



Reference no.:
App_9095/2025
UPC_CoA_166/2025

Order
of the Court of Appeal of the Unified Patent Court
issued on 18 April 2025
concerning an application for suspensive effect

APPLICANTS (DEFENDANTS IN THE PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE)

1. MERIL GMBH

Bornheimer Straße 135-137, 53119 Bonn, Germany

2. MERIL LIFE SCIENCES PVT LTD.

M1-M2, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396 191,
Gujarat, India

represented by attorney-at-law Dr. Andreas von Falck, assisted by representatives of the firms of
Hogan Lovells International LLP and Wildanger Kehrwald Graf von Schwerin & Partner

hereinafter together: Meril,

RESPONDENT (CLAIMANT IN THE PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE)

EDWARDS LIFESCIENCES CORPORATION

1 Edwards Way, Irvine, 92614 California, USA

represented by attorney-at-law Boris Kreye, assisted by representatives of the firms of Bird&Bird LLP,
Powell Gilbert LLP and Thum & Partner,

hereinafter: Edwards.

PATENT AT ISSUE

EP 3 646 825

PANEL AND DECIDING JUDGES

Panel 1:

Klaus Grabinski, president of the Court of Appeal
Peter Blok, legally qualified judge and judge-rapporteur
Emmanuel Gougé, legally qualified judge
Elisabetta Papa, technically qualified judge
Max Tilmann, technically qualified judge

LANGUAGE OF THE PROCEEDINGS

English

IMPUGNED DECISION OF THE COURT OF FIRST INSTANCE

Decision of the Munich Local Division, dated 15 November 2024, as rectified by the order of 17 February 2025

Reference numbers:

ACT_ 459987/2023
UPC_CFI_15/2023
ORD_ 598479/2023
ORD_ 68584/2024

FACTS AND REQUESTS OF THE PARTIES

1. Edwards is the proprietor of European patent 3 646 825 relating to a system comprising a prosthetic heart valve and a delivery catheter (hereinafter: the patent at issue).
2. On 1 June 2023, Edwards brought an infringement action against Meril before the Munich Local Division of the Court of First Instance, requesting inter alia an order prohibiting – in summary – the alleged infringement of the patent at issue by Meril (ACT_459987/2023 UPC_CFI_15/2023, hereinafter: the infringement action).
3. On 4 August 2023, Meril Italy Srl (hereinafter: Meril Italy) brought an action for revocation of the patent at issue against Edwards before the Central Division, Paris Seat (ACT_551308/2023 UPC_CFI_255/2023, hereinafter: the revocation action).
4. On 2 November 2023, Meril filed counterclaims for the revocation of the patent at issue in the infringement action (CC_584916/2023 and CC_585030/2023, hereinafter: the counterclaims for revocation).
5. By order dated 28 March 2024, the Munich Local Division referred the counterclaims for revocation to the Central Division, Paris Seat.
6. By decision of 19 July 2024, the Central Division, Paris Seat, rejected the revocation action and the counterclaims for revocation, and maintained the patent at issue in amended form.

7. Meril and Meril Italy lodged appeals against the decision of 19 July 2024, requesting – in summary – that the Court of Appeal set aside the impugned decision and revoke the patent at issue in its entirety.
8. On 15 November 2024, the Munich Local Division issued its decision in the infringement action (hereinafter: the impugned decision). It found that Meril had infringed the patent at issue and ordered Meril, inter alia, to cease and desist from infringing acts (order I), to communicate information (order IV), to recall infringing products (order V), to destroy infringing products (VI) and to pay preliminary damages (order IX). It also allowed Edwards to publish the Court's decision in five public media (order VII). The cease-and-desist order I.1 reads as follows, to the extent relevant to the application for suspensive effect:

