



## Central Division (Section Munich)

**UPC\_CFI\_1/2023**

**Procedural Order  
and  
Information on Next Steps**

**of the Court of First Instance of the Unified Patent Court  
delivered on *24/01/2024***

RELEVANT PROCEEDING PARTIES

- 1) **Sanofi-Aventis Deutschland GmbH**  
(Claimant) - Brüningstrasse 50 - 65926 -  
Frankfurt - DE  
Represented by Daniel Wise, Agathe  
Michel-de Cazotte
  
- 2) **Sanofi-Aventis Groupe**  
(Claimant) - 82 Avenue Raspail - 94250 -  
Gentilly - FR  
Represented by Daniel Wise, Agathe  
Michel-de Cazotte
  
- 3) **Sanofi Winthrop Industrie S.A.**  
(Claimant) - 82 Avenue Raspail - 94250 -  
Gentilly - FR  
Represented by Daniel Wise, Agathe  
Michel-de Cazotte

4) **Amgen, Inc.**  
(Defendant) - One Amgen Center Drive - CA  
91320-1799 - Thousand Oaks - US

Represented by Koen Bijvank

PATENT AT ISSUE

<i>Patent no.</i>	<i>Proprietor/s</i>
<b>EP3666797</b>	Amgen, Inc.

PANEL/DIVISION

Panel 1 of the Central Division (Section Munich) ('the Division').

DECIDING JUDGE

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

LANGUAGE OF PROCEEDINGS:

English.

SUBJECT-MATTER OF THE PROCEEDINGS

Revocation action. RoP 9.1 Application.

FACTS, BACKGROUND AND REQUESTS

The Claimants request that the Court exercises the discretion provided by Rule 9.1 RoP to make a procedural order that their letter dated 15 January 2024 (reference U010526UC) and its accompanying (expert) declarations be admitted into the proceedings ("the Application").

As reasons for the Application, Claimants state that the expert declarations accompanying Defendant's Rejoinder introduce a number of new points into the proceedings, some of which are inaccurate and require a response. In order to clarify matters for the Court, three expert declarations are enclosed (which according to Claimants are concise (six pages in total) and address a small number of discrete points). The Claimants also refer to the principles of flexibility and fairness.

Defendant, in its letter dated 19 January 2024 (reference KB/20160083/2266309, the “Response Letter”) opposes the request, stating that Claimants should have waited for the interim conference to request permission to file further expert declarations. Furthermore, according to the Defendant, the debate and the introduction of new evidence must close at some point. The Rules of Procedure recognize this by setting out, as a default, that the Rejoinder to the Reply is the final written pleading in the revocation action (Rule 43 RoP). If the Claimants’ application is allowed, the written evidence will further spiral out of control. Therefore, Defendant requests that the Application is dismissed and that the Judge-Rapporteur will discuss with the parties at the interim conference to what extent further submissions and evidence (e.g. expert declarations) are appropriate and allowed. In the alternative, if the Application would be allowed, then Defendant requests that it will be allowed to file a reply brief and expert declarations, as appropriate, in response to Claimants’ brief and expert declarations.

#### GROUNDS

Having taken note of the parties’ submissions and requests, the Application is granted.

Defendant essentially argues that the request to submit expert declarations should be rejected because it is premature. It should have been made in the interim procedure as all pleadings in the written procedure have been exchanged (2, 3 Response Letter). This view is not supported by the RoP. In the written procedure the judge-rapporteur may, on a reasoned request by a party, allow the exchange of further written pleadings (Rule 58 in connection with Rule 36 RoP). In addition, under Rule 9.1 RoP, the Court may *at any stage* of the proceedings, therefore also during the written procedure after the exchange of the pleadings in accordance with Rule 43 RoP, order a party to take any step, answer any question or provide any clarification or evidence. As pointed out by the Defendant, pursuant to Rules 103 and 104 RoP, the judge-rapporteur may order the production of further pleadings and evidence in the interim procedure. However, it does not follow from the fact that the judge-rapporteur may do so *also* in the interim procedure, that the present request (which was made before closure of the written procedure), is as such premature and should for that reason be rejected.

Even though in principle the RoP do not preclude the request made by the Claimants, this does not mean that there is an automatic right to reply to a Rejoinder, as also acknowledged by the Claimants. To the contrary, from the system of exchange of written pleadings in the written procedure against the background of the generally front-loaded character of UPC proceedings (e.g. Preamble RoP 7), it follows that the exchange of the written pleadings is normally limited in accordance with Rule 43 RoP (cf. Rule 58 in connection with Rule 35 RoP). Accordingly, it is to the discretion of the Court to assess whether the present request justifies departing from the general, fixed framework of written submissions which is designed to conduct UPC proceedings in an efficient, proportionate, fair and equitable way (Preamble RoP 2 and 4).

The request is allowable in view of the specific circumstances of the present case. It is undisputed by the Defendant that the letter and the expert declarations that the Claimants request to be allowed in the proceedings address a small number of discrete points raised for the first time in the expert declarations accompanying the Rejoinder. In addition, it is also undisputed that they are concise (six pages in total). Therefore, without assessing the substance or the potential relevance of the expert declarations, from a procedural point of view, the request seems a bona fide attempt to respond to new points made for the first time in the last written submission.

The Court does not follow Defendant in that to safeguard its right to be heard, it must be given an opportunity to react, by way of a reply brief and counter-opinions of its experts (point 6 Reply Letter, alternative request). As Defendant itself raised the new points in the Rejoinder, the Claimants are allowed to respond to those new points by way of the present (limited) submissions. The right to be heard does not entail that there should be yet another exchange between the parties. Furthermore, Defendant has the right to be heard at the oral hearing.

The Application is therefore granted and Defendant's requests as made in the Response Letter are rejected.

#### ORDER

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

- grants the Application and admits the letter dated 15 January 2024 (reference U010526UC) and its accompanying (expert) declarations into the proceedings.
- rejects Defendant's requests as made in the Response Letter.

#### INFORMATION ABOUT NEXT STEPS IN THE PROCEEDINGS

The judge-rapporteur would like to take this opportunity to inform the parties that, after deliberation with the panel, the Division has come to the conclusion that there is no need to hold an interim conference at this stage. After having seen parties' pleadings and further submissions, the panel has not currently identified any points that would require discussion at an interim conference. Reference is made to Rules 101 and 58 in connection with 35(b) RoP.

The judge-rapporteur intends to issue a Rule 103 RoP Order giving further directions in preparation for the oral hearing. Should an interim conference be deemed necessary later in the interim procedure, parties shall be informed accordingly.

The interim conference which was provisionally scheduled for 7 February 2024 will as a result not go ahead. Parties may clear that date in their diaries.

The judge-rapporteur intends to close the written procedure on **6 February 2024**.

Issued on 24 January 2024

KUPECZ

Judge-rapporteur

ORDER DETAILS

ACTION number: ACT\_459505/2023

UPC number: UPC\_CFI\_1/2023

ORDER number: ORD\_2233/2024

Action type: Revocation Action

Related proceeding no. Application No.: APP\_2196/2024

Application Type: Generic procedural Application

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.