Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Reference no.:

APL_45049/2024 UPC_CoA_464/2024	APL_51701/2024 UPC_CoA_530/2024	APL_1926/2025 UPC_CoA_21/2025
APL_44701/2024 UPC_CoA_457/2024	APL_51746/2024 UPC_CoA_532/2024	APL_2205/2025 UPC_CoA_27/2025
APL_44702/2024 UPC_CoA_458/2024	APL_51748/2024 UPC_CoA_533/2024	

Decision

of the Court of Appeal of the Unified Patent Court
concerning EP 3 646 825
issued on 25 November 2025

HEADNOTE

Competence

1. The concept of the "same parties" of Art. 33(4) UPCA must be understood as requiring the parties to be identical. There may be such a degree of identity between the interests of two legal entities that a judgment delivered against one of them would have the force of *res judicata* as against the other. In such a situation, the entities must be considered to be one and the same party for the purposes of the application of Art. 33(4) second sentence UPCA.

Admissibility of application to amend the patent

2. Under R. 49.2 RoP, the Defence to revocation may include an application to amend the patent. Pursuant to R. 50.2 in conjunction with R. 30.2 RoP, a subsequent request to amend the patent may only be admitted into the proceedings with the permission of the Court. When deciding on a subsequent request to amend the patent, the Court must take into account all the relevant circumstances of the case, including whether the party seeking the subsequent amendment is able to justify that i) the amendment in question could not have been made with reasonable diligence at an earlier stage, and ii) the amendment will not unreasonably hinder the other party in the conduct of the action. The Court of First Instance has a margin of discretion in this respect. The review by the Court of Appeal is therefore limited.

Claim construction

3. As a general rule, a product or process presented as an embodiment by the patent specification may be considered covered by the patent claims. However, there is room for an exception where the patent as a whole clearly teaches the person skilled in the art that the disclosed embodiment is not claimed, e.g. when it only illustrates a technical specification that is not addressed by the teaching of the patent claim.

Inventive step

4. A European patent is only validly granted for an invention if – apart from other requirements – it involves an inventive step. An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art (Art. 56 EPC).

5. National courts of the various EPC countries have different approaches and use different guidelines when assessing whether an invention involves an inventive step. One of those approaches is the so-called 'problem-solution-approach' used by the European Patent Office (EPO) and the Technical Boards of Appeal (TBA) of the EPO. In some jurisdictions, such as France, Italy, The Netherlands and Sweden, this approach is applied as well, but not necessarily as the only possible approach. In other jurisdictions, such as Germany and the UK, other approaches – sometimes referred to as more 'holistic' – are used. Despite the differences in approach, all of these are merely guidelines to assist in the establishment of inventive step as required by Art. 56 EPC, that, when properly applied, should and generally do lead to the same conclusion.

6. The burden and presentation of proof with regard to the facts from which the lack of validity of the patent is derived and other circumstances favourable to the invalidity or revocation lies with the claimant in a revocation action (Art. 54 and 65(1) UPCA, R. 44(e)-(g), 25.1(b)-(d) RoP). Even though proof of certain facts, if contested, may be required, the assessment of the relevant facts and circumstances is a question of law.

7. The approach taken by the Unified Patent Court when establishing inventive step, which can already be derived from the Order of the Court of Appeal in the Nanostring v 10X Genomics case (UPC_CoA_335/2023, Order of 26 February 2024), is as follows.

8. It first has to be established what the object of the invention is, i.e. the objective problem. This must be assessed from the perspective of the person skilled in the art, with their common general knowledge, as at the application or priority date (also referred to as the effective date) of the patent. This must be done by establishing what the invention adds to the state of the art, not by looking at the individual features of the claim, but by comparing the claim as a whole in the context of the specification and the drawings, thus also considering the inventive concept underlying the invention (the technical teaching), which must be based on the technical effect(s) that the person skilled in the art, on the basis of the application, understands is (are) achieved with the claimed invention.

9. In order to avoid hindsight, the objective problem should not contain pointers to the claimed solution. The claimed solution is obvious when at the effective date the person skilled in the art, starting from a realistic starting point in the state of the art in the relevant field of technology and wishing to solve the objective problem, would (and not only "could") have arrived at the claimed solution.

10. The relevant field of technology is the specific field relevant to the objective problem to be solved as well as any field in which the same or similar problem arises and of which the person skilled in the art in the art of the specific field must be expected to be aware.

11. A starting point is realistic if the teaching thereof would have been of interest to a person skilled in the art who, at the effective date, wishes to solve the objective problem. This may for instance be the case if the relevant piece of prior art already discloses several features similar to those relevant to the invention as claimed and/or addresses the same or a similar underlying problem as that of the claimed invention. There can be more than one realistic starting point, and the claimed invention must be inventive starting from each of them.

12. The person skilled in the art has no inventive skills and no imagination and requires a pointer or motivation (in German: "*Anlass*") that, starting from a realistic starting point, directs them to implement a next step in the direction of the claimed invention. As a general rule, a claimed solution must be considered not inventive/obvious when the person skilled in the art would take the next step, prompted by the pointer or as a matter of routine, and arrive at the claimed invention.

13. For an inventive step to be present, it is not necessary to show improvement of the technical teaching as defined by the patent claims over the prior art. Inventive step may also be found if the patent claims disclose a non-obvious alternative to solutions known in the prior art.

Permanent injunctions

14. Where the proprietor files an infringement action and the Court finds that an intellectual property right has been infringed or is threatened to be infringed, it shall issue an order prohibiting the continuation of the infringement unless there are special reasons for not doing so.

15. A special reason for denying an injunction may apply if, in the circumstances of the particular case, granting an injunction does not comply with the general obligations of Art. 3 of the Enforcement Directive, in particular the obligation that the remedies shall be proportionate.

16. When considering the proportionality of injunctive relief and corrective measures, not only the interests of the parties to the litigation but also the interests of third parties, such as patients, may be taken into account.

Interim award of costs

17. As a general rule, Art. 69(1) UPCA and R. 150(2) RoP do not entitle the successful party to an interim reimbursement of representation costs of more than 50% of the ceiling of recoverable costs as adopted by the Administrative Committee under R. 152.2 RoP.

KEYWORDS
Appeal; competence of the divisions; amendments of the patent; added matter; novelty; inventive step; scope of protection; permanent injunctions; interim award of costs

APPELLANT IN APPEAL 45049/2024 AND RESPONDENT IN APPEAL 51701/2024 (CLAIMANT IN PROCEEDINGS 551308/2023 BEFORE THE COURT OF FIRST INSTANCE)

Meril Italy Srl, Milan, Italy

represented by attorney-at-law Emmanuel Larere, Cabinet Gide Loyrette Nouel, and other representatives of that firm

APPELLANT IN APPEALS 44701/2024 AND 1926/2025 AND RESPONDENT IN APPEALS 51746/2024 AND 2205/2025 (DEFENDANT IN PROCEEDINGS 459987/2023 AND COUNTERCLAIMANT IN PROCEEDINGS 584916/2023 BEFORE THE COURT OF FIRST INSTANCE)

Meril GmbH, Bonn, Germany

represented by attorney-at-law Dr Andreas von Falck, Hogan Lovells International LLP, and other representatives of that firm

APPELLANT IN APPEALS 44702/2024 AND 1926/2025 AND RESPONDENT IN APPEALS 51748/2024 AND 2205/2025 (DEFENDANT IN PROCEEDINGS 459987/2023 AND COUNTERCLAIMANT IN PROCEEDINGS 585030/2023 BEFORE THE COURT OF FIRST INSTANCE)

Meril Life Sciences Pvt Ltd., Muktanand Marg, Chala, Vapi, Gujarat, India

represented by attorney-at-law Dr Andreas von Falck, Hogan Lovells International LLP, and other representatives of that firm

the appellants in the three appeals are hereinafter referred to individually as Meril Italy, Meril Germany and Meril India, and jointly as "**Meril**",

APPELLANT IN APPEALS 51701/2024, 51746/2024, 51748/2024 AND 2205/2025 AND RESPONDENT IN APPEALS 45049/2024, 44701/2024, 44702/2024 AND 1926/2025 (CLAIMANT IN PROCEEDINGS 459987/2023, DEFENDANT IN PROCEEDINGS 551308/2023 AND COUNTERDEFENDANT IN PROCEEDINGS 584916/2023 AND 585030/2023 BEFORE THE COURT OF FIRST INSTANCE)

Edwards Lifesciences Corporation, Irvine, California, USA

represented by attorneys-at-law Elsa Tzschoppe and Boris Kreye, Bird&Bird, and other representatives of that firm

hereinafter referred to as "**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

DATE OF THE ORAL HEARING
4 and 5 September 2025

IMPUGNED ORDERS AND DECISIONS OF THE COURT OF FIRST INSTANCE

I. Order of the Central Division, Paris Seat, dated 13 November 2023
Reference numbers:

Appeal no.	Court of First Instance no.
APL_51701/2024 UPC_CoA_530/2024	App_572915/2023 ACT_551308/2023 UPC_CFI_255/2023 ORD_578356/2023

II. Order of the Central Division, Paris Seat, dated 30 April 2024
Reference numbers:

Appeal no.	Court of First Instance no.
APL_45049/2024	App_19959/2024 and App_23242/2024

UPC_CoA_464/2024	ACT_551308/2023 UPC_CFI_255/2023 ORD_24620/2024

III. Decision of the Central Division, Paris Seat, in three actions, dated 19 July 2024
Reference numbers:

Appeal no.	Court of First Instance no.
APL_45049/2024 UPC_CoA_464/2024 APL_51701/2024 UPC_CoA_530/2024	ACT_551308/2023 UPC_CFI_255/2023 ORD_598365/2023
APL_44701/2024 UPC_CoA_457/2024 APL_51746/2024 UPC_CoA_532/2024	CC_584916/2023 ORD_598366/2023
APL_44702/2024 UPC_CoA_458/2024 APL_51748/2024 UPC_CoA_533/2024	CC_585030/2023 ORD_598367/2023

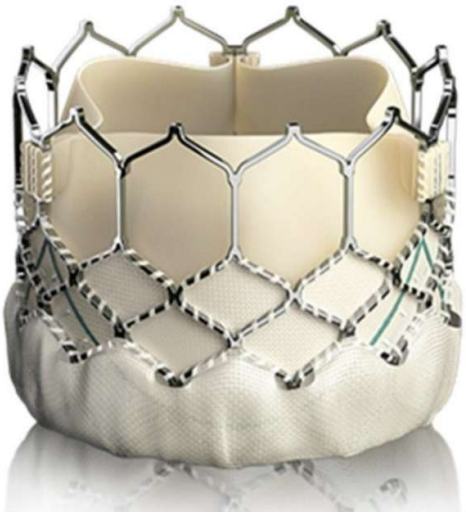
IV. Decision of the Munich Local Division, dated 15 November 2024
Reference numbers:

Appeal no.	Court of First Instance no.
APL_1926/2025 UPC_CoA_21/2025 APL_2205/2025 UPC_CoA_27/2025	ACT_459987/2023 UPC_CFI_15/2023 ORD_598479/2023

FACTS AND REQUESTS OF THE PARTIES

Edwards

1. Edwards is the parent company of the Edwards Lifesciences Group, which develops and manufactures, among other things, artificial heart valves and related accessories, including the SAPIEN 3 as shown below.



The patent at issue

2. Edwards is the registered proprietor of European patent 3 646 825 relating to a system comprising a prosthetic heart valve and a delivery catheter ("the patent"). The patent is a divisional application of EP 3 205 308 ("the parent application"), which in turn was filed as a divisional application of EP 2 731 552 ("the grandparent application"). The grandparent application was filed on 16 July 2012 as an international application, which was published as WO 2013/012801 ("WO 801"). The patent claims priority from the applications US 201161508456 of 15 July 2011 ("P1") and US 20123549068 of 13 July 2012 ("P2"). The date of publication and mention of the grant of the patent is 17 March 2021.

3. Claim 1 of the patent as granted reads as follows (the numbering of the features has been added by the Court in accordance with the numbering used by the parties):

1. A system comprising:

1.1 a prosthetic valve (100) comprising:

1.2 a collapsible and expandable annular frame (102), 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;

1.3 wherein the frame (102) comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114),

1.4 the angled struts (114) joined to each other so as to form a plurality of rows of hexagonal cells,

1.5 wherein the frame (102) is made up entirely of hexagonal cells, and

1.6 wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:

1.7 two opposing side struts (144) extending parallel to a flow axis of the valve (100),

1.8 a pair of lower angled struts (146), extending downwardly from respective lower ends of the side struts (144) and converging toward each other, and

1.9 a pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and

1.10 a delivery catheter comprising an inflatable balloon;

1.11 wherein the prosthetic valve (100) 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 valve (100) at the desired deployment location, preferably within a native aortic valve.

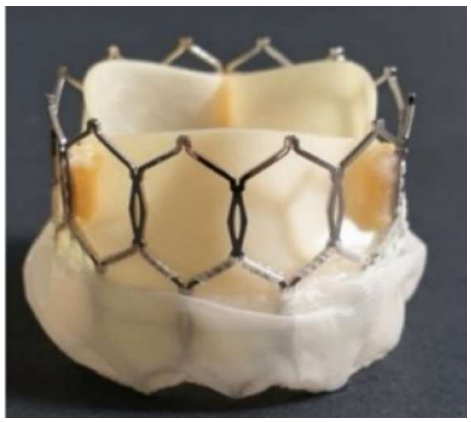
Meril

4. Meril India is a global medical device company. Meril Germany and Meril Italy are subsidiaries of Meril India. Meril Germany is responsible for the distribution of Meril India's products across Europe.

5. In 2019, Meril India launched the transcatheter heart valve as shown below under the name "Myval" in combination with a delivery system named "Navigator" and a crimper called "Val-de-Crimp (neo)".

These products have been the subject matter of various patent infringement proceedings between the parties and cease-and-desist undertakings.

6. More recently, Meril India attempted to enter the market with the modified transcatheter heart valve called "Myval Octacor" and the related "Navigator" and "Navigator Inception" delivery systems shown below.



Octacor

Navigator

Navigator Inception

The actions and the appeals

7. On 1 June 2023, Edwards brought an infringement action against Meril India and Meril Germany before the Munich Local Division, requesting *inter alia* an order prohibiting – in summary – the alleged infringement of the patent by Meril India and Meril Germany (ACT_459987/2023 UPC_CFI_15/2023) ("the infringement action").

8. On 4 August 2023, Meril Italy brought an action for revocation of the patent against Edwards before the Central Division, Paris Seat ("the Central Division") (ACT_551308/2023 UPC_CFI_255/2023) ("the direct revocation action").

9. Edwards filed a preliminary objection in the direct revocation action, challenging the competence of the Central Division on the grounds that an infringement action between the same parties on the same patent was already pending before the Munich Local Division (App_572915/2023 UPC_CFI_255/2023). By order of 13 November 2023, the Central Division rejected the preliminary objection (ORD_578356/2023) ("the impugned competence order").

10. On 16 October 2023, Edwards filed an application to amend the patent in the direct revocation action, consisting of a main request to uphold the patent as granted and 84 auxiliary requests ("the first application to amend the patent"). By order of 21 December 2023, the judge-rapporteur decided that the admissibility of the first application to amend the patent would be examined together with the merits of the case.

11. On 2 November 2023, Meril India and Meril Germany filed counterclaims for revocation of the patent in the infringement action (CC_584916/2023 and CC_585030/2023) ("the counterclaims for revocation"). On 9 January 2024, Edwards submitted its Statement of defence to the counterclaims and an application to amend the patent, consisting of a main request and 41 auxiliary requests (App_911/2024 and 919/2024).

12. On 22 January 2024, Edwards lodged a second application to amend the patent in the direct revocation action, consisting of the same main request and 41 auxiliary requests filed in the proceedings relating to the counterclaims for revocation (see above, para. 11). By order of 27 February 2024, the Central Division

declared this second application inadmissible. Edwards' request for leave to appeal was refused by the Central Division. Its request for discretionary review was rejected by the Court of Appeal by order of 28 March 2024 (APL_13220/2024, UPC_CoA_113/2024).

13. By order of 28 March 2024, the Munich Local Division referred the counterclaims for revocation to the Central Division.

14. On 11 April 2024, Edwards lodged its Statement of reply relating to its application to amend the patent in the proceedings relating to the counterclaims. In this statement, Edwards requested permission to limit its application to amend to the main request and auxiliary requests 1, 10, 13, 24, 33 and 41. It indicated that it maintained its application to amend the patent with all 41 auxiliary requests should the Court not permit the more limited application.

15. On 12 April 2024, Edwards lodged a third application to amend the patent in the direct revocation action, consisting of the same main request and six auxiliary requests filed in the proceedings relating to the counterclaims for revocation (see above, para. 14) ("the third application to amend the patent"). By the order of 30 April 2024, the Central Division granted the application ("the impugned claim amendment order"). Claim 1 of the patent in accordance with the main request of the third application to amend the patent reads as follows ("the Main Request") (the amendments in respect of the claim as granted have been underlined):

1. A system comprising:

1.1 a prosthetic heart valve (100) comprising:

1.2 a collapsible and expandable annular frame (102), 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;

1.3 wherein the frame (102) comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114),

1.4 the angled struts (114) joined to each other so as to form a plurality of rows of hexagonal cells,

1.5 wherein the frame (102) is made up entirely of hexagonal cells, and

1.6 wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:

1.7 two opposing side struts (144) extending parallel to a flow axis of the valve (100),

1.8 a pair of lower angled struts (146), extending downwardly from respective lower ends of the side struts (144) and converging toward each other, and

1.9 a pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and

1.10 a delivery catheter comprising an inflatable balloon;

1.11 wherein the prosthetic heart valve (100) 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 (100) at the desired deployment location, preferably within a native aortic valve.

Claim 1 of auxiliary request I of the third application to amend the patent ("Auxiliary Request I") is identical to claim 1 of the Main Request. The only difference between the Auxiliary Request I and the Main Request is the deletion of several dependent claims.

