



Appeal n°:
UPC_CoA_528/2024
UPC_CoA_529/2024

ORDER
of the Court of Appeal of the Unified Patent Court
issued on 18 February 2026
on an application for suspensive effect

APPLICANTS (RESPONDENTS BEFORE THE COURT OF APPEAL AND CLAIMANTS BEFORE THE COURT OF FIRST INSTANCE)

- 1. SANOFI-AVENTIS DEUTSCHLAND GMBH**, Brüningstrasse 50, 65926, Frankfurt am Main, Germany
- 2. SANOFI-AVENTIS GROUPE S.A.**, 82 Avenue Raspail, 94250 Gentilly, France
- 3. SANOFI WINTHROP INDUSTRIE S.A.**, 82 Avenue Raspail, 94250 Gentilly, France

hereinafter: ("**Sanofi**")

represented by Daniel Wise, attorney-at-law, Carpmaels & Ransford, London, The United Kingdom and other representatives from that law firm

and

Regeneron Pharmaceuticals Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, USA

hereinafter: ("**Regeneron**")

represented by Niels Hölder, attorney-at-law, Carpmaels & Ransford, London, United Kingdom, and other representatives from that law firm

RESPONDENT (APPELLANT BEFORE THE COURT OF APPEAL AND DEFENDANT BEFORE THE COURT OF FIRST INSTANCE)

AMGEN, INC, One Amgen Center Drive, CA 91320-1799, Thousand Oaks, USA

hereinafter: ("**Amgen**")

represented by represented by Koen Bijvank, attorney-at-law, Brinkhof N.V., Amsterdam, The Netherlands and representatives from Bardehle Pagenberg, Munich, Germany

PATENT AT ISSUE

EP 3 666 797

DECIDING JUDGES

Klaus Grabinski, President of the Court of Appeal

Nathalie Sabotier, legally qualified judge and judge-rapporteur

Peter Blok, legally qualified judge

LANGUAGE OF THE PROCEEDINGS

English

DECISION UNDER REVIEW

- Decision of the Court of Appeal of the Unified Patent Court dated 25 November 2025
- Numbers attributed by the Court of Appeal:
UPC_CoA_528/2024
UPC_CoA_529/2024

FACTS, REQUESTS AND SUBMISSIONS

1. On 1 June 2023, Sanofi brought a revocation action against the patent at issue before the Central Division, section Munich. On the same day, Amgen brought an infringement action based on the same patent before the Local Division Munich against Sanofi and Regeneron. Regeneron filed a counterclaim for revocation, which was subsequently, with the agreement of the parties, referred to the Central Division Munich, where it was joined to the pending revocation action lodged by Sanofi. The infringement action has been stayed.
2. On 16 July 2024, the Central Division Munich revoked the patent in its entirety and ordered Amgen to bear Respondents' legal costs.
3. Amgen timely lodged two appeals against this decision respectively regarding the counterclaim for revocation (UPC_CoA_529/2024) and the revocation action (UPC_CoA_528/2024).
4. On 25 November 2025, the Court of Appeal set aside the impugned decision, rejected the request for revocation of the patent at issue, ordered Sanofi and Regeneron (each separately) to pay Amgen a compensation for the costs of the first-instance proceedings, and ordered each of Sanofi and Regeneron (separately) to bear the costs of the appeal proceedings.
5. On 26 January 2026, Sanofi and Regeneron filed an application for rehearing. Together with this application for rehearing, Sanofi and Regeneron requested the Court of Appeal to order that the lodging of the application for rehearing has suspensive effect.
6. Sanofi and Regeneron argue that the decision dated 25 November 2025 was not based on grounds which had been submitted by the parties or introduced by an order of the Court of Appeal.