I.1 Defendants are ordered to cease and desist with respect to a system comprising: a prosthetic heart valve comprising: a collapsible and expandable annular frame configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body; wherein the frame is made of a nickel-cobalt-chromium-molybdenum alloy and comprises a plurality of rows of angled struts, the angled struts joined to each other so as to form a plurality of rows of hexagonal cells, wherein the frame is made up entirely of hexagonal cells, and wherein each of the hexagonal shaped cells is defined by six struts, including: two opposing side struts extending parallel to a flow axis of the valve, a pair of lower angled struts, extending downwardly from respective lower ends of the side struts and converging toward each other, and a pair of upper angled struts extending upwardly from respective upper ends of the side struts and converging toward each other; and a delivery catheter comprising an inflatable balloon; wherein the prosthetic heart valve is crimped in its radially compressed state on the balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic heart valve at the desired deployment location, preferably within a native aortic valve, wherein the frame of the prosthetic heart valve does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from an inflow end or an outflow end of the frame for mounting the frame to the delivery catheter.

(independent claim 1 of the Patent-in-Suit as upheld),

from offering, placing on the market, using, or importing or storing it for the said purposes in Belgium, Bulgaria, Denmark, Germany, Estonia, Finland, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Portugal, Sweden and Slovenia

[...]

especially if the system contains

a) a transcatheter heart valve prosthesis with the designation "Myval Octacor" as shown below [...]

and/or

b) a delivery apparatus of the type "Navigator" and/or "Navigator Inception" as shown below [...]

9. On 15 January 2025, Meril lodged an appeal against the impugned decision, requesting – in summary – that the Court of Appeal set aside the impugned decision to the extent that Edwards' requests were granted, dismiss the action and order Edwards to bear the costs of the first instance proceedings and the appeal proceedings.
10. On 25 February 2025, Meril filed an application for suspensive effect of its appeal, or alternatively, for a stay of the enforcement of the impugned decision subject to the lodging of a guarantee by

Meril. The grounds for its application can be summarized as follows:

- i. The impugned decision is not enforceable, since the scope of the obligation to be complied with and the relevant point in time are not clear;
- ii. The impugned decision is manifestly erroneous.
 - The Court of First Instance violated fundamental principles of claim construction when construing the claim features “strut”, “side struts extending parallel to a flow axis”, and “cell”. In addition, the reasoning on claim construction is inconclusive and incomplete;
 - The Court of First Instance manifestly erred in the exercise of its discretion when assessing whether or not to render the decision under a condition subsequent pursuant to R. 118.2(a) of the Rules of Procedure of the Unified Patent Court (hereinafter: RoP) and when considering Meril’s defence based on public interest;
 - The Court of First Instance granted claims in respect of acts committed before 1 June 2023 for which it partially lacked jurisdiction, and which could also not be granted on substantive grounds;The impugned decision is based on the violation of fundamental procedural rights, in particular the right to be heard, for
 - failing to consider relevant statements and evidence submitted by Meril;
 - disregarding Meril’s arguments against Edwards’ claim to allow publication of the impugned decision;
 - disregarding Meril’s arguments against Edwards’ claim to award interim damages;
- iii. The appeal against the decision to allow Edwards to publish the impugned decision would become devoid of purpose if suspensive effect was not ordered;
- iv. Meril’s interests in maintaining the status quo prevail over Edwards’ interests in enforcing the impugned decision, because
 - the patent at issue will be revoked in the appeal against the decision of 19 July 2024;
 - the impugned decision has a severe impact on Meril and the public;
 - Edwards failed to comply with the enforcement requirements of R. 118.8 RoP;
 - similar harm to Meril was caused by Edwards by litigation concerning another patent (EP3583920B1) with a scope of protection partially overlapping that of the patent in suit.

11. Edwards responded to the application for suspensive effect, requesting that the application be dismissed in its entirety or, in the alternative, that the impugned decision remain enforceable subject to the provision of security by Edwards. The reasons can be summarized as follows:
- The scope of Meril’s obligations is clear, and Meril purports to have already complied with them;
 - The impugned decision is not manifestly erroneous;
 - There has been no violation of fundamental procedural rights;
 - The appeal has purpose even if the application is refused;
 - Edwards’ interests outweigh those of Meril.