Claim 1 of auxiliary request II of the third application to amend the patent ("Auxiliary Request II") reads as follows (the amendments in respect of the claim as granted have been underlined):

1. A system comprising:

1.1 a prosthetic heart valve (100) comprising:

1.2 a collapsible and expandable annular frame (102), 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;

1.3 wherein the frame (102) is made of a nickel-cobalt-chromium-molybdenum alloy and comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114),

1.4 the angled struts (114) joined to each other so as to form a plurality of rows of hexagonal cells,

1.5 wherein the frame (102) is made up entirely of hexagonal cells, and

1.6 wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:

1.7 two opposing side struts (144) extending parallel to a flow axis of the valve (100),

1.8 a pair of lower angled struts (146), extending downwardly from respective lower ends of the side struts (144) and converging toward each other, and

1.9 a pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and

1.10 a delivery catheter comprising an inflatable balloon;

1.11 wherein the prosthetic heart valve (100) 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 (100) at the desired deployment location, preferably within a native aortic valve;

1.12 wherein the frame (102) of the prosthetic heart valve (100) 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 (108) or an outflow end (110) of the frame (102) for mounting the frame (102) to the delivery catheter.

16. By decision of 19 July 2024, the Central Division partially rejected the direct revocation action and the counterclaims for revocation and maintained the patent as amended by Auxiliary Request II ("the impugned revocation decision"). It ordered that the costs of the proceedings be borne by Meril in the amount of 60% and by Edwards for the remaining fraction.

17. Meril Italy lodged an appeal against the impugned claim amendment order and the impugned revocation decision, requesting – in summary – that the Court of Appeal set aside the order and the part of the decision rejecting the revocation of the patent according to Auxiliary request II to VI and revoke the patent in its entirety. Meril India and Meril Germany also lodged appeals against the impugned

revocation decision, requesting – in summary – that the Court of Appeal set aside the decision to the extent that the patent was not revoked.

18. Edwards lodged an appeal against the impugned competence order and the impugned revocation decision, requesting – in summary – that the Court of Appeal set aside the order and the part of the decision granting the revocation of the patent according to the Main Request and Auxiliary Request I and reject the direct revocation action as inadmissible or, alternatively, maintain the patent in the version of Edwards' Main Request or Auxiliary Request I and dismiss the remainder of the direct revocation action and counterclaims for revocation.

19. Meril's request for expedition of the appeal proceedings concerning the impugned revocation decision was rejected by the Court of Appeal by order of 6 September 2024.

20. On 15 November 2024, the Munich Local Division issued its decision in the infringement action ("the impugned infringement decision"). It found that Meril India and Meril Germany had infringed the patent as upheld by the Central Division and ordered them *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 interim 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 on appeal:

    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.

    […]

    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 […]

21. On 15 January 2025, Meril India and Meril Germany lodged an appeal against the impugned infringement decision, requesting – in summary – that the Court of Appeal set aside the 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.

22. In parallel, Edwards lodged an appeal against the impugned infringement decision, requesting – in summary – that the Court of Appeal set aside the decision to the extent that the injunction does not extend to the territory of Romania.

23. Following a request by Meril India and Meril Germany (App_66551/2024), the Munich Local Division issued an order partially rectifying the impugned infringement decision on 17 February 2025 (ORD_68584/2024). References to the impugned infringement decision below are references to the impugned infringement decision as rectified by the order of 17 February 2025.

24. On 25 February 2025, Meril India and Meril Germany filed an application for suspensive effect of their appeal, or alternatively, for a stay of the enforcement of the impugned infringement decision subject to the lodging of a guarantee. By order of 18 April 2025, the Court of Appeal dismissed the application.

REASONS FOR THE DECISION

Procedural issues

Admissibility of the appeals

25. All appeals filed against the impugned competence order, the impugned claim amendment order, the impugned infringement decision and the impugned revocation decision are admissible.

26. Meril India and Meril Germany's argument that Edwards' appeal against the impugned infringement decision is inadmissible for a lack of legal interest is rejected. They note that Edwards requests that the decision be set aside to the extent that the injunction does not extend to the territory of Romania, but failed to request that Romania be added to the list of countries in which the injunction takes effect. However, the request to set aside the impugned infringement decision to the extent that the injunction does not extend to the territory of Romania clearly implies the request to include Romania under the territorial scope of the injunction. Therefore, Edwards obviously has a legitimate interest in the appeal.

Admissibility of the direct revocation action

27. Edwards' appeal against the impugned competence order must be dismissed. The Central Division correctly concluded that it was competent to hear the direct revocation action pursuant to Art. 33(4) first sentence UPCA, under which revocation actions shall be brought before the Central Division.

28. Edwards' reference to Art. 33(4) second sentence UPCA cannot alter this assessment. Under this provision, if an infringement action between the same parties relating to the same patent has been brought before a local or regional division, actions for revocation may only be brought before the same local division or regional division. The concept of the "same parties" must be understood as requiring the parties to be identical. There may be such a degree of identity between the interests of two legal entities that a judgment delivered against one of them would have the force of *res judicata* as against the other. In such a situation, the entities must be considered to be one and the same party for the purposes of the application of Art. 33(4) second sentence UPCA.

29. This interpretation of the concept of the "same parties" is similar to the interpretation of the concept of the "same parties" of Art. 29 Brussels Reg I bis, which has a comparable purpose, namely to prevent parallel proceedings and to avoid conflicts between decisions which might result therefrom (see, for Art. 29 Brussels Reg I bis, ECJ 6 December 1994, Tatry, C-406/92, ECLI:EU:C:1994:400, paragraph 32).

30. It follows that the requirements of Art. 33(4) second sentence UPCA are not met in the present case. The parties to the direct revocation action and the infringement action are not the same. Meril Italy is not the same legal entity as Meril India or Meril Germany. There is not such a degree of identity between their interests that a judgment delivered against one of them would have the force of *res judicata* as against the other.

31. This interpretation may result in fragmentation of the proceedings. However, the UPCA and RoP offer the Court a number of instruments to mitigate this disadvantage, e.g. by referring the counterclaims for revocation to the Central Division (Art. 33(3)(b) UPCA), as the Munich Local Division has done in the present proceedings.

32. Edwards failed to demonstrate facts and circumstances supporting its argument that the initiation of the direct revocation action before the Central Division constituted an abuse of right. It argues that Meril Italy filed the direct revocation action with the intention to frustrate the proper administration of the proceedings in the infringement action. However, Meril Italy was established before the commencement of the infringement action and runs the business of distributing Meril's products in Italy. It therefore had a legitimate own interest in bringing a revocation action in anticipation of Edwards' potential actions against Meril Italy.

Admissibility of the patent claim amendments

33. The third application to amend the patent which Edwards submitted in the direct revocation action, comprising the Main Request and six auxiliary requests, is admissible. The objections which Meril Italy raised in the context of its appeal against the patent claim amendment order must be dismissed for the following reasons.

34. Under R. 49.2 RoP, the Defence to revocation may include an application to amend the patent. Pursuant to R. 50.2 in conjunction with R. 30.2 RoP, a subsequent request to amend the patent may only be admitted into the proceedings with the permission of the Court. When deciding on a subsequent request to amend the patent, the Court must take into account all the relevant circumstances of the case, including whether the party seeking the subsequent amendment is able to justify that i) the amendment in question could not have been made with reasonable diligence at an earlier stage, and ii) the amendment will not unreasonably hinder the other party in the conduct of the action. The Court of First Instance has a margin of discretion in this respect. The review by the Court of Appeal is therefore limited.

35. In the present case, the claim amendment order, permitting the patent claim amendments proposed by Edwards in its third application of 12 April 2024, remained within the boundaries of the discretion of the judge-rapporteur.

36. Edwards could not reasonably have introduced the amendments at an earlier stage. Edwards explained that the purpose of the amendments is to present a single set of requests in the direct revocation action and the counterclaims for revocation. This is a legitimate purpose which also serves the interest of procedural economy. Edwards could not have done so at the time of filing its Defence to revocation, since Meril India and Meril Germany had not yet lodged their counterclaims for revocation at that point in time. Once the counterclaims for revocation were filed, Edwards introduced an aligned set of requests in the direct revocation action and the counterclaims for revocation by means of its second application of 22 January 2024. The second application was however rejected by the Central Division. Following the suggestion of the judge-rapporteur to limit the number of auxiliary requests, Edwards submitted its third application, reducing the requests to the Main Request and six auxiliary requests, without adding new ones. As all the requests of the third application to amend the patent had already been submitted by the second application, Meril Italy's complaint that the request should have been submitted earlier is unfounded.

37. Nor did the third application unreasonably hinder Meril Italy in the conduct of the direct revocation action. Meril Italy was given the opportunity to respond to the requests submitted by Edwards' third application in writing within one month from the date of the claim amendment order, by which the judge-rapporteur permitted the third application to amend the patent (more than four months from the date of submission of the second application by which the requests were first introduced into the proceedings). In addition, Meril Italy had the opportunity to discuss the requests at the oral hearing. The grant of the third application did not result in a rescheduling of the oral hearing or any other delay either.

38. Meril Italy's argument that Edwards' third application should have been dismissed because the first application was inadmissible cannot succeed. R. 30.2 RoP does not require that the Court refuse any subsequent request to amend the patent for the mere reason that an earlier request was inadmissible. Whether the first application was admissible can therefore remain undecided.

39. The third application does not constitute a violation of the order of 22 March 2024 by which the judge-rapporteur invited the parties to explore the possibility to reach an agreement on a possible alternative set of amendments. Such an invitation does not limit the right of a party to file applications for patent claim amendments.

40. The admissibility of Edwards' third application to amend the patent is not called into question by Meril Italy's contention that Edwards' previous applications have caused it a lot of work. The work done on the previous applications is not relevant to the admissibility of the third application. Submitting a very large number of auxiliary requests may, however, have consequences for the cost decision. For instance, the costs the claimant in a revocation action has incurred for its defence to the application to amend the patent may, under circumstances, be considered unnecessary costs within the meaning of Art. 69(3) UPCA if the patentee withdraws a substantial number of the auxiliary requests in the course of the proceedings. Similarly, if the patent is maintained in amended form, the Court may order that costs be apportioned equitably pursuant to Art. 69(2) UPCA where a number of auxiliary requests were found to be invalid, as the Central Division has done in the impugned revocation decision. There is no need to assess whether the submission of the first and second applications to amend the patent in the present case supports a different allocation of costs than the one ordered by the Central Division since this was not argued by Meril Italy.

Combined reasoning

41. The Central Division correctly considered that the action for revocation by Meril Italy and the counterclaims for revocation by Meril India and Germany are separate actions and must be adjudicated separately even though the decision in the actions is issued in a single document. The same applies to the appeals against the revocation decision. Still, Meril Italy and Meril India and Meril Germany submitted highly similar arguments. The Court of Appeal will therefore give a combined reasoning for its decision on the appeals against the impugned revocation decision.

Right to be heard

42. Meril complains that the Central Division and Munich Local Division violated its right to be heard (Art. 76(2) UPCA and Art. 6 ECHR) and the rule that decisions of the Court be reasoned (Art. 77(1) UPCA and R. 350 RoP) by not expressly discussing some of its arguments and evidence, such as expert opinions.

43. The Court must consider all arguments brought forward by the parties, but it is, however, not required to expressly and exhaustively address in its order or decision each and every argument advanced by a party in detail in the order or decision. The Court may disregard arguments that are irrelevant or obviously flawed or dismiss an argument implicitly, e.g. when its dismissal follows from the further considerations of the Court. That applies even more to arguments advanced in exhibits, such as expert opinions (UPC_CoA_402/2024, decision of 19 June 2025, para. 22).

44. On the basis of this standard, there has been no violation of the right to be heard. The Central Division and Munich Local Division have given reasoned decisions. They may not have expressly discussed each of Meril's arguments, but that does not mean that it insufficiently addressed those arguments. For instance, Meril complains that the Central Division did not discuss the embodiment shown in Figures 44 and 45 of Levi in the context of its assessment of novelty and inventive step. The Central Division did, however, extensively discuss novelty and inventive step of the patent in respect of the embodiment shown in Figures 1-10 of Levi. Meril failed to show that the overall reasoning of the first instance decision does not apply as well to the second embodiment. Therefore, the dismissal of Meril's argumentation relating to the embodiment shown in Figures 44 and 45 follows from the dismissal of the argumentation regarding the embodiment shown in Figures 1-10 of Levi. Similarly, Meril India and Meril Germany complain that the Munich Local Division did not discuss or mention some of their expert opinions in the context of *inter alia* the interpretation of the claim elements "strut" and the perception of the Myval Octacor by the person skilled in the art. The Munich Local Division, however, did discuss the main arguments in support of which Meril India and Meril Germany submitted the expert opinions.

45. Furthermore, the Court of Appeal has taken all the allegedly disregarded arguments and evidence into account in deciding the appeals. To the extent that the Court of First Instance has not adequately addressed some of the issues in the impugned decisions, this is resolved by the present decision of the Court of Appeal.

Admissibility of submissions

46. In the context of its appeal against the impugned revocation decision, Edwards argues that the Court of Appeal must disregard a number of grounds for revocation which Meril introduced in their Statement of reply at first instance (see section D of Edwards' Statement of grounds of appeal in APL_51746/2024 and APL_51748/2024 and section F of Edwards' Statement of grounds of appeal in APL_51701/2024). This objection can remain undecided. The Central Division's decision to partially revoke the patent, against which Edwards has appealed, was not based on the grounds for revocation to which Edwards objects, but on the issue of added matter, which Meril already presented in the Statement for revocation and Counterclaims for revocation (see Section E of the Counterclaims). The objection would be relevant if the Court of Appeal would disagree with the Central Division's opinion that the Main Request and Auxiliary Request I must be revoked on the basis of added matter – which is not the case.

47. For similar reasons, the complaint by Meril India and Meril Germany that Edwards in its appeal against the impugned revocation decision should not have raised arguments relating to other grounds than the ones used by the Central Division in support of the decision to partially revoke the patent (the inadmissibility of new grounds for revocation and the priority claim) (Statement of response in APL_51746/2024 and APL_51748/2024, p. 4) is irrelevant. It would be relevant only if the Court of Appeal were to disagree with the Central Division's opinion on added matter in the Main Request and Auxiliary Request I – which is not the case. Moreover, the complaint is ill-founded. Edwards was free to present arguments in its grounds of appeal which may become relevant if the Court of Appeal were to accept Edwards' view that the Central Division wrongly assessed the added matter challenge relating to the Main Request and Auxiliary Request I.

48. The same applies to the objection by Meril Italy against the submissions relating to the priority claim which Edwards presented in its appeal against the impugned revocation decision (Statement of response in APL_51701/2024, para I.2.1). Also, that complaint can remain undecided because it would be relevant only if the Court of Appeal were to disagree with the Central Division's opinion on added matter in the Main Request and Auxiliary Request I – which is not the case.

49. In addition, Edwards objects to submissions by Meril India and Meril Germany in their Statement of grounds of appeal in relation to the impugned revocation decision (see Edwards' Statement of response, requests II-VI, in APL_44701/2024 and APL_44702/2024). Edwards argues – in summary – that these submissions should have been filed in the first instance proceedings (exhibits HLB 4, 5 and 6 and figures

18 and 24 and the parts of the Statement relating to these exhibits and figures) or are insufficiently substantiated (added matter challenges presented at p. 27 and 28 of the Grounds of appeal; inventive step challenges using DiMatteo, Benichou and the Melody valve; challenges against the dependent claims). The objections concerning the lack of substantiation must be rejected. The alleged lack of substantiation may result in the dismissal of the arguments, not in their inadmissibility. Moreover, there is no lack of substantiation. Meril India and Meril Germany refer in the Statement of grounds of appeal to their quite detailed submissions before the Central Division. Given the fact that the Central Division dismissed these arguments without a detailed reasoning, it was sufficient for Meril India and Meril Germany to note the lack of reasoning by the Central Division and mainly repeat their first instance submissions. The objections concerning the new submissions on appeal can remain undecided. Even if the submissions were admissible, they do not alter the Court of Appeal's assessment of the arguments which Meril India and Meril Germany put forward on the basis of these submissions.

Claim interpretation

Claim construction principles

50. The principles applicable to claim construction have been set out by this Court in its final order in the case of NanoString v 10x Genomics (UPC_CoA_335/2023, Order of 26 February 2024, as rectified). The patent claim is not only the starting point but the decisive basis for determining the protective scope of a European patent under Art. 69 EPC in conjunction with the Protocol on the Interpretation of Art. 69 EPC. The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. These principles for the interpretation of a patent claim apply equally to the assessment of the infringement and the validity of a European patent.

The patent

51. The patent concerns a system comprising a prosthetic heart valve and a delivery catheter comprising an inflatable balloon.

52. The patent specification states that a prosthetic valve is mounted in a crimped state on the end portion of a flexible catheter and advanced through a blood vessel of the patient until the valve reaches the implantation site. The valve at the catheter tip is then expanded to its functional size at the site of the defective native valve such as by inflating a balloon on which the valve is mounted (paragraph [0003]).

53. According to the specification, sealing devices that are needed to seal the interface between the prosthetic valve and the surrounding tissue to avoid regurgitation (leaking of blood) may increase the overall profile of the prosthetic valve in the compressed state (paragraph [0004]). In this context it is mentioned that a prosthetic valve that has a relatively large profile or diameter in the compressed state can inhibit the physician's ability to advance the prosthetic valve through the femoral artery or vein and that a smaller profile allows for treatment of a wider population of patients, with enhanced safety (paragraph [0005]).

54. Against this background, the patent aims at improving the design of a balloon-expandable transcatheter prosthetic heart valve. To achieve this aim, the patent teaches to use a system as defined by the patent claims, which *inter alia* reduces the crimping profile of the valve and provides stability during crimping and subsequent expansion ([0039]) (the objective problem underlying the patent is discussed more exhaustively in paragraphs 137 ff. below).

