



**Headnotes:**

Unanimous requests by all parties directed to a Local or Regional Division to refer a counterclaim for revocation to the Central Division for decision will be granted unless strong counterarguments require a different decision.

**Keywords:**

Article 33(3) UPCA; Rule 37 RoP; agreement of parties; discretion to refer counterclaim for revocation to central division; discretion to proceed with infringement proceedings; discretion to stay infringement proceedings.

**Order**  
**in the proceedings before the**  
**Court of First Instance of the Unified Patent Court**  
**relating to European Patent 3 666 797**  
**delivered on 02/02/2024**

Date of receipt of Statement of claim : 01/06/2023

CLAIMANT

- |    |  |  |
|----|--|--|
| 1) | <b>Amgen Inc.</b><br>One Amgen Center Drive, Mail-Stop 28-2-C -<br>91320-1799 - Thousand Oaks - US | Represented by<br>Johannes Heselberger |
|----|--|--|

DEFENDANTS

- |    |  |                                |
|----|--|--------------------------------|
| 1) | <b>Sanofi-Aventis Deutschland GmbH</b><br>Industriepark Höchst, Brüningstraße 50 -<br>65926 - Frankfurt am Main - DE | Represented by<br>Niels Hölder |
| 2) | <b>Sanofi-Aventis Groupe S.A.</b><br>54 rue La Boétie - 75008 - Paris - FR   | Represented by<br>Niels Hölder |
| 3) | <b>Sanofi Winthrop Industrie S.A.</b><br>82 avenue Raspail - 94250 - Gentilly - FR                                   | Represented by<br>Niels Hölder |
| 4) | <b>Regeneron Pharmaceuticals Inc.</b><br>81 Columbia Turnpike - 12144 - Rensselaer -<br>US                           | Represented by<br>Niels Hölder |

PATENT AT ISSUE

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

DECIDING JUDGESCOMPOSITION OF PANEL – FULL PANEL

Presiding judge and Judge-rapporteur	<b>Matthias Zigann</b>
Legally qualified judge	<b>Tobias Pichlmaier</b>
Legally qualified judge	<b>Samuel Granata</b>
Technically qualified judge	<b>Xavier Dorland-Galliot</b>

This order has been issued by the full panel.

LANGUAGE OF PROCEEDINGS: English

SUBJECT-MATTER OF THE PROCEEDINGS

Patent infringement and counterclaim for revocation.  
here: decision according to Rule 37 RoP.

SUMMARY OF FACTS

The Claimant alleges infringement of European Patent 3 666 797 by the defendants` drug Praluent (Alirocumab).

Defendants 1-3 have filed oppositions with the European Patent Office and a stand-alone nullity action with the Central Division (ACT\_459505/2023 UPC\_CFI\_1/2023). The Claimant`s preliminary objections in this respect were unsuccessful. The oral hearing is scheduled for 04/06/2024. The Central Division has decided not to hold an interim conference.

Defendant 4 has filed a counterclaim for revocation with the Local Division Munich (CC\_586764/2023).

The Local Division Munich has set the following dates:

Interim Conference by video conference: 01/07/2024

Main oral hearing in person: 16/10/2024

Main oral hearing in person (additional day): 17/10/2024

The Panel has informed the parties that it intends to take an early decision under Rule 37.2 of the Rules of Procedure on how to proceed with the counterclaim. The parties were invited to submit observations. The Claimant and all four defendants agree that the counterclaim for revocation should be referred to the Central Division. However, the parties disagree on how to proceed with the infringement action.

**Claimant requests** that the infringement proceedings be continued.

**Defendants request** that the infringement proceedings be stayed pending a final decision in the revocation action.

Defendants also request a stay for other reasons not directly related to the revocation action.

### GROUNDS

I. Pursuant to Rule 37.1 of the Rules of Procedure, the panel shall, as soon as practicable after the conclusion of the written procedure, decide by way of order how to proceed with respect to the application of Article 33(3) of the Agreement. The parties shall be given an opportunity to be heard [Rule 264]. In its order, the panel shall briefly state the reasons for its decision. Under Rule 37.2 of the Rules of Procedure, the panel may, if appropriate, by order give an earlier decision after considering the parties' written submissions and after giving the parties an opportunity to be heard [Rule 264].

According to Art. 33(3) UPCA, the local or regional division concerned may, after hearing the parties, either

- (a) proceed with both the action for infringement and the counterclaim for revocation and request the President of the Court of First Instance to designate from the pool of judges referred in Article 18(3) a technically qualified judge with qualifications and experience in the field of technology concerned; or
- (b) refer the counterclaim for revocation to the central division for decision and stay or proceed with the action for infringement; or
- (c) with the agreement of the parties, refer the case to the Central Division for decision.

II. In the exercise of its discretion, this Panel refers the counterclaim of Defendant Regeneron (CC\_586764/2023) to the Central Division for decision.

While it is true that there are usually advantages in having the infringement action and the counterclaim for revocation heard together by the same panel, the circumstances of this case require a different decision.

1. All parties requested that the counterclaim be referred to the Central Division. Unanimous requests by all parties will be granted unless strong counterarguments require a different decision.