7. In this regard, Sanofi and Regeneron advance that the reasoning of the Court of Appeal on the interpretation of claim 1 of the patent at stake was not based on grounds submitted by the parties so they have been deprived of any possibility to challenge this reasoning. Sanofi and Regeneron also state that the assessment of inventive step of the same patent was based on a case law which was not available nor foreseeable at the date of the oral hearing, and that some of their relevant grounds (the routine pathway of the skilled person and the reasonable expectations of success) have been disregarded by the Court of Appeal. Sanofi and Regeneron add that the assessment of the argument of insufficient disclosure by the Court of Appeal was not based on grounds brought by the parties who did not have the opportunity to comment on the threshold defined by the decision dated 25 November 2025.
8. In case the Court of Appeal were to consider that the decision dated 25 November 2025 satisfies the requirements of Art. 76 UPCA, Sanofi and Regeneron request the referral of a question to the European Court of Justice.
9. In its reply dated 5 February 2026 to the Court of Appeal's request for comments, Amgen requested the Court of Appeal to dismiss the application for suspensive effect.
10. In substance, Amgen advances that a parallel may be drawn with appeals, which also do not have suspensive effect unless the Court decides otherwise (Art. 74(1) UPCA). For appeals, there is an explicit requirement that a request for suspensive effect is motivated (Art. 74(1) UPCA and Rule 223 RoP). The same should apply to an application for a rehearing, in particular as a successful one should be exceptional contrary to an appeal.
11. Amgen in this regard argues that the applicants have failed to provide any reasoning in support of their request and have therefore not explicitly substantiated it. In any case, Amgen argues that the applicants have not demonstrated the existence of circumstances justifying the grant of suspensive effect, in particular, that the impugned decision is manifestly erroneous or that, without the suspensive effect, the application would become devoid of purpose. Moreover, Amgen states that the arguments brought in support of the application for rehearing by Sanofi and Regeneron merely reflect their disagreement with the decision of the Court of Appeal, which does not constitute a valid ground nor for rehearing neither for suspensive effect. Amgen adds that, in the absence of suspensive effect, the application for rehearing would not be rendered devoid of purpose, as the applicants' products are still on the market and the hearing on the infringement action is scheduled in November 2026. Amgen also recalls that their comments on the request for rehearing the case are to be filed by 26 February 2026.

GROUND FOR THE ORDER

12. The application for suspensive effect is admissible but must be dismissed for the following reasons.
13. Pursuant to Art. 81(1)(b) UPCA, a request for rehearing after a final decision of the Court may exceptionally be granted by the Court of Appeal, notably, in the event of a fundamental procedural defect. According to R. 247.c RoP, a fundamental procedural defect under Art. 81(1) UPCA may have occurred, for example, where a fundamental violation of Art. 76 UPCA occurred in the proceedings which have led to the final decision.
14. R. 252 RoP states that the lodging of an application for rehearing does not have suspensive effect unless the Court of Appeal decides otherwise.

15. According to this provision, as a matter of principle, an application for rehearing has no suspensive effect. It is therefore for the applicant to provide the Court of Appeal with the specific circumstances of the case that would justify an exception to this principle, by way of analogy with Art. 74 (1) UPCA. An exception to the principle may apply, for instance, if the decision of the Court of Appeal was based on a manifest fundamental procedural defect.
16. In the present case, the Court of Appeal agrees with Amgen that the applicants failed to provide any argument in support of their application for suspensive effect of the lodging of the application for rehearing. In their statements, they merely presented arguments for a rehearing. They did not state that the alleged fundamental procedural defects are manifest. For that reason alone, the application must be dismissed.
17. In addition, the Court of Appeal fails to see any possibility to suspend the decision with regard to the validity of the patent.
18. It is recalled that the Court of First Instance revoked the patent and that, according to Art. 74(2) UPCA, an appeal against a decision on actions or counterclaims for revocation always have suspensive effect. As a result, following the appeal of this decision of the Court of First Instance, the patent at stake remained valid, as this decision has not been sent to any national office of the Contracting Members States pursuant to Art. 65(5) UPCA. The decision of the Court of Appeal dated 25 November 2025 rejected the requests for revocation and, eventually, did not modify anything in the situation of the parties. In other words, this decision of the Court of Appeal had no effect regarding the patent that could be suspended by the Court of Appeal seized with an application for rehearing.
19. If Sanofi and Regeneron seek a further stay of the infringement proceedings, this cannot be realized by means of an application for suspensive effect regarding the decision rejecting the requests for revocation.
20. For these reasons, the application for suspensive effect is rejected.

ORDER

The application for suspensive effect is rejected.

This order was issued on 18 February 2026.

Klaus Grabinski, President of the Court of Appeal

Nathalie Sabotier, legally qualified judge and judge-rapporteur

Peter Blok, legally qualified judge