Person skilled in the art

55. The Central Division and the Munich Local Division both defined the person skilled in the art as a group consisting of a medical device engineer with an interest in prosthetic heart valves and an interventional cardiologist. This definition has not been challenged by any of the parties and will therefore also be used by the Court of Appeal.

Strut

56. The claim feature "strut" refers to an element of the frame that is elongated and connected to neighbouring struts. These two characteristics of a strut are, as such, not in dispute between the parties. They are also present in the interpretations of the claim feature provided by the Central Division and the Munich Local Division. The Central Division defined a strut as "*a single, unitary elongated piece that connects neighbouring struts*". Similarly, the Munich Local Division defined a strut as "*an individual, distinct and rigid piece that is connected to neighbouring struts in connecting areas or apices*" and assumed that it has a longitudinal extension.

57. Meril's argument that only a strut that does not vary in width and shape along its longitudinal extension and does not become broader towards its centre is a strut in accordance with the patent must be dismissed. The patent provides no basis for such a restrictive interpretation. On the contrary, as correctly observed by the Munich Local Division, the embodiment shown in fig. 6 of the patent clearly has curving angled struts (146 and 148) and side struts (144) of tapered shape in the axial direction.

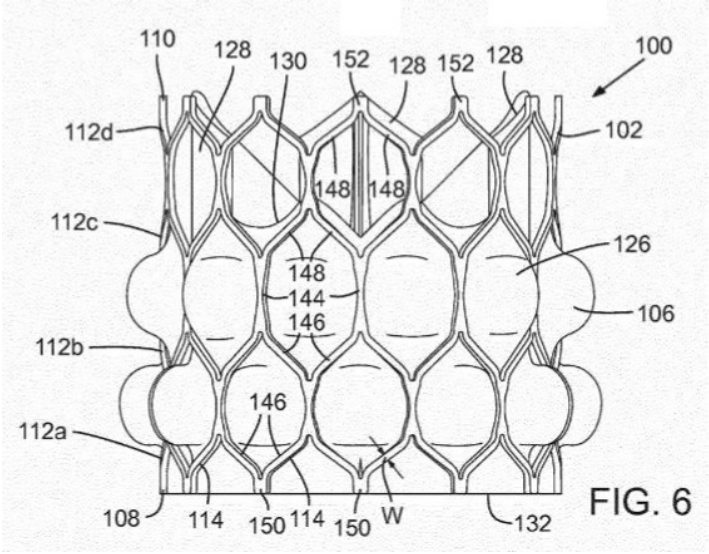
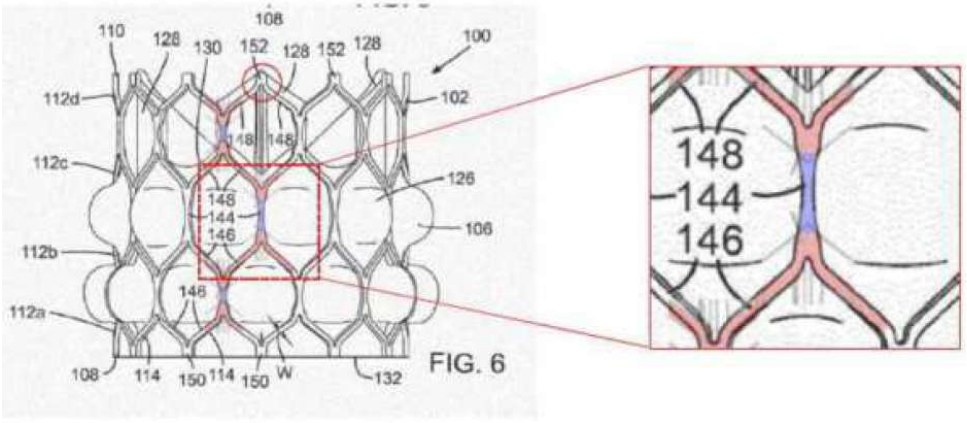


FIG. 6

Contrary to Meril's opinion, this interpretation of Figure 6 does not depend on a precise identification of the ends of the struts. Moreover, a precise identification of the ends further confirms the interpretation of the feature "strut". As the Court of Appeal will point out below (see para. 65), the intersections between the angled struts, such as the apices 152 and 150 in the top row and bottom row, are part of the angled struts. This underscores that the angled struts in Figure 6 are curved towards their ends. It does not affect the conclusion that the axially extending side struts are tapered, as can be seen in the following annotated version of Figure 6 provided by Edwards and also relied on by Meril in this context:



58. That the claimed invention is not limited to a prosthetic heart valve frame of struts having a particular shape or width is further confirmed by paragraph [0039] of the patent which teaches that the honeycomb structure of the frame is "*less sensitive to variations in strut width*". Even if the person skilled in the art were to understand this passage as referring to unwanted variations in strut width caused by the manufacturing process, as Meril contends, the fact remains that it confirms that the width of struts can vary to some extent.

59. This interpretation of the claim feature "strut" is not called into question by the fact that paragraph [0039] of the description of the patent states that in a specific embodiment "*the struts have a width W (FIG. 6) of about 0.4 mm and a thickness T (FIG. 8) of about 0.45 mm*". This paragraph does not teach that struts must have a single width and a single thickness. It merely discloses specific dimensions that can be used, and leaves open the possibility that the struts may vary in width and shape. Indeed, this is apparent from the reference in paragraph [0039] to Figure 6, which discloses tapered shaped struts, as already established above. Moreover, the dimensions are only specified for "*a specific embodiment*" of the claimed invention. As a general rule, the interpretation of a claim feature must not be reduced to a specific embodiment.

60. The fact that paragraph [0005] of the "background" section of the patent also refers to the effect of a reduced crimping profile of the valve does not change the assessment either. Meril rightly observes that the person skilled in the art will take this background of the claimed invention into account in the interpretation of the patent claims, since it specifies the object of the claimed invention (i.e. improving the design of a balloon-expandable transcatheter prosthetic heart valve). However, paragraph [0039] teaches that this effect – in addition to a number of other advantageous effects – is realized by "the honeycomb structure of the frame", not by a specific strut shape or width. Accordingly, the patent claims do not contain any limitations relating to the shape or width of the struts. These limitations cannot be read into the claim merely on the basis of the object of the claimed invention.

61. The fact that the person skilled in the art knows that the shape and width of the struts affect the crimping profile is not relevant. If a prosthetic heart valve frame has the claimed frame configuration it benefits from the effects related to that configuration, even if some of the benefits are lessened by the shape or width of the struts.

62. Meril Italy's further objections against the Central Division's definition of the concept of a "strut" do not need to be assessed, since Meril Italy did not contest the two characteristics of the concept that the Court of Appeal presented above.

Side strut

63. It follows from the interpretation of the claim feature "strut" and the wording of the claim that a side strut is an elongated piece that is:
    - one of the six struts defining a hexagonal cell (feature 1.6),
    - extending parallel to a flow axis of the valve (feature 1.7),
    - connected at its lower end to a pair of lower angled struts extending downwardly and converging toward each other (feature 1.8), and
    - connected at its upper end to a pair of upper angled struts extending upwardly and converging toward each other (feature 1.9).

    In combination, these characteristics teach the person skilled in the art that the side struts space the rows of angled struts apart and connect these rows so as to form a pattern of hexagonal cells. By contrast, there are no side struts if the rows of angled struts are connected directly to each other by joining the locations where the pairs of angled struts converge without any additional extension in the axial direction. In that case, the struts form rhomboid cells, not hexagonal cells.

64. The Court of Appeal therefore concurs with the Central Division's finding that the person skilled in the art, in the context of the patent, would make a distinction between side struts that space the rows of angled struts apart, and parts of a frame where the rows of angled struts are connected directly to each other, referred to by the Central Division as "welding points" or "nodes". Meril's complaint against the Central Division's use of the term "welding points" does not call this interpretation into question. Meril submits that the use of the term suggests that the Central Division's interpretation is based on the assumption that a heart valve frame is assembled piece by piece and welded. In Meril's view, that assumption is incorrect. It submits that heart valve frames are manufactured by laser cutting. This argument cannot succeed for several reasons. Firstly, the interpretation of the claim feature "side strut" does not depend on the manufacturing process of the frame. Parts of the frame where rows of angled struts are connected directly to each other and frame elements that space the rows of angled struts apart can be distinguished from each other irrespective of the way the frame is made. Secondly, the mere use of the term "welding points" does not imply that the Central Division assumed that heart valve frames can only be made by welding. The Central Division used this term alongside the term "nodes", which does not suggest a particular manufacturing process. Thirdly, Edwards demonstrated that, at the effective date, welding actually was used in the production of some heart valve frames, including the frames of Alon and Melody to which Meril refers (see para. 163 ff. and 169 ff. below).

65. The Court of Appeal rejects Meril's argument that the junctions between the angled struts are part of the side struts. Meril's interpretation does not follow from the fact that the claim features 1.8 and 1.9 require that the angled struts extend from the ends of the side strut. In addition, Meril's interpretation would imply that any connection between the rows of angled struts would be a side strut since any junction of angled struts will extend somewhat in the axial direction. That interpretation would not be in accordance with the function of the side strut to space the rows of angled struts apart and would make the feature redundant. For instance, as correctly observed by the Central Division, Figure 6 of the patent shows that neighbouring struts are joined at apices 150 and 152 at the topmost and lowermost row of angled struts and in correspondingly shaped connecting portions at intermediate rows of angled struts. The person skilled in the art will note that these apices include an axially extending component (see the small portions marked in red in the following annotated version of Figure 6, submitted by Edwards in its Statement of response in the appeals 44701/2024 and 44702/2024, Fig. 11).

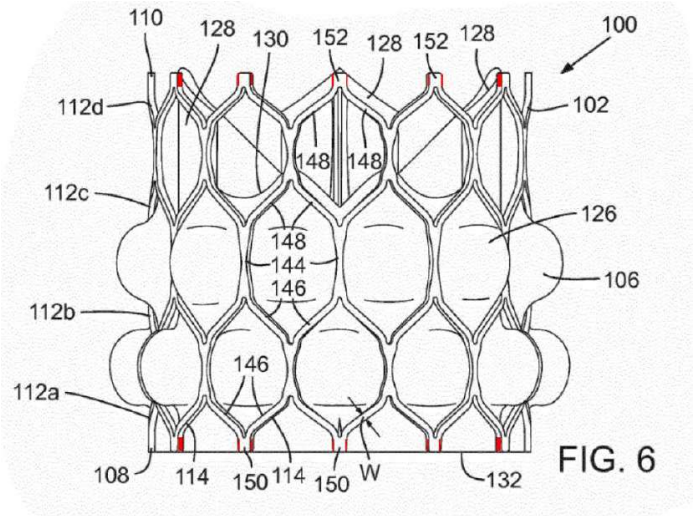
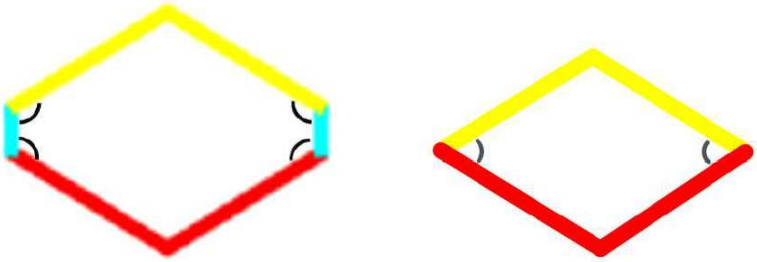


FIG. 6

Even though the apices extend in the axial direction, the patent in paragraph [0037] expressly presents them as intersections of the angled struts. On that basis, the person skilled in the art will not consider the apices as constituting separate struts. For the same reasons, the person skilled in the art will not consider the parts of the frame where rows of angled struts are connected to each other to be side struts, if these parts merely join the intersections of angled struts without adding a significant extension in the axial direction. In that case, the parts do not space the rows of angled struts apart, but are – as Edwards puts it – simply the place where the rows of angled struts meet (Statement of response in the appeals 44701/2024 and 44702/2024, para. 60).

66. Contrary to Meril's opinion, the reference to the apices of Figure 6 of the patent in this context does not mean that the scope of protection is reduced to frames having apices. The reference to the apices is used only as a confirmation and illustration of that fact that the person skilled in the art will not perceive the intersections of the angled struts as separate struts or part of the side struts.

67. Meril's argument that the function of the side struts is to avoid acute corners must be rejected. Referring to the following illustrations and an expert opinion of Prof. Dasi (Exhibit HLB 5), Meril argues that the side struts in a hexagonal cell (figure shown left) distribute strain to two corners instead of just one corner in a rhomboid cell (figure shown right).



This functional interpretation is not supported by the patent. The problem of acute corners and the distribution of strain is not expressly disclosed in the patent. Meril failed to demonstrate that the person skilled in the art would read that function into the patent on the basis of their common general knowledge. Meril's interpretation is based on the assumption that the person skilled in the art would consider rhomboid cells in frames of prosthetic heart valves to always have acute corners. However, Edwards showed that the rhomboid cells of prior art valves in fact did not exhibit acute corners, because the designers of heart valve frames would be well aware that sharp angles are to be avoided. In this context, Edwards referred, for instance, to the following frame of the Melody valve (Exhibit Gide 30), which Meril agrees consists of rhomboid cells.

It is clear and uncontested that this frame does not have acute corners.

68. Meril's reference to the heart valve frame shown in Figures 1 to 4 of the patent does not lead to a different interpretation either. The Court of Appeal shares the opinion of the Munich Local Division that this frame has no side struts and no hexagonal cells and is therefore not an embodiment of the claimed invention. As a general rule, a product or process presented as an embodiment by the patent specification may be considered covered by the patent claims. However, there is room for an exception where the patent as a whole clearly teaches the person skilled in the art that the disclosed embodiment is not claimed, e.g. when it only illustrates a technical specification that is not addressed by the teaching of the patent claim. For the following reasons, such an exception applies in this case.

69. The description of the patent discusses the concept of hexagonal cells with side struts and the effects of using such cells only in paragraphs [0014] and [0037] to [0039]. Paragraphs [0037] to [0039] describe an embodiment shown in Figures 5 to 9, which clearly has a frame made entirely of hexagonal cells with side struts in accordance with the patent claim. Paragraphs [0014] and [0036] present this embodiment expressly as "another embodiment", i.e. an embodiment different from the embodiments described in the preceding paragraphs. Those other embodiments are shown in Figures 1 to 4. As can be seen in the following Figure 1, the cells in these embodiments clearly consist of only four angled struts and are rhomboid, not hexagonal shaped.

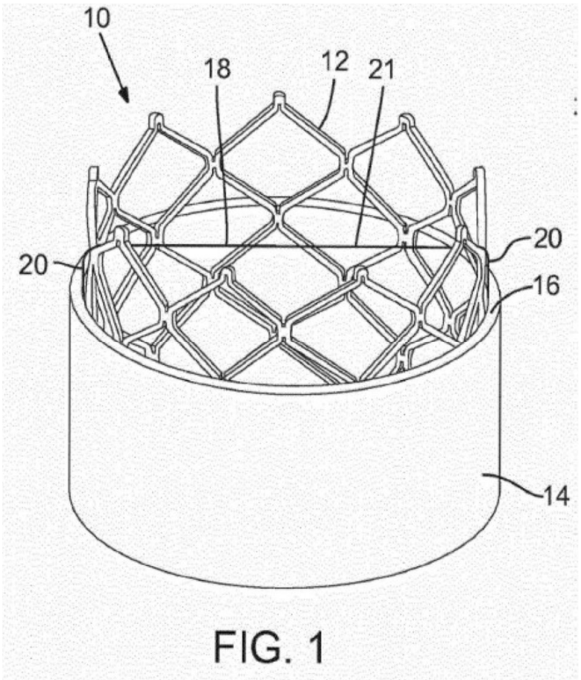


FIG. 1

Accordingly, the description does not refer to the cells shown in Figures 1 to 4 as hexagonal shaped cells. Nor does the description suggest that the advantageous effects of using hexagonal shaped cells can be

achieved with the frame shown in Figures 1 to 4. This makes clear that the frame of Figure 1 is not in accordance with the patent claims. In addition, Figure 1 shows that the angled struts in the top row are joined at apices or, in the words of Edwards, "U-shaped crown portions". The lower rows of angled struts are connected directly to each other by joining two such U-shaped crown portions to each other without adding any extension in the axial direction. The person skilled in the art would therefore have understood that the cells of the frame shown in Figure 1 do not have side struts.

70. Contrary to Meril's opinion, paragraph [0020] of the patent does not teach the person skilled in the art that the frame depicted in Figure 1 to 4 is a frame according to the claimed invention and that this frame therefore has the claimed side struts and hexagonal cells. Meril refers to the first sentence of this paragraph, which states that *"[t]he frame 12 as claimed can be made of any of various suitable plastically-expandable materials*" and argues that therefore the frame 12 shown in Figure 1 to 4 is claimed. However, paragraph [0020] merely discusses the crimping and expansion of the frame and in that context discloses suitable frame materials. It does not discuss the configuration of the frame and does not refer to cells and struts. Given this context, the person skilled in the art will understand the cited sentence to mean that a frame as claimed can be made of plastically-expandable materials. Even if the person skilled in the art would notice that reference number 12 is only used in Figure 1 to 4, that alone would be insufficient to put aside their understanding that the frame disclosed in those figures is not the frame as claimed.

71. The parts of the European Patent Office examination file cited by the parties do not shed any new light on this interpretation of paragraph [0020]. In fact, they confirm that the point of the sentence concerns the frame material, not the frame geometry. The sentence was amended to clarify that the frame is not made from self-expanding material, as the claim is limited to a balloon-expandable device. Therefore, the Court of Appeal in this case does not need to address the question of whether the prosecution history can be taken into account in the context of the interpretation of the claims of a European patent.

