce their experts** (not included in the word count for the case summary).

Confirmation oral hearing date

The date for the oral hearing, already communicated to the parties in the Rule 28 RoP order in the Revocation action, was confirmed, also for the Counterclaim action, for:

4 June 2024, 09.30 CET
Cincinnatistraße 64, 81549 Munich, Germany

The hearing room will be announced in the summons to the oral hearing (Rule 108 RoP).

The judge-rapporteur informed the parties that it is the Court's firm intention to conclude the hearing in one day. The second day (5 June 2024, reserved as per the Rule 28 RoP Order in the Revocation action) is in principle only reserved for unforeseen events, like technical difficulties.

ORDER

For these grounds, having heard the parties on all aspects of relevance for the following order, the judge-rapporteur orders:

- In agreement with all parties, the actions are dealt with jointly under the conditions as set out above.
- Further submissions (succinct reply, rejoinder, slides, case summaries, submissions on costs) may be filed as set out above.
- Documents D99 and C10a are admitted into the proceedings.
- The hearing date is confirmed as set out above.
- The value of the action for the purpose of applying the scale of ceilings for recoverable costs in case ACT_459505/2023 is set at EUR 100,000,000 (one hundred million euro).
- The value of the action for the purpose of applying the scale of ceilings for recoverable costs in case CC_586764/2023 is set at EUR 100,000,000 (one hundred million euro).

- Any further request made in application 6308/2024 and/or application 6331/2024 beyond what has been explicitly granted (or rejected) in this order is rejected.

INFORMATION FOR THE PARTIES

This order is issued using a Rule 9 generic procedural order workflow in both actions. This order is in lieu of the Rule 103 RoP order that was announced by the judge-rapporteur in the Revocation action (order of 24 January 2024). No (further) Rule 103 RoP order is foreseen in either action. The judge-rapporteur intends to close the written procedure in the Counterclaim action (case CC_586764/2023) on **25 March 2024**.

Regeneron should use the workflow “reply to defence” in case CC_586764/2023 for lodging the “succinct reply”. Amgen should use the workflow “rejoinder” in case CC_586764/2023 to lodge its rejoinder to the reply.

In order to have complete and up-to-date files in the CMS in both actions, going forward, all documents need to be filed in both actions. The reply and rejoinder referred to above should be submitted by the Sanofi Claimants and Amgen, respectively, as an exhibit together with the case summary on the deadline set in this order. An opportunity to lodge the case summaries will be provided as an opportunity to comply with this Rule 9 RoP order in the CMS. Further submissions are to be filed using generic procedural applications in the CMS, again always in both actions.

Issued on 27 February 2024
KUPECZ
Judge-rapporteur

ORDER DETAILS

Order no. ORD_10396/2024 in ACTION NUMBER: ACT_459505/2023
and
Order no. ORD_10398/2024 in ACTION NUMBER: CC_586764/2023
Action type: Revocation Action and Counterclaim for revocation

REVIEW:

Pursuant to Rule 333 RoP, the above Order shall be reviewed by the panel on a reasoned application by a party. An application for the review of this order shall be lodged within 15 days of service of this Order.