2. This Panel cannot find a single strong counterargument. Indeed, this panel considers that, in the circumstances of this case, a referral of the counterclaim to the Central Division is the most practical solution to avoid inconsistent decisions and duplication of work on validity. In view of the date of the oral hearing scheduled by the Central Division, an early decision by this panel is

necessary.

III. In the exercise of its discretion, the Panel decides to proceed with the infringement proceeding, but reserves the right to consider the possibility of suspending the infringement proceeding pursuant to Art. 33.3.c UPCA or to suspend the proceedings for any other reason put forward by the Defendants.

1. Where the panel decides to proceed under Article 33(3)(b) of the Agreement, the panel may stay the infringement proceedings under Rule 37.4 RoP pending a final decision in the revocation proceedings and shall stay the infringement proceedings if there is a strong likelihood that the final decision in the revocation proceedings will invalidate the relevant claims of the patent for any reason.

2. According to the timetable set by both the Central Division and the Local Division Munich, it is expected that a first instance decision of the UPC on validity will be available before the summer break. This decision can then be taken into account by this panel when considering the possibility of suspending the infringement proceedings pursuant to Art. 33.3.c UPC and Rule 37.4 RoP. Therefore, there is no need for this panel to consider now whether the defendants have demonstrated a strong likelihood that the relevant claims of the patent will be held invalid on any ground by the final decision in the revocation proceedings.

3. The date for the interim conference, currently scheduled for 01/07/2024, may be postponed to allow the Central Division the full six weeks to issue the written decision on validity. The Interim Conference may then be held with knowledge of the outcome and the written reasons.

4. The dates for the main oral hearing in the infringement action, currently 16/10/2024 and 17/10/2024, may be maintained for the time being.

5. If defendants 1-3 had wished to have the Local Division Munich decide exclusively on the validity arguments, they could have filed counterclaims for revocation pursuant to Rule 75 of the Rules of Procedure together with their Statement of Defence, in addition to the independent revocation actions already filed. If they had done so, the Local Division Munich would have been able to decide on all four counterclaims. The Central Division would have been obliged to stay the proceedings on the individual revocation actions pursuant to Rule 75(3) of the Rules of Procedure.

IV. In the exercise of its discretion, the Panel decides to proceed with the infringement proceeding, but reserves the right to reconsider the possibility of suspending the proceeding for any other reason put forward by the Defendants.

1. Under the Rules of Procedure, the panel has ample power to stay proceedings. The defendants have put forward many reasons, not directly related to the invalidity arguments, why this Panel should stay the infringement proceedings.

2. This Panel considers that the main question to be answered first is whether the patent is valid. If the patent was invalid, there would be no reason to consider the other issues. Therefore, it is





efficient to proceed with the infringement proceedings for the time being and to consider these other issues at a later stage.

ORDER

- 1) The Local Division Munich refers the counterclaim of the Defendant Regeneron Pharmaceuticals Inc. (CC\_586764/2023) to the Central Division for decision and proceeds with the infringement action (Art. 33.3.b UPCA).
- 2) The Local Division Munich reserves the right to reconsider the possibility of suspending the infringement action pursuant to Art. 33.3.c UPCA or to stay the proceedings for any other reason put forward by the Defendants.

INSTRUCTIONS TO THE JUDGE-RAPPORTEUR

- (1) The judge-rapporteur shall communicate to the Central Division the dates fixed for the interim conference and the oral hearing pursuant to Rule 28 RoP (Rule 37.5).
- (2) The judge-rapporteur may, after hearing the parties, consider postponing the interim conference.

<p>DR. ZIGANN PRESIDING JUDGE AND JUDGE-RAPPORTEUR</p>	<p><b>Matthias ZIGANN</b>  Digital unterschrieben von Matthias ZIGANN Datum: 2024.02.02 16:17:57 +01'00'</p>
<p>PICHLMAIER LEGALLY QUALIFIED JUDGE</p>	<p><b>Tobias Günther Pichlmaier</b>  Digital unterschrieben von Tobias Günther Pichlmaier Datum: 2024.02.03 14:54:58 +01'00'</p>
<p>GRANATA LEGALLY QUALIFIED JUDGE</p>	<p><b>Samuel Rocco M Granata</b>  Digitally signed by Samuel Rocco M Granata Date: 2024.02.03 15:23:34 +01'00'</p>
<p>DORLAND-GALLIOT TECHNICALLY QUALIFIED JUDGE</p>	<p><b>XAVIER THOMAS OLIVIER DORLAND</b>  Signature numérique de XAVIER THOMAS OLIVIER DORLAND Date : 2024.02.05 06:49:03 +01'00'</p>

INFORMATION FOR THE PARTIES AND THE REGISTRY

- 1) The Registry is requested to execute the referral of the counterclaim of Regeneron Pharmaceuticals Inc. (CC\_586764/2023) to the Central Division.
- 2) The next step in the infringement proceedings will be the filing of the Rejoinder to the Reply to the Defence (Rule 29.d RoP), due on 25/03/2024.

INFORMATION ABOUT APPEAL

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).

ORDER DETAILS

UPC number:	UPC_CFI_14/2023
Action number:	ACT_459916/2023
Counterclaim number:	CC_586764/2023
Order number:	ORD_392/2024
Order type:	R 37