Extending parallel to a flow axis of the valve

72. Claim element 1.7 requires that the side struts extend parallel to a flow axis of the valve. The Munich Local Division observed that the alignment of the side struts with the flow axis has the technical effect that the orientation of the side struts is not changed upon crimping. It held that, accordingly, a parallel orientation of the side strut relative to the low axis requires that the two end points of the struts be positioned on the longitudinal axis of the valve. In the opinion of the Munich Local Division, it is not required that the thickness of the side strut does not vary along the extension of the side strut in the direction of the flow axis. The Court of Appeal concurs with this interpretation.

Hexagonal shaped cell

73. The wording of claim 1 of the patent makes clear that a hexagonal shaped cell is a component of the frame of the heart valve (feature 1.5) and that a hexagonal shaped cell is defined by six struts (feature 1.6), including: two opposing side struts extending parallel to a flow axis of the valve (feature 1.7), a pair of lower angled struts, extending downwardly from respective lower ends of the side struts and converging toward each other (feature 1.8), and a pair of upper angled struts extending upwardly from respective upper ends of the side struts and converging toward each other (feature 1.9). This definition is in accordance with the description of hexagonal shaped cells in the description of the patent, which in paragraph [0037] defines such cells in similar words.

74. In addition, the definition of a hexagonal cell is in accordance with the geometrical concept of a hexagon, with which the person skilled in the art would be familiar on the basis of their common general knowledge. In the field of geometry, a hexagon is defined as a polygon defined by six angles and six sides. Contrary to Meril's opinion, it does not follow that the six angles of the hexagonal shaped cells must be six acute corners. Arguably, a typical hexagon by geometric standards has acute corners. However, what is decisive for the interpretation of the claim of the patent is not a geometric standard, but the meaning

of the terms of the patent claim in the context of the patent from the perspective of the person skilled in the art, i.e. a team consisting of a medical device engineer with an interest in prosthetic heart valves and an interventional cardiologist. As considered above (see paragraph 67), such a person would know that acute corners must be avoided in prosthetic valve frames and are therefore not required to constitute a hexagonal shaped cell.

Expert evidence

75. The expert opinions of Prof. Dasi (Exhibit HL 11) and Dr Mayer (Exhibit HL 12) do not lead to a different interpretation of the claim elements. All the arguments presented by the experts have been discussed above to the extent relevant to the decision.

Appeals by Edwards against the impugned revocation decision (APL_51746/2024, APL_51748/2024 and APL_51701/2024)

76. The complaints by Edwards against the impugned revocation decision must be rejected. The Court of Appeal concurs with the Central Division's finding that the claims of the Main Request and Auxiliary Request I contain added matter and that the patent to that extent must therefore be revoked pursuant to Art. 138(1)(c) EPC.

Principles

77. There is added matter if the claim as granted or amended contains subject-matter that extends beyond the content of the application as filed (Art. 123(2) and 138(1)(c) EPC). In order to ascertain whether there is added matter, the Court must thus, after having given an interpretation of the patent claim to the extent necessary, ascertain what the average skilled person would derive directly and unambiguously using their common general knowledge and seen objectively and relative to the date of filing, from the whole of the application as filed, whereby implicitly disclosed subject-matter, i.e. matter that is a clear and unambiguous consequence of what is explicitly mentioned, shall also be considered as part of its content (UPC_CoA_382/2024, order of 14 February 2025, Abbott v Sibio, paragraph 52).

78. Where, as here, the patent results from a divisional application, this requirement applies to each earlier application (Art. 76(1) EPC). The subject matter of the claims thus may not extend beyond the disclosure of (1) the application as filed for the patent, (2) the parent application, and (3) the grandparent application, WO 801 (cf. UPC_CoA_764/2024, UPC_CoA_774/2024, decision of 2 October 2025, Expert v Viosys, paragraph 65).

79. As correctly observed by the Central Division, added matter may result from an intermediate generalisation, i.e. the extraction of a specific claim feature from an originally disclosed combination of features. There will be added matter where the person skilled in the art would not consider the use of omitted features necessary for achieving the overall aim and effect of the invention based on their common general knowledge (UPC_CoA_382/2024, order of 14 February 2025, Abbott v Sibio, paragraph 75).

Main Request

80. Claim feature 1.5 requires that the frame is made up entirely of hexagonal cells. This feature is not directly and unambiguously disclosed in WO 801 as such, without the feature that the frame 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 the inflow end or outflow end for mounting the frame to a delivery apparatus.

81. Paragraph [054] of WO 801 reads as follows:

The frame 102 in the illustrated embodiment has what can be referred to as a "homogenous" pattern of hexagonal cells, meaning that the frame is made up entirely of hexagonal cells and 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 the inflow end or outflow end for mounting the frame to a delivery apparatus.

This paragraph discloses a frame with a homogenous pattern of hexagonal cells. It presents the feature that the frame is made up entirely of hexagonal cells as one element of the definition of such a pattern, next to the feature that the frame does not include any struts that do not form part of one of the hexagonal cells, except for struts that extend axially away from the inflow end or outflow end for mounting the frame to a delivery apparatus. By means of this two-part definition the features are inextricably linked to each other. The paragraph therefore discloses these two features only in combination and does not directly and unambiguously teach the person skilled in the art to use a frame made up entirely of hexagonal cells as such, irrespective of the absence of any struts that do not form part of the hexagonal cells.

82. Nor is claim feature 1.5 directly and unambiguously disclosed in paragraph [013] or claim 15 or 16 of WO 801. Paragraph [013] discloses the following:

[013] […] The frame comprises a homogenous pattern of hexagonal cells, each of which comprises six struts, including two side struts extending parallel to the flow axis of the valve, a pair of lower angled struts, and a pair of upper angled struts. The lower angled struts extend downwardly from respective lower ends of the side struts and converge toward each other. The upper angled struts extend upwardly from respective upper ends of the side struts and converge toward each other.

Claims 15 and 16 read as follows:

15. The prosthetic heart valve of claim 7, wherein the frame comprises a homogenous pattern of hexagonal cells.

16. The prosthetic heart valve of claim 15, wherein each cell comprises six struts, including two side struts extending parallel to the flow axis of the valve, a pair of lower angled struts, and a pair of upper angled struts, the pair of lower angled struts extending downwardly from respective lower ends of the side struts and converging toward each other, and the pair of upper angled struts extending upwardly from respective upper ends of the side struts and converging toward each other.

The person skilled in the art will interpret these parts of WO 801 in the light of the application as a whole. More specifically, the average skilled person will consider the express definition of the concept of “a homogenous pattern of hexagonal cells” in paragraph [054] of WO 801. These parts of WO 801 therefore do not directly and unambiguously disclose claim feature 1.5 without the feature that the frame 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 the inflow end or outflow end for mounting the frame to a delivery apparatus.

83. For similar reasons, Edwards’ reference to paragraph [055] of WO 801 must fail. Paragraph [055] discloses that “the honeycomb structure of the frame” has a number of advantageous effects. However, WO 801 does not provide a definition of the concept of a honeycomb structure and Edwards failed to demonstrate that the person skilled in the art on the basis of their common general knowledge would equate this concept with a frame made up entirely of hexagonal cells as such and not the homogenous pattern of hexagonal cells presented and defined in the preceding paragraph [054].

84. Edwards’ reference to the following Figure 6 of WO 801 does not alter that assessment.

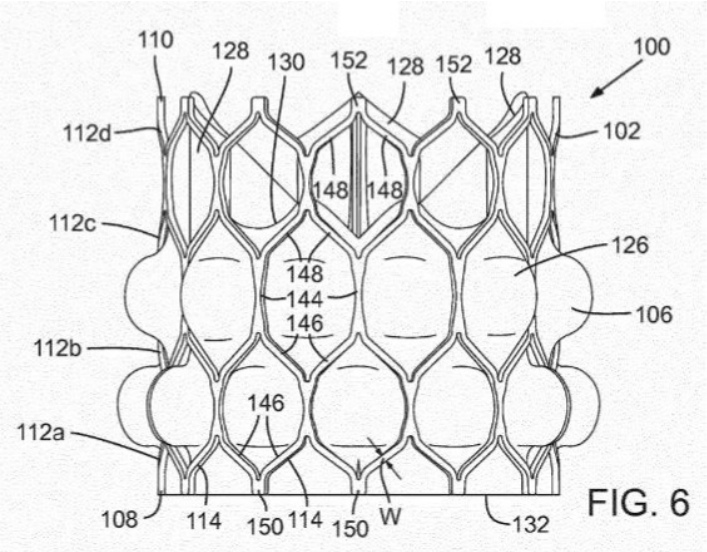


FIG. 6

The person skilled in the art will interpret this figure in the context of the disclosure of WO 801 as a whole. More particularly, the average skilled person will interpret the figure in the light of those paragraphs of WO 801 that specifically describe the embodiment shown in the figure, i.e. paragraphs [052] et seq. The person skilled in the art will therefore know that Figure 6 shows a specific example of a frame with a homogenous pattern of hexagonal cells described in paragraph [054] and of the honeycomb structure described in paragraph [055]. It does not directly and unambiguously disclose a general teaching to make up a frame entirely of hexagonal cells.

85. Edwards' argument that a hypothetical prior art document with the content of WO 801 would be novelty-destroying for claim 1 of the Main Request must fail. Novelty and added matter are distinct legal concepts and are not governed by identical requirements. As a general rule, a specific disclosure, such as a disclosure of the combination of features A and B, takes away the novelty of a more general patent claim claiming feature A as such. In contrast, a patent claim claiming feature A as such may extend beyond a more specific disclosure of the combination of A and B in the application.

86. Edwards' contention that WO 801 presents the omitted feature (that the frame 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 the inflow end or outflow end for mounting the frame to a delivery apparatus) as a "non-mandatory possibility" is incorrect. The wording of the omitted feature clearly requires the absence of any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from the inflow end or outflow end for mounting the frame to a delivery apparatus. Therefore, the presence of axially extending struts at the inflow and outflow end may be optional, but the absence of any other struts that do not form part of one of the hexagonal cells is not – and certainly not directly and unambiguously – disclosed as non-mandatory.

87. It follows that claim 1 of the Main Request contains added matter. The other claims are dependent on claim 1 and none of them introduces the omitted limitation. They consequently contain the same added matter. The Central Division's conclusion that the patent cannot be maintained on the basis of the Main Request is therefore correct.

88. The Court of Appeal notes that its finding on added matter is in conformity with the decision of the EPO's Opposition Division of 15 December 2022 (Exhibit HLNK 4) and the decision of the Board of Appeal of 1 December 2023 (Exhibit HLNK 51) concerning a European patent from the same family, EP 3 583 920 (EP 920). Also, the Opposition Division and the Board of Appeal found that subject-matter had been added by including in the claim only the first part of the definition of the term "homogenous pattern of hexagonal cells" from paragraph [054] of WO 801.

Auxiliary Request I

89. The claims of Edwards' Auxiliary Request I are identical to the Main Request. The only difference is that several dependent claims are deleted. Therefore, the claims of Auxiliary Request I contain the same added matter as the claims of the Main Request. It follows that there is no basis for maintaining the patent in accordance with Auxiliary Request I.

Cost decision

90. The Central Division ordered that 60% of the costs of the revocation proceedings be borne by Meril and 40% by Edwards, considering that the revocation action was dismissed solely because Edwards submitted a limitation of the patent during the proceedings. Edwards' complaint against this decision must be rejected. Edwards argues that the changes which Auxiliary Request II introduces over the Main Request are minor, but it failed to counter Meril's point that the Main Request itself entails a substantial limitation of the patent as granted. The decision of the Central Division not to allocate 100% of the costs to Meril is therefore well-founded. Nor did the Central Division err in allocating 60% of the costs to Meril, taking into account that the Court of First Instance has some discretion over the exact apportionment.

Appeals by Meril against the impugned revocation decision (APL_44701/2024, APL_44702/2024 and APL_45049/2024)

91. The appeals by Meril against the impugned revocation decision are not well-founded. The Court of Appeal concurs with the Central Division's finding that the patent must be maintained on the basis of Auxiliary Request II.

Clarity

92. Meril's argument that the new claim feature 1.12 in Auxiliary Request II does not satisfy the requirements of Art. 84 EPC must be rejected. Meril argues that it is ambiguous whether a strut is "*for mounting the frame to the delivery catheter*", because the patent provides no guidance and no examples. However, the fact that the patent does not expressly provide such information does not mean that the claim feature is unclear to the person skilled in the art, since sufficient clarity may follow from the common general knowledge with which the person skilled in the art reads the patent. Edwards submitted that the person skilled in the art understands the feature as referring to axial struts at the inflow or outflow ends of a frame that are suitable for supporting the mounting of the frame on the delivery catheter. Meril failed to demonstrate that the average skilled person would understand the feature differently or that such understanding is unclear in itself.

Added matter: omission of a sealing member

93. Meril argues that Auxiliary Request II contains added matter for several reasons. Firstly, it argues that Auxiliary Request II extends beyond the content of the original application because, in Meril's view, WO 801 discloses claim feature 1.5 (a frame made up entirely of hexagonal cells) only in combination with a sealing member in the form of an inner skirt. Applying the principles set out above in paragraphs 77 to 79, this argument must be rejected for the following reasons.

94. Paragraph [013] of WO 801 discloses a frame that comprises a homogenous pattern of hexagonal cells without reference to a sealing device. A similar disclosure can be found in claims 15 and 16 of WO 801, claiming a heart valve with a frame comprising a homogenous pattern of hexagonal cells, without a sealing device.

95. Given the express definition of the concept of "a homogenous pattern of hexagonal cells" in paragraph [054], the person skilled in the art will understand paragraph [013] and claims 15 and 16 as a clear and unambiguous disclosure of the combination of claim features 1.5 and 1.12 (frame is made up entirely of

hexagonal cells and 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 the inflow end or outflow end for mounting the frame on a delivery apparatus) without a sealing device. Therefore, the fact that paragraph [013] and claims 15 and 16 use the term "comprises" does not mean that the frame can have other cells than hexagonal cells.

96. In addition, paragraphs [006] and [033] state that the disclosure of WO 801 "is directed to embodiments of catheter-based prosthetic valves, and, in particular, prosthetic heart valves having sealing devices". This wording ("in particular") confirms that it is possible for the claimed valves to *not* have a sealing device.

97. Furthermore, the person skilled in the art would understand that claim feature 1.5 is not inextricably linked to the sealing device. Paragraph [055] of WO 801 discloses several advantageous effects of "the honeycomb structure", without reference to a sealing device. The person skilled in the art will understand that the concept of "the honeycomb structure" refers to the homogenous pattern of hexagonal cells as disclosed in the preceding paragraph [054] of WO 801, which defines the concept as a combination of claim features 1.5 and 1.12. Thus, paragraph [055] of WO 801 teaches that the use of this combination as such has advantageous effects unrelated to the use of a sealing device.

98. These findings are not called into question by paragraph [052] ff. and Figure 5 ff. of WO 801, which disclose an embodiment having a frame made up entirely of hexagonal shaped cells and a sealing device. The embodiment described in those paragraphs and shown in those figures clearly is an exemplary embodiment. The disclosure of WO 801 is not limited to the combination of all the features of such an example.

99. The fact that considerable parts of WO 801, including the sections relating to the field of the invention (paragraph [001]) and the background of the invention (paragraphs [002] to [005]), concern heart valves having sealing devices, does not alter the assessment either. The fact remains that WO 801 also discloses a frame having claim features 1.5 and 1.12 without a sealing device. Meril's argument that Figures 5-9 and paragraphs [056], [057] and [058] of WO 801 discloses an interaction between the openings of the frame and a sealing device, does not change the assessment either. These parts disclose that the inner skirt may protrude through the openings of the frame and makes an outer skirt redundant. Still, WO 801 also discloses that the configuration of the frame as such contributes to the improvement of the design of a balloon-expandable transcatheter prosthetic heart valve. That teaching is not limited to the interaction of the openings of the frame and a sealing device.

Added matter: omission of features of the embodiment disclosed in Figures 5-14

100. Secondly, Meril argues that Auxiliary Request II extends beyond the content of the original application because, in Meril's view, WO 801 discloses the claimed configuration of the frame only in combination with the following features:
    - a frame having three rows of cells and four rows of angled struts;
    - specific means of attaching the leaflets to the frame (leaflet tabs, leaflet clips, and commissure securement portions);
    - a valvular structure/leaflet structure with three leaflets;
    - intersecting angled struts to form apices at the inflow end and the outflow end of the frame.

    These objections must be rejected for similar reasons as the first objection.

101. The objections are based on the assumption that WO 801 discloses the claimed configuration of the frame, in particular the frame being made up entirely of hexagonal cells, only in paragraph [052] ff. and Figures 5-14. This assumption is incorrect. As set out above, WO 801 in paragraph [013] and claims 15 and 16 directly and unambiguously disclose the combination of claim features 1.5 and 1.12 as such, without reference to the features listed by Meril.

102. The fact that Figures 5-14 of WO 801 show an embodiment having the allegedly omitted features, does not alter the assessment. These figures clearly relate to an exemplary embodiment and therefore do not limit the more general disclosures in WO 801. This is confirmed by the way the additional features are described in WO 801. The wording confirms that these features are optional. For instance, in respect of the number of rows, paragraph [053] states:

> *[…] Referring to FIG. 6, the frame 102 in the illustrated embodiment can comprise a plurality of rows 112a, 112b, 112c, 112d of angled struts 114 joined to each other to form a plurality of hexagonal, or "honeycomb" shaped cells.*

Both the use of the word "*can*" and the general term "*plurality*" indicate that the disclosure is not limited to a specific number of rows. The fact that the sentence lists four reference numbers (112a, 112b, 112c, 112d) is explained by the fact that the illustrative embodiment shown in Figure 6 has four rows. It does not teach that the frame must have four rows. Similarly, paragraph [059] uses the word "*can*" in the description of the means of attaching the leaflets to the frame (e.g., "*each leaflet 104 can have slightly curved, or scalloped lower edge portion 134 that can be secured to the frame 102 and/or the skirt 106 using sutures*"). Paragraph [052] presents the three leaflets in the valvular structure expressly as an example ("*a leaflet structure comprising a plurality of leaflets 104 (e.g., three leaflets 104 as shown)*").