GROUND FOR THE ORDER

12. Meril’s application for suspensive effect is admissible but must be dismissed as unfounded for the following reasons.
13. Pursuant to Article 74(1) of the Agreement on a Unified Patent Court (hereinafter: UPCA), an appeal shall not have suspensive effect unless the Court of Appeal decides otherwise at the motivated request of one of the parties. The Court of Appeal may therefore grant the application only if the circumstances of the case justify an exception to the principle that an appeal shall have no suspensive effect. It must be examined whether, on the basis of these circumstances, the appellant’s interest in maintaining the status quo until the decision on its appeal

exceptionally outweighs the respondent's interest. An exception to the principle that an appeal has no suspensive effect may apply, for instance, if the appealed order or decision is manifestly erroneous, or if the appeal becomes devoid of purpose in the absence of suspensive effect (Court of Appeal 19 June 2024, UPC_CoA_301/2024 APL_33746/2024 App_35055/2024 - ICPillar vs. ARM).

Appeal not devoid of purpose

14. Meril's argument that its appeal against the order allowing the publication of the impugned decision would become devoid of purpose in the absence of suspensive effect, must be rejected. Edwards declared that it has not published, and will not publish, the impugned decision pending the appeal. In the light of this commitment, Meril has failed to properly set out the reasons why the appeal, in this respect, must have suspensive effect. Meril has not demonstrated that granting suspensive effect is necessary to prevent Edwards from publishing the impugned decision. In addition, Meril has failed to show that the consequences of the publication of the decision as permitted by the Court of First Instance, i.e. the publication of the decision in its entirety or the full text of its "rubric" and operational part, could not be remedied if the appeal is successful.

No manifest errors

15. Whether the Court of First Instance's construction of the claims of the patent at issue, its refusal to render a conditional decision, its consideration of the public interest and its assessment of the claims in respect of acts committed before 1 June 2023 are correct and whether its reasoning is complete and conclusive, are matters to be decided by the Court of Appeal in its decision in the main appeal proceedings. In any event, Meril has failed to demonstrate that the Court of First Instance's findings and considerations constitute *manifest* errors, i.e. factual findings or legal considerations that are clearly untenable even on the basis of a summary assessment (Court of Appeal 29 October 2024, UPC_CoA_549/2024 APL_51838/2024 App_53031/2024 - Belkin vs. Philips).

Clarity of substantive scope of obligations

16. Meril also failed to demonstrate that the substantive scope of its obligations under the orders contained in the impugned decision is so unclear as to render those orders unenforceable. Indeed, there appears to be no lack of clarity, as the parties agree on the scope.

17. Meril argues that the use of the clause "and/or" in the reference to Meril's products in order number I.1 makes it unclear whether the order applies to a system comprising any type of transcatheter heart valve prosthesis, provided Meril's delivery apparatus Navigator/Navigator Inception is included in that system. However, Meril itself has not taken the position that the order must be interpreted in that way and has not submitted that it relied on this interpretation when carrying out the order. Edwards even expressly rejected such an interpretation. It acknowledged that a delivery device referred to in claim 1 of the patent at issue as upheld by the Central Division, such as Meril's Navigator or the Navigator Inception, only falls within the scope of the orders if it is used in conjunction with a prosthetic heart valve having all the relevant features of that claim, such as Meril's Myval Octacor.

Clarity of temporal scope of specific obligations

18. There is no need to determine the starting date of the time limit for compliance with the orders to provide information, to recall and destroy products and to pay preliminary damages. Meril did not file its application for suspensive effect before the expiry of the time limit as calculated by Edwards. Instead, as submitted by Meril and acknowledged by Edwards (application for suspensive effect, paragraphs 162 and 281; Response to Meril's application for suspensive effect, paragraphs 11 and 32), Meril carried out the orders within that time limit and then waited more than three months before filing its application for suspensive effect. In that light, Meril's application must be dismissed for failing to properly set out the reasons why the appeal in this respect should have suspensive effect.