103. Furthermore, the person skilled in the art will understand that the claimed configuration of the frame is not inextricably linked to the allegedly omitted features. Paragraph [055] of WO 801 discloses several advantageous effects of "the honeycomb structure of the frame". It does not mention a contribution to these effects by other features of the embodiment, such as the number of rows, the means of attaching the leaflets, the number of leaflets and the apices at the inflow end and the outflow end of the frame. Under the considerations set out in paragraph 79, any possible intermediate generalisation brought about by the omission of the particular features discussed here does not constitute an inadmissible intermediate generalisation.

104. Relying on an opinion of Edwards' expert Prof. Bressloff (Exhibit Gide 50) and an opinion of its own expert Dr Solar (Exhibit Gide 57), Meril contends that the person skilled in the art would know that the number of rows has an effect on the crimping profile of the valve and the stability and radial strength of the frame. However, the fact that the person skilled in the art knows that the number of rows has similar effects as the ones paragraph [055] discloses for the honeycomb structure does not mean that they would assume that these features are inextricably linked and contribute to the technical teaching of the disclosed invention only in combination.

105. Meril's statement that WO 801 discloses different means of attaching the leaflet to the frame in Figure 5 and Figure 15 cannot succeed either. The fact that WO 801 discloses different ways of attaching the leaflets does not mean that the person skilled in the art would assume that the frame disclosed in Figure 5 can only be used in combination with the leaflet attachment means shown in that figure.

Added matter: combination of features 1.1, 1.10 and 1.11 and omission of a collapsible and expandable valve structure

106. Thirdly, Meril argues that Auxiliary Request II extends beyond the content of the original application because, in Meril's view, i) WO 801 does not disclose the combination of claim features 1.1 (*a prosthetic heart valve*), 1.10 (*a delivery catheter comprising an inflatable balloon*) and 1.11 (*the prosthetic heart valve (100) 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 (100) at the desired deployment location, preferably within a native aortic valve*) and ii) the claim does not contain the feature of a collapsible and expandable valve structure.

107. These arguments must be rejected. The Central Division established that WO 801 clearly and unambiguously discloses the combination of claim features 1.1, 1.10 and 1.11 in paragraphs [013], [036],

[043] and [044] and that the feature of a collapsible and expandable valve structure is implicitly comprised in the teaching that the prosthetic heart valve is configured to be radially collapsed in the crimped state and radially expanded when implanted. Meril failed to submit any reason why the Central Division's assessment is incorrect. For that reason alone, Meril's argument must be dismissed. Furthermore, the Court of Appeal concurs with the Central Division's assessment of the disclosure of the features 1.1., 1.10 and 1.11 in WO 801. The Court of Appeal also agrees that there is no added matter issue regarding the collapsible and expandable valve structure.

Added matter: combination of alloy and inflatable balloon

108. Fourthly, Meril argues that Auxiliary Request II extends beyond the content of the original application because, in Meril's view, the combination of the specific alloy claimed in feature 1.3 and the inflatable balloon of feature 1.10 is an inadmissible selection from multiple lists.

109. This argument cannot succeed. Paragraph [049] of WO 801 discloses two examples of delivery devices: "*on a balloon if plastically-expandable"* and *"within a delivery shaft if self-expandable*". In addition, paragraph [037] of WO 801 discloses that the claimed alloy of feature 1.3 is a plastically-expandable material. In combination, these paragraphs directly and unambiguously teach using the inflatable balloon of claim feature 1.10 in combination with the plastically-expandable material of claim feature 1.3.

Added matter: no basis for an inflow end and an outflow end

110. Finally, Meril argues that Auxiliary Request II extends beyond the content of the original application because, in Meril's view, WO 801 provides no direct and unambiguous basis for an inflow end and an outflow end.

111. This argument is without merit. The Central Division established that the replacement of the definite article "*the*", which WO 801 uses in connection with the ends of the valve, by the indefinite article "*a*" in claim feature 1.12 does not appear to be relevant. Meril failed to provide any reason why this assessment is incorrect. For that reason alone, the argument must fail. In addition, the Court of Appeal concurs with the findings of the Central Division.

Priority

112. In the impugned revocation decision, the Central Division held that the patent's claim to priority on the basis of P1 is not valid and considered 13 July 2012 as the effective date of the patent. There is no need to review this decision on appeal, since the subject matter of Auxiliary Request II is novel and involves an inventive step even if the priority claim based on P1 is not valid, as the Court of Appeal will point out in the following paragraphs. Edwards' complaints about the Central Division's opinion on the priority claim and Meril's further arguments against the priority claim will therefore not be assessed by the Court of Appeal.

Novelty: Figures 44 and 45 of Levi

113. Meril's argument that claim 1 of Auxiliary Request II is not novel over the embodiment shown in the following Figures 44 and 45 of Levi (WO2012/48035, Exhibits HLNK 39 and Gide 47) cannot succeed. These figures do not directly and unambiguously disclose rows of hexagonal cells at the inflow end of the valve, which is the bottom row of Figure 44 and the top row of Figure 45. The figures therefore do not directly and unambiguously disclose claim feature 1.5 (the frame is made up entirely of hexagonal cells).

FIG. 44

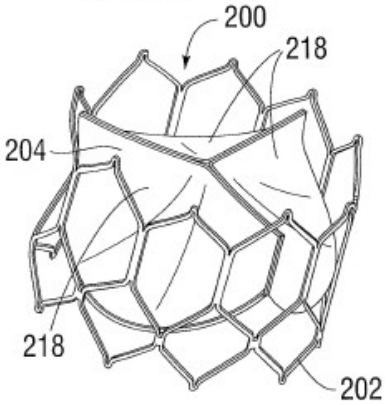
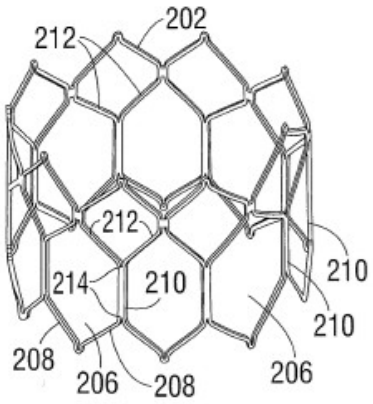


FIG. 45



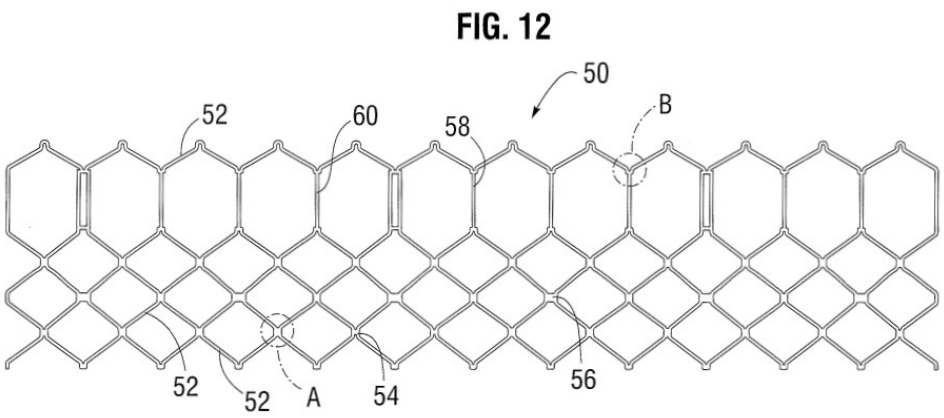
114. Meril's argument that claim 1 of Auxiliary Request II is not novel over Levi is primarily based on the assumption that the embodiment shown in Figures 1 to 4 of the patent is covered by the patent claims and that the frame shown in these figures is thus made up entirely of hexagonal shaped cells. However, as pointed out above in paragraphs 68 to 70, the person skilled in the art would not construe the claims in that way and would note that the frame shown in Figures 1 to 4 is made up entirely of rhomboid cells, not hexagonal shaped cells. For the same reasons, the cells at the inflow end of the frame shown in Figures 44 and 45 of Levi do not – and certainly not directly and unambiguously – disclose hexagonal shaped cells.

115. In addition, Meril argues that the cells at the inflow end of the frame shown in figures 44 and 45 of Levi have side struts. However, as set out above in paragraph 64, the person skilled in the art would distinguish between side struts, which space the rows of angled struts apart, and parts of a frame where the rows of angled struts are connected directly to each other without adding any extension in the axial direction. Starting from this definition of side struts, Figures 44 and 45 of Levi do not – and certainly not directly and unambiguously – disclose side struts in the cells at the inflow end. Considering that the angled struts at the inflow and outflow end are interconnected by U-shaped junctions, the parts of the frame that Meril considers side struts appear to be the locations where two such U-shaped junctions meet back-to-back. The rows of angled struts are therefore not – and certainly not directly and unambiguously – disclosed as being spaced apart, but appear to be connected directly to each other without any additional axial extension.

116. The fact that the parts of the cells at the inflow end where the rows of angled struts meet have some extension in the axial direction and that therefore the only difference with respect to the cells at the outflow end is the axial length of the connection, does not alter the assessment. Because of the width of the angled struts, any connection between them will have a certain extension in the axial direction, if measured from the top of the junction of the upper row of angled struts to the bottom of the junction of the lower row of angled struts. What is decisive, however, is whether the rows of angled struts are spaced apart (see the construction of the claim feature "side strut" above in paragraphs 63 and 64). The relevant question is therefore whether there is any axial extension in addition to that of the junctions of the angled struts. Such an axial extension is not disclosed directly and unambiguously in Figures 44 and 45 of Levi.

117. Furthermore, the person skilled in the art would not take note of Figures 44 and 45 of Levi in isolation, but in the context of the disclosure of Levi as a whole. As the Central Division and the Munich Local Division correctly observed, Levi makes a distinction between rows of angled struts that are connected to each other at nodes or connecting portions, and rows of angled struts connected by axially extending struts. Levi teaches to use the latter at the inflow and/or outflow end of the valve, in order to create a better crimping profile. Levi presents these two distinct ways of connecting rows of angled struts, for

instance, in paragraph [062] by reference to the following Figure 12 in which the nodes/portions 54 and 56 connect the lower rows, and the axially extending struts 58 connect the upper rows.



The same two ways of connecting rows of angled struts can be found in the embodiment shown in Figures 44 and 45. This is confirmed by the description. Paragraph [088] of Levi describes that in Figure 45 the frame has relatively large openings 206 at the outflow end to allow parts of the leaflet structure 204 to protrude outwardly through the openings 206. It points out that these openings 206 of the frame are defined by a row of angled struts 208 at the outflow end, a plurality of axially extending struts 210 and an intermediate row of angled struts 212. It does not disclose that the relatively small cells at the inflow end also have such axially extending struts.

118. Referring to the following annotated version of Figure 45 of Levi, Meril argues that the rows are spaced apart because the lines drawn along the angled struts are offset.

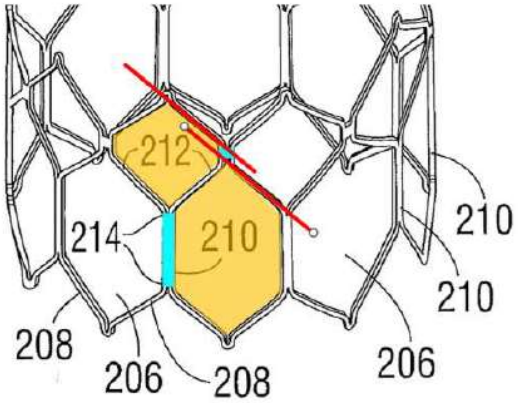
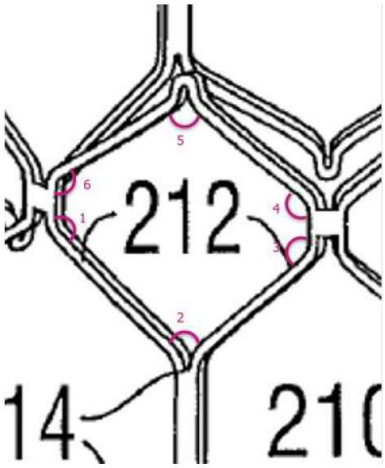
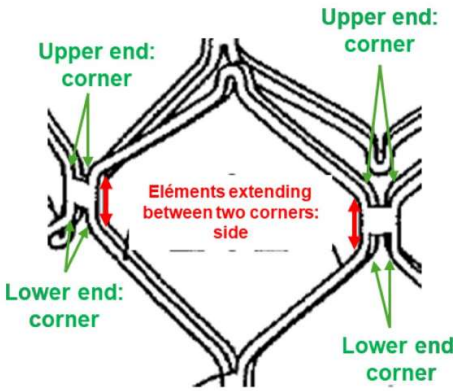


Figure 12: Offset angled struts in Figure 45 of Levi not running in a straight line (annotations added)

This argument cannot succeed for several reasons. Firstly, the person skilled in the art will know that the figures of Levi are *schematic* drawings. The person skilled in the art would therefore not draw any conclusion based on measurements of details of the figures, in particular not since the conclusion goes against the express teaching of the document as a whole. Secondly, as can been seen in the top row of angled struts, the angled struts shown in Figure 45 of Levi do not intersect in acute corners. Instead, the angled struts curve and meet in U-shaped junctions. Establishing an offset between lines drawn along the straight part of the angled struts is therefore not an accurate way of determining whether the rows of angled struts are spaced apart. It does not take the junction of the angled struts into account.

119. In addition, Meril argues that all cells are hexagonal cells and have side struts since the cells disclose six angles. In this context, Meril refers to the following annotated versions of Figure 45 of Levi.

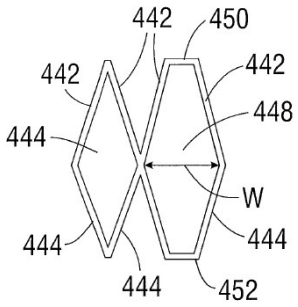




This argument must be rejected for several reasons. Firstly, as considered above, the person skilled in the art would not draw such a conclusion on the basis of the details of the schematic drawings, in particular not since the conclusion goes against the express teaching of the document as a whole. Secondly, the fact that Figures 44 and 45 of Levi do not disclose acute corners is insufficient to conclude that the figures directly and unambiguously disclose hexagonal shaped cells and side struts. The person skilled in the art would rather consider the cells at the inflow end to be rhomboid cells with rounded corners, as known from other prior art valves.

120. Meril's reference to the description in Levi of the following Figure 49 cannot alter that assessment.

FIG. 49



Paragraph [090] of Levi makes a distinction between "diamond shaped openings" (the cell shown on the left) and "larger openings" formed by four adjacent struts 442 and two horizontal struts 450 (the cell shown on the right). In line with the general teaching of Levi discussed above, the paragraph thus clearly distinguishes rhomboid cells from hexagonal shaped cells. However, contrary to Meril's opinion, it does not follow that only diamond shaped cells with the specific configuration shown in Figure 49 are non-hexagonal cells within the meaning of the patent and that the cells at the inflow end of the frame shown in Figures 44 and 45 are hexagonal shaped cells.

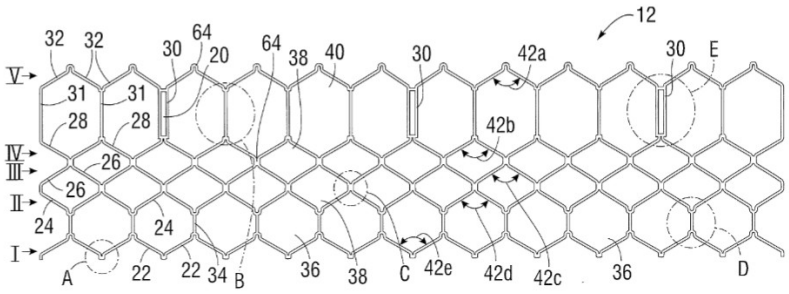
121. Meril's references to statements of Edwards' experts and representatives on Figure 5 of Levi in proceedings relating to other patents do not call these findings into question. These statements are not decisive for the interpretation of the claims of the patent at issue or the understanding of Figure 5 of Levi. To the extent that they provide any indication of the view of the person skilled in the art, these indications are in this case not sufficient to support another interpretation of the patent claims or another understanding of what is disclosed in Levi.

Novelty: Levi (further embodiments), Benichou and Hariton

122. For similar reasons, the subject-matter claimed in claim 1 of Auxiliary Request II is not directly and unambiguously disclosed in Figures 1 to 10 and 60 to 61 of Levi, nor in Figures 27 to 29 of Hariton (WO2009/149462, Exhibit HLNK 50 and Gide 81) or Figure 23 of Benichou (WO2011/109801, Exhibit HLNK 43 and Gide 52). All these figures do not directly and unambiguously disclose claim feature 1.5 (a frame made up entirely of hexagonal shaped cells), since the frames include rhomboid cells.

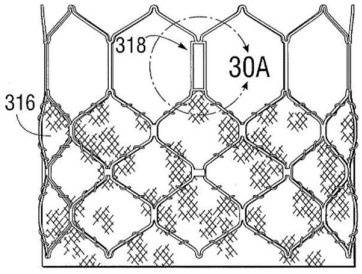
123. As can be seen in the following Figure 5 of Levi, the embodiments shown in figures 1 to 10 of Levi do not have a frame entirely made up of hexagonal cells. The two rows of cells in the centre of the frame, formed by the rows II, III and IV of angled struts, do not directly and unambiguously disclose hexagonal shaped cells with side struts, for the same reasons as those features are missing in the cells at the inflow end of the embodiment shown in Figures 44 and 45 of Levi.