Alleged violation of the right to be heard

19. Meril failed to demonstrate a manifest violation of fundamental procedural rights. Meril argues that the Court of First Instance violated its right to be heard by presenting a construction of the patent claims without considering the expert opinions of Professor Dasi and Dr. Mayer and without deciding on its request to appoint a court expert and to hear its own expert. Meril, however, failed to show that the impugned decision suffers from such a manifest lack of reasoning in this respect that the suspensive effect of its appeal would be justified. The mere fact that the Court of First Instance did not expressly address the expert opinions and did not expressly decide on Meril's requests to appoint and hear experts is not sufficient, since the Court may have implicitly addressed Meril's evidence and requests in the impugned decision.

20. The same applies to Meril's argument that the Court of First Instance disregarded its arguments against Edwards' requests for permission to publish the decision and for the award of interim damages. Meril has failed to demonstrate that the impugned decision suffers from such a manifest lack of reasoning in this respect as to justify the suspensive effect of its appeal. In addition, Meril failed to set out why the appeal should have suspensive effect in relation to the award of interim damages and the permission to publish the decision, given that Meril has already paid the interim damages and Edwards has declared that it has not published, and will not publish, the impugned decision in the media pending the appeal.

No overriding interest in maintaining the status quo

21. Meril's argument that the circumstances of the case weigh in favour of ordering suspensive effect, must be rejected.

22. Meril argues, firstly, that the patent at issue will be revoked in its entirety in the pending appeal against the Central Division's decision of 19 July 2024. The mere fact that an appeal is pending against a decision concerning an action and counterclaims for revocation is, however, not sufficient to order suspensive effect of the appeal against the decision in the related infringement action.

23. Secondly, Meril argues that the impugned decision causes severe economic harm to Meril and the public. These alleged harms were taken into account by the Court of First Instance in its decision to grant the orders. Edwards' interest in the enforcement of the impugned decision pending appeal must therefore, as a general rule, be deemed to outweigh the interests invoked by Meril. An exception may apply if the decision is manifestly erroneous in this respect, but that

is not the case here. Meril has also failed to set out why the appeal must have suspensive effect in relation to the orders to communicate information, to recall products, to destroy products and to pay interim damages, in the light of the fact that Meril already carried out these orders. The fact that Meril carried out the orders following “enforcement pressure” by Edwards does not alter that.

24. The fact that, following the impugned decision, Edwards contacted distributors of Meril’s products, does not lead to a different assessment, since the impugned decision does not apply to these third parties. Suspensive effect will therefore not alter the legal position of these parties.
25. The fact that the Technical Board of Appeal revoked another patent owned by Edwards after Edwards had initiated infringement proceedings against Meril and local distributors, does not lead to a different assessment either.
26. Meril’s argument that the performance of clinical studies is affected by the injunction, must be rejected for lack of substantiation. Meril did not specify which studies are jeopardized by the impugned decision.

No stay subject to security

27. Meril’s alternative request for a stay of the enforcement of the impugned decision against payment of a security by Meril, must be dismissed. Meril failed to provide a proper legal basis for this request. It refers to R. 223.1 and R. 352.1 RoP. However, these provisions concern the suspensive effect of an appeal and the binding effect of decisions and orders, not the stay of the enforcement of decisions and orders.
28. Even if it were assumed that there is a legal basis for a stay of enforcement subject to the provision of security, the grounds put forward by Meril do not justify such a stay in the present case. As considered above, the general rule under Art. 74 UPCA is that decisions are enforceable pending appeal. Meril has failed to demonstrate that an exception to this rule should apply in this case. The provision of security by Meril does not alter this assessment, as the refusal to suspend or stay enforcement is not based on concerns regarding Meril’s ability to pay damages to Edwards.

Conclusion

29. It follows that Meril’s requests must be rejected. Edwards’ alternative request can therefore remain undecided.
30. The Court of Appeal will not decide on costs in this order, since it does not constitute an order concluding the actions.

ORDER

The application is rejected.

This order was issued on 18 April 2025.

Klaus Grabinski President of the Court of Appeal	
Peter Blok Legally qualified judge and judge-rapporteur	
Emmanuel Gougé Legally qualified judge	
Elisabetta Papa Technically qualified judge	
Max Tilmann Technically qualified judge	