FIG. 5

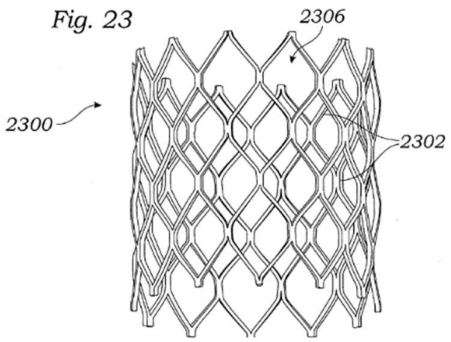


This is confirmed by paragraph [054] of the description of Levi. This paragraph describes that the embodiment shown in Figure 5 comprises five rows of angled struts. It mentions axially extending struts only in connection with the top and bottom rows of cells, referring to struts 31 and 34. It is also in accordance with the general teaching of Levi, which distinguishes between cells with and without axial struts and teaches to use the ones with axial struts at the inflow and/or outflow end to create larger openings.

124. The same applies to the embodiment shown in Figures 60 and 61 of Levi. As can be seen in the following Figure 60, the disclosed frame has again – and in accordance with the general teaching of Levi – a combination of rhomboid and hexagonal shaped cells.



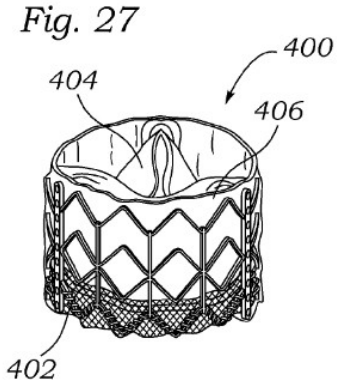
125. For similar reasons, a frame made up entirely of hexagonal shaped cells is not directly and unambiguously disclosed in the following Figure 23 of Benichou.



The Central Division held that Benichou does not disclose claim feature 1.5, considering that Benichou does not mention the type of struts which form the cells and that the figures lack a clear depiction of side struts. Meril failed to present any reasons why these findings are incorrect. The fact that Benichou in Figure 8A discloses another frame of rhomboid cells with more acute corners does not imply that the person skilled in the art would consider the cells in Figure 23 to be hexagonal shaped cells, not rhomboid cells with relatively rounded corners.

126. Nor is a frame made up entirely of hexagonal cells directly and unambiguously disclosed in Figures 27 to 29 of Hariton. Hariton discloses an implantable prosthetic heart valve. The technical problem underlying the Hariton disclosure is the reduction of the crimped profile of the valve (par. [006]). Hariton discloses specific angles between adjacent struts and relative strut thickness to optimize radial strength (par. [048], [050]). Specific configurations of cell rows and columns, as well as orientation of the struts, to minimize the overall crimped profile, are also discussed (par. [052]-[054]). Hariton uses specific language to identify interconnecting crown-shaped portions and nodes (Fig. 7, denoted by 26 and 32, respectively; par. [049]) and struts, including vertical axial struts (30).

127. Meril specifically refers to the embodiment shown in Figures 27 to 29 of Hariton. However, as correctly established by the Central Division, these figures do not directly and unambiguously disclose a frame made up entirely of hexagonal cells. Meril failed to provide any reasons why the Central Division's findings were incorrect. Moreover, the Court of Appeal concurs with these findings. As can be seen in the following Figure 27, the disclosed frame has rhomboid cells and chevron shaped cells, not hexagonal shaped cells.



Meril's view that the figures disclose two overlapping hexagonal cells must be dismissed. As observed by the Central Division, a cell is an entity defined by struts around an opening. Figures 27 to 29 of Hariton disclose three rows of openings and therefore two rows of chevron shaped cells and one row of rhomboid cells, not two rows of hexagonal cells.

Inventive step: general principles

128. A European patent is only validly granted for an invention if – apart from other requirements – it involves an inventive step. An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art (Art. 56 EPC).

129. National courts of the various EPC countries have different approaches and use different guidelines when assessing whether an invention involves an inventive step. One of those approaches is the so-called 'problem-solution-approach' used by the European Patent Office (EPO) and the Technical Boards of Appeal (TBA) of the EPO. In some jurisdictions, such as France, Italy, The Netherlands and Sweden, this approach is applied as well, but not necessarily as the only possible approach. In other jurisdictions, such as Germany and the UK, other approaches – sometimes referred to as more 'holistic' – are used. Despite the differences in approach, all of these are merely guidelines to assist in the establishment of inventive step as required by Art. 56 EPC, that, when properly applied, should and generally do lead to the same conclusion.

130. The burden and presentation of proof with regard to the facts from which the lack of validity of the patent is derived and other circumstances favourable to the invalidity or revocation lies with the claimant in a revocation action (Art. 54 and 65(1) UPCA, R. 44(e)-(g), 25.1(b)-(d) RoP). Even though proof of certain facts, if contested, may be required, the assessment of the relevant facts and circumstances is a question of law.

131. The approach taken by the Unified Patent Court when establishing inventive step, which can already be derived from the Order of the Court of Appeal in the Nanostring v 10X Genomics case (UPC_CoA_335/2023, Order of 26 February 2024), is as follows.

132. It first has to be established what the object of the invention is, i.e. the objective problem. This must be assessed from the perspective of the person skilled in the art, with their common general knowledge, as at the application or priority date (also referred to as the effective date) of the patent. This must be done by establishing what the invention adds to the state of the art, not by looking at the individual features of the claim, but by comparing the claim as a whole in the context of the specification and the drawings, thus also considering the inventive concept underlying the invention (the technical teaching), which must be based on the technical effect(s) that the person skilled in the art, on the basis of the application, understands is (are) achieved with the claimed invention.

133. In order to avoid hindsight, the objective problem should not contain pointers to the claimed solution. The claimed solution is obvious when at the effective date the person skilled in the art, starting from a realistic starting point in the state of the art in the relevant field of technology and wishing to solve the objective problem, would (and not only "could") have arrived at the claimed solution.

134. The relevant field of technology is the specific field relevant to the objective problem to be solved as well as any field in which the same or similar problem arises and of which the person skilled in the art of the specific field must be expected to be aware.

135. A starting point is realistic if the teaching thereof would have been of interest to a person skilled in the art who, at the effective date, wishes to solve the objective problem. This may for instance be the case if the relevant piece of prior art already discloses several features similar to those relevant to the invention as claimed and/or addresses the same or a similar underlying problem as that of the claimed invention. There can be more than one realistic starting point, and the claimed invention must be inventive starting from each of them.

136. The person skilled in the art has no inventive skills and no imagination and requires a pointer or motivation (in German: "*Anlass*") that, starting from a realistic starting point, directs them to implement a next step in the direction of the claimed invention. As a general rule, a claimed solution must be

considered not inventive/obvious when the person skilled in the art would take the next step, prompted by the pointer or as a matter of routine, and arrive at the claimed invention.

Objective problem

137. As observed above in paragraph 54, the patent aims at improving the design of a balloon-expandable transcatheter prosthetic heart valve. To achieve this aim, the patent teaches to use a system as defined by the patent claims, which *inter alia* reduces the crimping profile of the valve and provides stability during crimping and subsequent expansion (paragraph [0039] of the patent).

138. Meril submits that claim 1 of Auxiliary Request II does not solve any technical problem over the prior art. It argues that therefore the problem underlying the patent must be redefined as providing a mere alternative to the known prosthetic heart valve frame.

139. First, it should be noted that for an inventive step to be present, it is not necessary to show improvement of the technical teaching as defined by the patent claims over the prior art. Inventive step may also be found if the patent claims disclose a non-obvious alternative to solutions known in the prior art (cf. Case Law of the EPO Boards of Appeal, 11th ed./July 2025, I.D.4.5).

140. Second, the argument that claim 1 of Auxiliary Request II does not solve any technical problem must be rejected for the following reasons.

141. Edwards has submitted that side struts in a frame made up entirely of hexagonal cells have several technical effects, including stability during crimping and subsequent expansion and a reduced crimping profile of the valve. Meril contests the reduction of the crimping profile but failed to provide any reasons why the side struts would not improve the stability of the frame during crimping and subsequent expansion. It did not contest Edwards' explanation that the side struts provide stability because they do not change angle but maintain their height in all configurations. For that reason alone, Meril's argument that the claimed invention does not solve any technical problem must fail.

142. In addition, Meril's objections against the effect of a reduced crimping profile of the valve are ill-founded. Meril argues that Edwards cannot rely on the technical effect of a reduced crimping profile, since i) the effect is not derivable from the application as filed, and ii) Edwards failed to prove that the claimed invention actually has that effect.

143. A patent proprietor may rely upon a technical effect for inventive step, if the skilled person having the common general knowledge in mind, and based on the application as originally filed, would consider said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention (cf G 2/21, mn 94). The effect of a reduced crimping profile is encompassed by the technical teaching of the application as filed (WO 801) under this standard. Paragraph [055] of WO 801 expressly states that the honeycomb structure of the frame reduces the crimping profile of the valve. Meril's attempt to associate this effect with particular embodiments, namely very specific dimensions mentioned in paragraph [055] or the presence of a sealing mechanism, must fail. As indicated above in paragraph 81 to 84, the honeycomb structure described in paragraph [055] of WO 801 is the homogenous pattern of hexagonal cells of paragraph [054] of WO 801, which forms part of the technical teaching that paragraph [013] of WO 801 discloses without any reference to particular dimensions or the presence of a sealing mechanism. The fact that in the prior art the term "honeycomb" was in some cases used also in connection with frames made up of rhomboid cells or a combination of rhomboid and hexagonal cells, does not alter the assessment. To the extent that such a broader use of the term was part of the common general knowledge, the fact remains that the patent uses it more restrictively, only referring to frames made up entirely of hexagonal cells.

144. Meril's argument that Edwards failed to prove that the described effect actually occurs cannot succeed either. The Central Division correctly held that the burden of proof is on Meril, since Meril relies on the

alleged absence of the effect to support its revocation claim (see above paragraph 130). Furthermore, Edwards pointed out why a frame made up entirely of hexagonal shaped cells has the disclosed effect of a reduced crimping profile, submitting that the introduction of side struts provides for cells with larger openings with less material in a given area. Meril failed to demonstrate that this explanation is incorrect.

Inventive step: Levi

145. The Court of Appeal concurs with the Central Division's finding that the subject matter of claim 1 of Auxiliary Request II is not obvious to the person skilled in the art starting from Levi. The same conclusion must be drawn if a specific embodiment that was not expressly discussed by the Central Division is considered, i.e. the embodiment depicted in Figures 44 and 45 of Levi. In accordance with the parties' appeal pleadings, the following reasoning will focus on this specific embodiment. However, the same reasons apply to the embodiment shown in Figures 1 to 10 of Levi, which the Central Division did expressly discuss.

146. Levi relates to prosthetic heart valves and aims to reduce the crimped profile. Levi is therefore a realistic starting point for the inventive step analysis. It would have been of interest to a skilled person who, at the effective date of the patent, sought to solve the objective problem underlying the patent.

147. As pointed out above in paragraph 117, Levi makes a distinction between rows of angled struts that are connected to each other at nodes or connecting portions (forming rhomboid cells), and rows of angled struts connected by axially extending struts (forming hexagonal shaped cells within the meaning of the patent). Levi consistently teaches to use frames with a combination of these cells, wherein different parts of the frame have different functions and therefore employ different structures. For instance, in paragraph [061], Levi explains that the relatively large openings of the hexagonal cells at the inflow end of the frame shown in figure 5 can accommodate an outer skirt. The interplay of such hexagonal shaped cells at the inflow end with rhomboid cells in the intermediate rows create a frame with a "tapered shape" which, according to Levi, ensures a constant overall diameter of the complete valve, including the outer skirt.

148. There is for the person skilled in the art no incentive in Levi to change the frame disclosed in Figures 44 and 45 of Levi into a frame made up entirely of hexagonal shaped cells. On the contrary, such a modification would go against the teaching of Levi. In accordance with the general teaching, Levi discloses hexagonal cells only at a specific location of the frame shown in Figures 44 and 45, namely along that area of the frame that supports the leaflet structure. Levi explains that the relatively large openings of the frame at this location allow portions of the leaflet structure to protrude outwardly when the valve is radially compressed. This enables the valve to be crimped to a smaller diameter than if the entire leaflet material were constrained within the crimped frame. On the basis of this teaching, using hexagonal cells along areas of the frame that do not support the leaflet structure does not make sense.

149. Meril's argument that the person skilled in the art would wish to add an outer skirt to the frame of Figures 44 of 45 does not alter the assessment. Even if the person skilled in the art wished to add an outer skirt, it would not be obvious to make the frame consist entirely of hexagonal shaped cells. Levi discloses various frames having outer skirts, for instance in Figures 2 and 43. None of these frames are made up entirely of hexagonal shaped cells. In accordance with the general teaching of Levi, the frames have a combination of rhombus and hexagonal shaped cells. If the person skilled in the art were to consider it necessary to increase the axial length of the frame of Figures 44 and 45 in order to attach the outer skirt, the obvious choice would therefore be to use the solution shown in Figures 2 and 43 and add one or more rows of rhomboid cells at the inflow end. Alternatively, the person skilled in the art could use the solution shown in Figure 5, which discloses a frame with hexagonal cells at the region of the frame covered by the outer skirt. However, also in this configuration, Levi teaches to use a combination of rhombus and hexagonal shaped cells, with the rhomboid cells in the intermediate rows. Meril's contention that the crimped frame of Figure 46 uses elongated side elements for the attachment of the skirt does not alter the assessment. Paragraph [088] of Levi describes that this figure shows the

protrusion of portions of the leaflet structure in a frame according to Figure 45. As considered above, this frame has rhombus shaped cells at the inflow end.

150. Meril's argument that the person skilled in the art would modify the frame shown in Figures 44 and 45 to ensure symmetric foreshortening cannot succeed either. The parties agree that predictable foreshortening is important, as this would allow the clinician to accurately determine the final position of the valve once expanded. However, Meril failed to demonstrate that the person skilled in the art, reading Levi, would assume that predictable foreshortening requires symmetry. Levi itself merely discloses asymmetrical frames. Meril and its experts have not submitted any prior art publication that could support the contention that the need for symmetrical foreshortening was common general knowledge at the effective date of the patent. In addition, even if the person skilled in the art did wish to realise a frame that provides for symmetrical foreshortening, the obvious choice starting from Levi would be to add a row of hexagonal cells at the inflow end of the frame depicted in Figures 44 and 45. Such a frame is similar to the frame shown in Figure 5 of Levi and in accordance with the general teaching of Levi. In contrast, none of the frames disclosed in Levi are made up entirely of rhomboid cells or hexagonal shaped cells.

151. Meril's argument that the person skilled in the art would wish to increase the height of the frame of the embodiment shown in Figures 44 and 45 to make it suitable to be used as a transcatheter pulmonary valve must be dismissed as well. Levi discloses various embodiments of differing heights. Still, all disclosed frames are made up of a combination of rhomboid cells and hexagonal cells, whereby the hexagonal cells are used to perform specific functions in specific areas of the frame. A person skilled in the art who wishes to create a prosthetic heart valve of a given length, starting from Levi, would therefore either select the embodiment shown in Levi that matches the required height or adapt the height of an embodiment by changing the number of rows. The last solution would also be consistent with the design of the Melody valve (Exhibit HLNK 19), which was the only transcatheter pulmonary valve commercially available at the effective date of the patent. This valve had five rows of cells. It follows that there would be no need for the average skilled person to go against the general teaching of Levi and configure a frame entirely of hexagonal cells merely to achieve a frame height sufficient for a transcatheter pulmonary valve.

152. Meril's reference to the incentive to create a frame with increased radial strength does not alter the assessment either. The parties agree that the person skilled in the art would be interested in providing a frame with sufficient radial strength. They also agree that the average skilled person would be aware that the radial strength of the frame can be improved by means of larger opening angles, i.e. the angle between the angled struts. Moreover, paragraph [058] and Figures 15A and 15B of Levi expressly disclose the related relationship between the opening angle and the force required to expand the frame. Furthermore, it is common ground that increasing the opening angles will reduce the height of the valve. However, Meril has not shown that this knowledge would motivate the person skilled in the art to introduce side struts in the rhomboid cells. If the person skilled in the art wished to maintain the height of the valve, he or she could decide to use the balance of radial strength and height taught by Levi or add a row of cells. The latter option would be in accordance with the object of increasing radial strength since, as submitted by both Edwards and Meril, a greater number of rows of angled struts in a given area increases radial strength (see *inter alia* the Grounds of Appeal of Meril India and Meril Germany in the appeals APL_44702/2024 and APL_44701/2024, p. 27 and Grounds of Appeal of Meril Italy in appeal APL_45049/2024, para. 91).

153. Meril's argument that changing the frame disclosed in figures 44 and 45 of Levi to a frame made up entirely of hexagonal shaped cells is merely a "*quantitative modification*" must be dismissed. The argument is based on the assumption that the average skilled person would perceive the nodes/connection areas and side struts as similar frame elements with only slightly differing extents in the axial direction. However, this assumption is not in accordance with the teaching of Levi. As observed in paragraph 117 above, Levi expressly distinguishes the rows of cells connected by nodes from rows of cells connected by axial struts and teaches to use the latter to perform specific functions in specific areas

of the frame. Replacing the row of rhomboid cells at the inflow end of the frame depicted in Figures 44 and 45 with a row of hexagonal cells is therefore not merely a quantitative modification, but a qualitative one that goes against the general teaching of Levi.

154. Meril's reference to the preliminary opinion of the EPO Opposition Division of 1 August 2025 (Exhibit HLB 8) relating to Edwards' patent EP 4 108 210, which belongs to the same family as the patent at issue, cannot alter the assessment. The opinion is admissible as evidence, even though it was filed at a very late stage of the appeal proceedings. That is because the opinion was issued very recently and concerns a patent that the parties had already discussed in the proceedings before the Central Division. However, the opinion does not change the Court of Appeal's assessment. The Opposition Division was of the preliminary opinion that it cannot be considered inventive to provide the frame of a prosthetic heart valve as disclosed in Levi wherein the frame comprises only hexagonal cells. To the extent that a *preliminary* opinion on another patent is relevant and the opinion of the Opposition Division is based on the same arguments and evidence submitted in the present proceedings, the Court of Appeal respectfully disagrees with this part of the opinion for the reasons given above.

Inventive step: combination of Levi and stents

155. Meril's argument that the subject matter of claim 1 of Auxiliary Request II is obvious in the light of a combination of Levi with prior art documents on stents cannot succeed. In accordance with the pleadings of the parties, the following reasoning will focus on the combination of Levi and an article by Fontaine on a vascular stent prototype (Exhibit HLNK 25 and Gide 35), but the same reasons apply to the other prior art publications submitted by Meril, such as the publication on the PURA-A stent (Exhibit Gide 11) and the Symphony stent (Exhibit Gide 36).

156. In the impugned revocation decision, the Central Division found that the person skilled in the art would be aware of the prior art in the field of vascular stents, but that such person would always bear in mind that stents and heart valves are very different devices with very different requirements. Therefore, a reference to the prior art in the field of stents would require careful consideration and strong motivation for application to prosthetic heart valves, according to the Central Division. Meril failed to demonstrate that these findings are incorrect.

157. The Central Division considered that Fontaine stents exhibit a high flexibility, in particular in the partially expanded state, allowing for an almost 180-degree bend. It observed that such flexibility is not required for heart valves, which are introduced through the femoral artery. In addition, the Central Division established that the person skilled in the art would think that such a large degree of flexibility could compromise a safe anchoring of the prosthetic heart valve in the native annulus. In response, Meril submitted that flexibility of the frame would contribute to the deliverability of a catheter-based prosthetic heart valve. However, Meril did not demonstrate that the person skilled in the art would consider the very high degree of flexibility disclosed in Fontaine suitable for the prosthetic heart valves, let alone for the balloon-expandable prosthetic heart valves claimed in the patent.

158. In addition, the Central Division pointed out that radial strength plays different roles in vascular stents and prosthetic heart valves. In a stent, it fulfils the function of maintaining the opening of the vessel and preventing restenosis, while in prosthetic heart valves, it ensures tight closure and prevents blood reflux. In response, Meril submits that the person skilled in the art would know that aortic stents "*may also be required to have substantial radial strength*". However, that does not mean that the skilled person would assume that the radial strength of the stents disclosed in Fontaine is suitable for prosthetic heart valves. In fact, Meril's expert opinion of Prof. Becker confirms that "*there are clearly differences in the […] magnitude of radial force between coronary stents and THV frames*" (Exhibit HLNK 45a, p. 9). Although these differences may not cause the person skilled in the art to disregard stents, as acknowledged by the Central Division, the person skilled in the art would take the differences into account when contemplating a modification of the prosthetic heart valve disclosed in Levi.

159. Given the differing requirements, the Central Division correctly concluded that the person skilled in the art, starting from the prosthetic heart valve disclosed in Levi, would need a strong motivation to replace a feature of the heart valve frame taught by Levi with a feature disclosed for stents in Fontaine. Such a strong motivation cannot be found in Levi (see the discussion of Levi, paragraphs 148 ff. above), nor in Fontaine.

160. Meril argues that Fontaine teaches that the shape of the "*honeycomb cell*" provides radial strength. However, as considered in paragraph 158 above, the radial strength requirements for stents and prosthetic heart valves are not identical. Moreover, in Fontaine, the radial strength of the stent is realised by expanding the frame to a very large extent. When fully expanded, each cell assumes a "*boxlike configuration*" with two vertical and two nearly horizontal struts. Edwards pointed out that in a stent such an extent of expansion is not an issue since stents are empty on the inside. In contrast, in prosthetic heart valves several components are on the inside, in particular the leaflet structure. The person skilled in the art would know that exerting a high pressure from within to expand the cells to a boxlike configuration could risk damaging this leaflet structure. Meril failed to demonstrate that the skilled person would read Fontaine differently.

161. The lack of a strong motivation is underscored by the fact that Fontaine relates to a "*stent prototype*". The publication describes a preclinical evaluation and states in the concluding paragraph that "*[i]f results of future tests are favorable, this prototype stent may be added to the inventory of the interventionalist*". Given that Fontaine warns that additional tests are required, the person skilled in the art would be even more reluctant to transfer any stent feature from Fontaine to a prosthetic heart valve according to Levi.

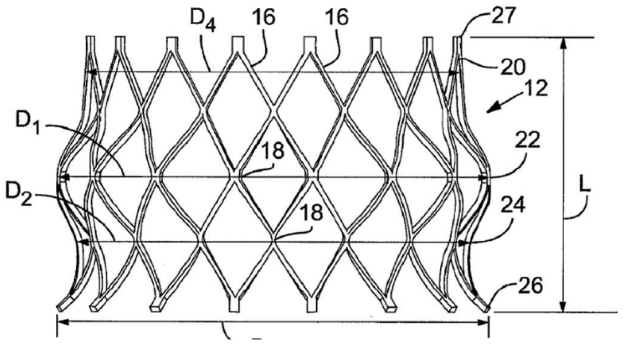
Inventive step: combination of Levi and Dimatteo

162. Meril's argument that the subject matter of claim 1 of Auxiliary Request II is obvious in the light of a combination of Levi and Dimatteo (WO 01/28459, Exhibits HLNK 32 and Gide 35) cannot succeed for similar reasons as given above for the combination of Levi and Fontaine. Dimatteo concerns a venous valve (see more elaborately paragraph 171 below). Given the different requirements relating to venous valves and prosthetic heart valves, combining Levi with Dimatteo would for the person skilled in the art be as inventive as combining Levi with Fontaine. Moreover, Dimatteo does not describe any advantages of using hexagonal cells and therefore does not expressly motivate the person skilled in the art to use such cells in any frame.

Inventive step: Alon

163. Meril's argument that the subject matter of claim 1 of Auxiliary Request II is obvious starting from the heart valve disclosed in Alon (US2010/0049313, Exhibits HLNK 49 and Gide 63) must be dismissed for the same reasons as those for which Meril's inventive step challenge on the basis of Levi must fail.

164. Meril's argumentation in relation to Alon is very similar to its argumentation in relation to Levi and must therefore be rejected on similar grounds. As can be seen in the following Figure 3 of Alon, Alon discloses prosthetic heart valve frames made up of rhomboid cells:



That the frame does not have side struts is confirmed by paragraph [091] of Alon, which describes that the struts are "*welded or otherwise secured to each other at nodes 18 formed from the vertices of adjacent bends so as to form a mesh structure*". Therefore, in order to arrive at the claimed invention, the person skilled in the art would have to add side struts to the cells. Adding side struts would not have been obvious for the same reasons as it was not obvious starting from Levi.

165. In addition, Alon is primarily concerned with the problem of anchoring the valve and teaches that this can be solved by using a valve with different diameters at different axial positions. The varying diameter gives the frame an undulating outer contour, as can been seen in Figure 3 of Alon depicted above and described in paragraph [092]. Meril does not contend that this teaching points the person skilled in the art in the direction of adding side struts. On the other hand, Edwards pointed out that a combination of the undulating contour taught by Alon and side struts is complicated and affects the stability of the frame. Adding side struts to the frame of Alon would therefore not be obvious to the person skilled in the art.

166. Moreover, even if the person skilled in the art were to add side struts in all the cells, the resulting heart valve would not be covered by claim 1 of Auxiliary Request II, since Alon does not disclose the nickel-cobalt-chromium-molybdenum alloy of claim feature 1.3. Also in this respect, the claimed invention is more non-obvious starting from Alon than it is starting from Levi.

167. The claimed invention is not obvious on the basis of a combination of Alon with Fontaine either, for the same reasons as given above in relation to the combination of Levi with Fontaine.

168. The Court of Appeal is aware that the EPO Board of Appeal, in oral proceedings relating to the "sister patent" EP 920, held that the subject matter of an auxiliary request was obvious. According to the minutes of the oral hearing, the Board of Appeal found that the distinguishing feature of a frame made up entirely of hexagonal cells was obvious based on a combination of Alon and Fontaine and the distinguishing feature of the specific alloy lacked inventive step based on a combination of Alon and a document similar to Hariton (Exhibits HLNK 54 and Gide 62). However, Edwards withdrew the auxiliary request. Consequently, there is no reasoning on inventive step available and the Court of Appeal cannot assess whether the opinion of the Board of Appeal is based on the same arguments that have been submitted in the proceedings before this Court.

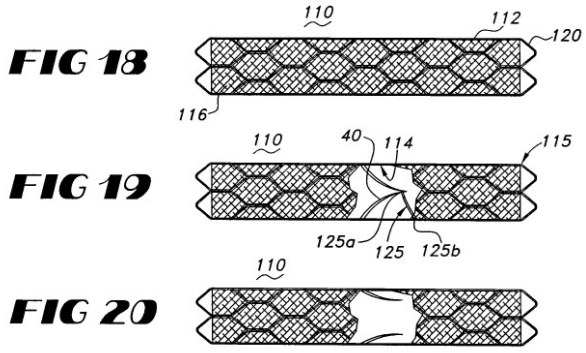
Inventive step: Benichou, Colibri and Melody

169. Meril's argument that the subject matter of claim 1 of Auxiliary Request II is obvious starting from the heart valve disclosed in Benichou, the Colibri valve (Exhibits HLNK 34, HKLNK 34a and HLNK 46 and Gide 39) and the Melody valve (Exhibits HLNK 19, HLNK 58 and HLNK 59 and Gide 29) must be dismissed for the same reasons as those for which Meril's inventive step challenge on the basis of Levi must fail. None of these prior art documents discloses a frame made up entirely of hexagonal shaped cells. Moreover, the documents do not concern the problem of reducing the crimping profile and/or have further distinguishing features such as the use of a frame material different from claim feature 1.3. The claimed invention is therefore even more non-obvious starting from these documents than it is starting from Levi. Meril did not specify or demonstrate in which respects these documents provide additional incentives for the person skilled in the art to modify the valve frame into one made up entirely of hexagonal shaped cells or combine them with prior art publications on stents, such as Fontaine.

Inventive step: Dimatteo

170. Meril's argument that claim 1 of Auxiliary Request II lacks inventive step based on Dimatteo must be rejected.

171. Dimatteo discloses valves which can be implanted using a minimally invasive endoscopic technique, in particular a balloon catheter. The technical problem underlying Dimatteo relates to leaflet support. The parties agree that Dimatteo does not disclose the nickel-cobalt-chromium-molybdenum alloy of claim feature 1.3. In addition, the Central Division found that the embodiment shown in the following Figures 18-20 of Dimatteo, on which Meril relies, discloses a venous valve rather than a heart valve and therefore do not disclose claim feature 1.1 either.



In support, the Central Division referred to the description of Dimatteo, stating that the "*second conduit 112 further maintains the patency of the body lumen to either side of the valve*" (Dimatteo, p. 22, lines 27-28), and to the size and the arrangement of the leaflets within the valve.

172. Meril failed to demonstrate that these findings are incorrect. The fact that the introductory paragraphs of Dimatteo discuss valves in general, including "*cardiac*" and aortic valves, does not mean that Dimatteo directly and unambiguously discloses that each embodiment can be applied in any type of valve. To the extent that Meril and its expert Prof. Brecker (Exhibit Gide 74) have meant to contest Edwards' statement that the dimensions of the frame and the arrangement of the leaflets are typical for venous valves and unsuitable for heart valves, they have not sufficiently substantiated their views. The fact that pulmonary valve replacements can be longer than aortic valve replacements does not necessarily mean that the dimensions of the disclosed embodiment are suitable for pulmonary valves. The fact that the arrangement of leaflets is presented as optional does not change the fact that the specific arrangement is typical for venous valves and unsuitable for heart valves.

173. Meril failed to demonstrate that the embodiment shown in Figures 18-20 of Dimatteo would be considered by a person skilled in the art seeking for a solution to the objective problem underlying the patent, i.e. improving the design of a balloon-expandable transcatheter prosthetic heart valve by reducing the crimping profile and increasing stability. Dimatteo would not be considered, given the differences between venous valves and heart valves (see above paragraphs 156 ff.) and the different objectives of the patent and Dimatteo.

174. Meril suggests that the problem starting from Dimatteo is how to modify the disclosed venous valve into a prosthetic heart valve. However, in this formulation the problem contains a clear pointer to the claimed invention. It therefore is not an (alternative) objective problem underlying the patent. Furthermore, even if the skilled person did wish to modify the disclosed venous valve into a prosthetic heart valve, Meril's statement that the person skilled in the art could adapt the design of a valve does not imply that she or he *would* arrive at the specific combination of features claimed in the patent. Edwards pointed out that in a prosthetic valve the various components are fine-tuned with respect to each other in order to ensure reliable function and safe operation of the valve. The person skilled in the art would therefore not combine parts from different valves without a clear motivation. Such a clear motivation is lacking in this case. Meril failed to show that the person skilled in the art, starting from the embodiment shown in Figures 18-20 of Dimatteo, would maintain only the feature of a frame made up entirely of hexagonal

cells, even though Dimatteo does not present any advantage of this feature as such, and introduce it in a known prosthetic heart valve having a different frame configuration.

Expert opinions

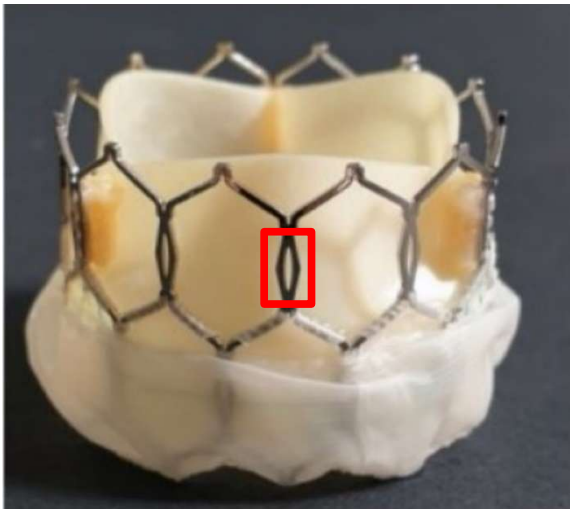
175. The Court of Appeal can decide the appeals on the basis of the submissions of the parties. There is no need to appoint a Court expert or hear the parties' experts. The Court of Appeal will therefore uphold the order of the judge-rapporteur of 17 June 2025, dismissing Meril's requests:
- to appoint a court expert (request VII);
- to obtain an expert report (request VIII);
- to summon the court expert to the oral hearing (request IX); and
- to summon the experts of Meril Germany and Meril India to the oral hearing (requests X and XI).

176. The expert opinions of Dr Solar (Exhibit HLB 4) and Prof. Dasi (Exhibit HLB 5) do not lead to a different assessment of the validity of the patent. All essential arguments presented by the experts have been discussed above to the extent relevant to the decision. As concluded above in paragraph 49, it can therefore be left open whether the expert opinions are admissible, even though Meril submitted them for the first time on appeal.

Appeal by Meril India and Meril Germany against the impugned infringement decision (APL_1926/2025)

Scope of protection

177. The question of whether the combination of Meril's Myval Octacor valve and the related "Navigator" and "Navigator Inception" delivery systems is within the scope of protection of Auxiliary Request II hinges primarily on the qualification of the part of the valve marked by the red square in the following annotated picture:



Edwards takes the position that the indicated part is a single strut, more in particular a side strut of a hexagonal cell. According to Meril, it is a rhombic shaped cell defined by four struts.

178. The Court of Appeal concurs with the opinion of the Munich Local Division that the indicated part is a single strut within the meaning of the patent (see, on the interpretation of this claim feature, paragraphs 56 ff. above). The part is an element of the frame that is elongated and connected to neighbouring struts. The fact that the part varies in width and shape along its longitudinal extent and becomes broader towards its centre does not rule out that it is a strut (see above, paragraph 57). Similarly, the fact that the part has an elliptically shaped hole in the centre does not exclude it from being a strut within the

meaning of the patent. Nor does the fact that the width and shape of the indicated part differ from that of the angled struts. The patent claim does not require that all struts have similar shapes and widths.

179. The finding that the indicated part is a single strut instead of a combination of four struts is confirmed by the fact that the part functions as a single element during the crimping and expansion of the valve, as correctly observed by the Munich Local Division. It established that the indicated part does not change in its axial and radial extent during crimping and expansion, and that the opening is not compressed when the valve is in its crimped state. The part thus behaves like a unitary strut. Meril India and Meril Germany did not challenge these findings on appeal.

180. The Court of Appeal also concurs with the qualification of the indicated part as a side strut of a hexagonal shaped cell. Meril India and Meril Germany and their experts Prof. Dasi (Exhibit HL 11) and Dr Mayer (Exhibit HL 12) argue that it is an element of an octagonal cell, but this view is based on the incorrect assumption that the indicated part is a rhombic cell defined by four struts. Starting from the correct qualification of the indicated part as a single strut, there is no dispute that it is one of six struts defining a hexagonal shaped cell. Nor did Meril India and Meril Germany contest that the indicated part is connected at its lower end to a pair of lower angled struts extending downwardly and converging toward each other and connected at its upper end to a pair of upper angled struts extending upwardly end and converging toward each other. The part thus performs the function of a side strut, i.e. spacing the rows of angled struts apart.

181. The indicated part also extends parallel to the flow axis of the valve, as required by claim feature 1.7. The Munich Local Division established that the upper and lower ends of the indicated part are positioned on the flow axis and that the orientation remains essentially parallel to the flow axis upon crimping. Meril India and Meril Germany failed to demonstrate that these findings are incorrect. Referring to the expert opinions by Prof. Dasi (Exhibit HL 11) and Dr Mayer (Exhibit HL 12), they reiterate their view that the indicated part consists of four struts and show by means of the following annotated picture of the relevant part of the Myval Octacor that these struts do not extend parallel to the flow axis:

However, this part is not a cell of four struts but a single side strut. The lines of red dots in the picture therefore merely show that width and shape of the strut varies along the longitudinal direction. It does not call into question the conclusion that the part as a whole extends parallel to a flow axis of the valve.

182. The assertion by Meril India and Meril Germany that the shape of the indicated part was chosen to keep leaflet material inside the frame does not alter the assessment. The additional function of the indicated part does not rule out that it is a strut within the meaning of the patent. The argument by Meril India and Meril Germany and their experts Prof. Dasi (Exhibit HL 11) and Dr Mayer (Exhibit HL 12) that keeping the leaflet material increases the crimping profile of the valve and therefore goes against one of the aims of the patented invention does not change the outcome either. A prosthetic heart valve frame that has the claimed frame configuration benefits from the effects related to that configuration, even if some of the benefits are contravened by the shape or width of the struts. A less-than-optimal implementation of the claimed system, if this is indeed the case with the Myval Octacor, is still an embodiment of such a system.

183. For the same reasons, the component of the frame of the Myval Octacor which Meril India and Meril Germany refer to as “commissure posts” are side struts within the meaning of the patent. This element is marked by the red square in the annotated picture below:

In addition, this component is an element of the frame that is elongated and connected to neighbouring struts. It behaves like a unitary strut and has all the characteristics of a side strut, including the function of spacing the rows of angled struts apart. That a “*commissure post*” has the additional function of receiving suture material for securing leaflets to the frame, as Meril India and Meril Germany and their experts Prof. Dasi (Exhibit HL 11) and Dr Mayer (Exhibit HL 12) note, does not rule out that it is a side strut. The patent claim does not exclude that struts fulfil such other functions. The fact that the commissure posts are not as slim as a side strut could be does not alter the assessment. As noted above, a less-than-optimal implementation of the claimed system is still an embodiment of such a system.

Infringement

184. The Munich Local Division established that Meril India and Meril Germany committed infringing acts. These findings are not challenged on appeal and therefore need no further assessment by the Court of Appeal.

Injunction and corrective measures

185. Pursuant to Art. 64(1) UPCA, the Court may, at the request of the applicant, order that appropriate measures be taken, inter alia, with regard to products found to be infringing a patent, without prejudice to any claims for damages by the injured party by reason of the infringement and without compensation of any kind. According to Art. 64(2) UPCA, such measures include the measures requested by Edwards, namely the recall of the products from the distribution channels (b), the final removal of the products from the distribution channels (d) and the destruction of the products (e).

186. In considering a request for corrective measures, the Court shall, in accordance with Art. 64(4) UPCA, take into account the need for proportionality between the seriousness of the infringement and the remedies to be ordered, the willingness of the infringer to convert the materials into a non-infringing state, and the interests of third parties.

187. Art. 64 UPCA does not merely confer on the Court the power to grant the measures requested. The Court has no discretion. Rather, Art. 64 UPCA grants the patent proprietor a civil law claim to the measures mentioned, provided that this is not precluded by reasons of proportionality. Art. 64 UPCA implements Art. 10 of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 (OJ L 157/45, “the Enforcement Directive”). The background to the Enforcement Directive was that in some Member States, procedures and remedies such as the recall of infringing goods from the market at the expense of the infringer were not available (Recital 7). The Enforcement Directive was intended to approximate these legal provisions in order to ensure a high, equivalent and homogeneous level of protection for intellectual property in the internal market (Recital 10). This high level of protection can only be guaranteed if the remedies of recall, removal from the distribution channels and destruction are the norm. Only if the measures are disproportionate, which may be the case, for example, if the infringement is minor or if the infringer is willing and able to eliminate the infringing nature of the

product, can they be refused. However, all circumstances of the individual case must always be taken into account. For example, an infringement that can be classified as serious may justify ordering recall, removal from distribution channels and destruction even if the infringer is willing and able to eliminate the infringing nature of the product (UPC_CoA_534/2024, decision of 3 October 2025, Philips v Belkin para. 232).

188. The same applies to permanent injunctions. Pursuant to Art. 63(1) UPCA, where a decision is taken finding an infringement of a patent, the Court may grant an injunction aimed at prohibiting the continuation of the infringement. Also, this provision does not merely confer on the Court the power to grant prohibitory injunctions.

189. Art. 63(1) UPCA implements Art. 11 of the Enforcement Directive. In accordance with Article 17(2) of the Charter of Fundamental Rights of the European Union ("The Charter") and the right to effective judicial protection guaranteed by Article 47 of the Charter, the Enforcement Directive provides for a range of legal remedies aimed at ensuring a high level of protection for intellectual property rights in the internal market. This need for a high level of protection for intellectual-property rights means that, in principle, the proprietor may not be deprived of the right to have recourse to legal proceedings to ensure effective enforcement of his exclusive rights, and that, in principle, the user of those rights, if he is not the proprietor, is required to obtain a licence prior to any use (CJEU, judgement of 16 July 2015, Huawei – ZTE, C-170/13, ECLI:EU:C:2015:477, paragraphs 57 and 58). Accordingly, where the proprietor files an infringement action and the Court finds that an intellectual property right has been infringed or is threatened to be infringed, it shall issue an order prohibiting the continuation of the infringement unless there are special reasons for not doing so (cf. for EU trade marks and EU designs, respectively, Art. 89(1)(a) Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs and Art. 130(1) Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark).

190. A special reason for denying an injunction may apply if, in the circumstances of the particular case, granting an injunction does not comply with the general obligations of Art. 3 of the Enforcement Directive, in particular the obligation that the remedies shall be proportionate. In addition, the Court must ensure that the application of its power under Art. 63(1) UPCA is not in conflict with fundamental rights protected by the European Union legal order or with other general principles of EU law, such as the principle of proportionality (CJEU, judgement of 29 January 2008, Promusicae, C-275/06, ECLI:EU:C:2008:54, paragraph 68; judgement of 27 March 2014, UPC Telekabel Wien, C-314/12, ECLI:EU:C:2014:192, paragraph 46; judgement of 16 July 2015, Coty Germany, C-580/13, ECLI:EU:2015:485, paragraph 34).

191. When considering the proportionality of injunctive relief and corrective measures, the Court may take into account not only the interests of the parties to the litigation but also the interests of third parties, such as patients. The Munich Local Division correctly held that the interests of the patients justify an exception to the right to injunctive relief and corrective measures if it is established that the infringing embodiment is the sole available treatment method or represents an improvement upon the available treatment methods, resulting in a notable enhancement of patient care.

192. Meril India and Meril Germany offer valve prostheses in different sizes than the other manufacturers, such as Edwards. They argue that the availability of these different sizes is crucial from a clinical standpoint, as it permits the selection of an appropriate model tailored to the individual patient's needs. The Munich Local Division held that this argument has merit in respect of Meril's XL devices (30.5 mm and 32 mm for the Myval Octacor and 30,5 mm x 35 mm and 32 mm x 35 mm for the Navigator Inception), but not in respect of Meril's intermediate-sized products (sizes 21.5, 24.5 and 27.5 mm), which are recommended for native valve annulus sizes of 17.5-20.5, 19.5-23.5 and 22.5-26.5 mm. Edwards' products are indicated for native valve annulus sizes in the same ranges. The Munich Local Division established that, compared to these products, Meril's intermediate-sized valve prostheses do not result in a notable enhancement of patient care. It observed that Meril does not have data to support

its contention that the infringing embodiment is superior and that a "LANDMARK" clinical trial sponsored by Meril India did not even show that it is non-inferior to Edwards' products (Exhibit K-B1). It also referred to a TCT conference presentation (Exhibit K94), which according to the Munich Local Division shows that the infringing embodiments perform worse than the Edwards valves in many respects and refutes the contention of Meril India and Meril Germany that their intermediate-sized products reduce the risk of valve leakage and the need for subsequent pacemaker implantation.

193. Meril India and Meril Germany failed to demonstrate that the findings of the Munich Local Division on the lack of an enhancement of patient care are incorrect. They reiterated their assertion that the availability of different models assists the treating physician when implanting a heart valve and reduces the risk of mal-implantation and over- and under-expansion. However, they did not contest that they do not have data to support the superiority of their intermediate-sized valves, that their LANDMARK study does not show such superiority, or that the TCT conference presentation shows that Meril's prostheses actually perform worse and instead refutes the alleged risks of using Edwards' products. They only refer to a recently published comparison of the Myval-THV-series with the Sapien-THV-series (Exhibit HL-Appeal 7) but failed to draw any conclusions from this publication and did not show that this publication does support their assertions.

194. As far as Meril's XL devices are concerned, the Munich Local Division acknowledged a legitimate interest in their availability. It established that there may be patients who can only be adequately treated with Meril's XL devices, in view of *inter alia* the fact that Edwards' products are not recommended for native annulus sizes of more than 28 mm. It therefore exempted XL devices that were scheduled for implementation in an individualized patient by 15 November 2024 from the injunction and the corrective measures. This part of the judgment is not challenged on appeal.

195. In respect of XL devices not scheduled for implementation, the Munich Local Division held that the interest in their availability is adequately addressed through Edwards' Medical Request Portal. Via this online portal, practitioners can upload relevant patient data. A team of doctors at Edwards review the data and determine whether use of Edwards' product is an option. If the doctors find that using Edwards' products is not an option, Edwards will grant an exception to the injunction.

196. The Court of Appeal agrees with Meril India and Meril Germany that Edwards' portal does not adequately address the legitimate interest in the availability of Meril's XL devices. The availability of these products should not depend on the willingness of Edwards to maintain the portal or on the assessment by Edwards' team of doctors. A notification of an intention to use Meril's XL device by a physician confirming that such product is the only available treatment option for a particular patient should be sufficient. The Court of Appeal will therefore amend the injunction and orders for corrective measures accordingly and maintain them on the basis of an auxiliary request which the parties have drafted in common accord during the oral hearing in the appeal proceedings.

197. Under the amended orders, the making, offering, placing on the market and use of Meril's XL devices, and the importing and storing of the products for those purposes, are not covered by the injunction and corrective measures, provided that a physician has submitted the required notification. Contrary to the concerns put forward by Meril India and Meril Germany, this implies that the injunction does not prohibit them from making doctors aware of the availability of the XL devices where it is the only treatment option for a particular patient.

198. The complaints by Meril India and Meril Germany about the findings of the Munich Local Division on their willingness to obtain a licence can remain undecided. The findings were not decisive for the Court's decision to grant the injunction and the corrective measures. Although the Munich Local Division regarded Meril India and Meril Germany as unwilling licensees, it examined the interests in the availability of the valves. To the extent that it denied the requested exemption, the decision is based on the lack of notable enhancement of patient care, not the unwillingness to take a licence.

Publication

199. The Munich Local Division allowed Edwards to publish the Court's decision in whole or in part, including the announcement of the decision, in five public media including industry journals of its choice. The complaint by Meril India and Meril Germany that the Munich Local Division failed to "*engage*" with their arguments against such publication is ill-founded. The Munich Local Division expressly considered that Edwards has a legitimate interest in the publication of the decision and granted the order. In so doing, it dismissed the arguments of Meril India and Meril Germany that there is no need for publication of the decision and that the order should be rejected because of the punitive effect of the publication.

200. The Court of Appeal concurs with the opinion of the Munich Local Division that Edwards has a legitimate interest in publication of the decision, *inter alia* to inform doctors and patients about the unavailability of the infringing devices. The interests of Meril India and Meril Germany do not outweigh this interest. Although Art. 80 UPCA confers the power to order publication of information regarding the Court's decision "*at the expense of the infringer*", Edwards did not request this, and the Munich Local Division did not order it. The order therefore merely confirms Edwards' right to republish the Court's decision, which Edwards has within certain limits also without a Court order. Moreover, the order takes the interests of Meril India and Meril Germany into account by specifying that the publication must either comprise the entire text of the decision or the rubric and operational part of the decision. The order thereby ensures that the public is comprehensively informed about the decision.

Interim damages or costs

201. The Munich Local Division ordered Meril India and Meril Germany to pay preliminary damages in the amount of € 663,000 to Edwards. It considered that the proposed sum had not been contested by Meril India and Meril Germany. The complaint by Meril India and Meril Germany regarding this order and the reasoning are partially well-founded.

202. Edwards explained that it calculated the claimed amount by adding the Court fees to the reimbursable representation costs for a value of the matter in dispute of € 8,000,000. However, contrary to Edwards' view, the legal basis for a request for an interim award of such costs is not Art. 68 UPCA and R. 119 RoP, but Art. 69(1) UPCA and R. 150(2) RoP.

203. As a general rule, Art. 69(1) UPCA and R. 150(2) RoP do not entitle the successful party to an interim reimbursement of representation costs of more than 50% of the ceiling of recoverable costs as adopted by the Administrative Committee under R. 152.2 RoP. To what extent the successful party is entitled to a reimbursement of representation costs is to be determined in the proceedings for a cost decision pursuant to Chapter 5 of Part 1 RoP. In general, the Court may assume that the successful party will be entitled to 50% of the applicable ceiling and may order reimbursement of that amount by means of an interim award, unless there are clear indications that the successful party in fact incurred fewer representation costs or that 50% of the applicable ceiling is more than what would be reasonable or proportionate in the particular circumstances of the case. At the same time, as a general rule, the Court cannot assume that the successful party is entitled to more than 50% of the applicable ceiling before the conclusion of the cost proceedings according to Chapter 5 of Part 1 RoP. An exception may apply if parties have submitted and discussed cost specifications during the proceedings or have agreed on the costs to be reimbursed.

204. It follows that Edwards in this case is entitled to an interim award of 50% of the applicable ceiling of representation costs (50% of € 600,000 = € 300,000) plus the court fee (€ 63,000). There are no indications that Edwards in fact incurred fewer costs or that this amount is more than what would be reasonable and proportionate in the circumstances of the present case. Nor is there any reason to exceptionally reimburse more than 50% of the applicable ceiling as an interim award.

No conditional orders

205. There is no need for the Court of Appeal to decide upon the complaint by Meril India and Meril Germany concerning the application of Art. 56(1) UPCA and R. 118.2(a) RoP. The Court of Appeal heard the infringement action and the action and counterclaims for revocation together. Therefore, there is no need to render the decision on the merits of the infringement claim or any of its orders under the condition subsequent that the patent is not held to be invalid by the final decision in the revocation proceedings.

Claims predating 1 June 2023

206. The argument by Meril India and Meril Germany that the Court does not have competence to hear claims regarding acts that occurred before the entry into force of the UPCA on 1 June 2023 must be rejected. For the reasons given by the Court of Appeal in the decisions in the cases of Fives v REEL (UPC_CoA_30/2024 APL_4000/2024, decision of 16 January 2025) and XSYS v ESKO (UPC_CoA_156/2025 APL_8790/2025, order of 2 June 2025), the competence of the Court is not limited in temporal scope.

207. The complaint by Meril India and Meril Germany that Edwards failed to present facts supporting its claims predating 1 June 2023 must be rejected. In the Statement of claim, Edwards submitted that Meril India and Meril Germany committed various infringing acts prior to 1 June 2023. These submissions are sufficient to support the claims predating 1 June 2023.

Cost decision first instance

208. The complaints against the cost decision must be dismissed. The main complaint is based on the assumption that the Court of Appeal will set aside the impugned infringement decision and dismiss the infringement action. This assumption is not correct. The impugned infringement decision will be upheld to a large extent.

209. The fact that the Munich Local Division dismissed some of Edwards' requests does not rule out that Meril India and Meril Germany are the unsuccessful parties within the meaning of Art. 69(1) UPCA and does not mean that the Court must order that Edwards bear a part of the costs on the basis of Art. 69(2) UPCA. This is because the dismissed parts of the request concern issues of relatively minor importance, such as the rejection of requests relating to the territory of Romania (next to the granting of the requests for the territory of sixteen other Member States) (see further below) and the dismissal of the order to publish the operative part of the decision on the websites of Meril India and Meril Germany (next to the grant of, *inter alia*, the injunction, the corrective measures and damages). The same applies to the part of the requests which the Court of Appeal dismisses, i.e. the exemption for the XL devices and part of the payment order.

Enforceability

210. Meril India and Meril Germany failed to demonstrate that the scope of their obligations under the orders contained in the impugned infringement decision is so unclear as to render those orders unenforceable.

211. There is no lack of clarity on the substantive scope of the obligations. In fact, the parties agree on the substantive scope. Meril India and Meril Germany argue 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 that Meril's delivery apparatus Navigator/Navigator Inception is included in that system. However, Meril India and Meril Germany themselves have not taken the position that the order must be interpreted in that way and have not submitted that they 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.

212. Nor is the temporal scope of the obligations unclear. The time period for compliance with a penalty-reinforced order contained in a decision on the merits starts upon service of the notification pursuant to R. 118.8 RoP if all other requirements for enforcement are met (UPC_CoA_669/2025, order of 14 October 2025, Kodak v Fujifilm, paragraph 47). The fact that the operative part of the impugned infringement decision provides that some of the orders are to be complied with "*from the date of service of the decision*", without referring to the notification requirement of R. 118.8 RoP, does not mean that the notification requirement does not apply or that the time period for compliance starts before the service of the notification. Moreover, Meril India and Meril Germany have not demonstrated that the alleged unclarity has caused any problems in complying with the orders. On the contrary, as stated by Meril India and Meril Germany 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 the time period for compliance, even if calculated from the date of service of the decision.

Appeal by Edwards against the impugned infringement decision (APL_2205/2025)

Main request

213. Edwards' appeal against the rejection of its main request is not well-founded.

214. In its main request, Edwards sought an injunction ordering Meril India and Meril Germany to cease and desist from – in summary – infringing the patent at issue "*within the territory of the Agreement on a Unified Patent Court at the time of the oral hearing*", without specifying the relevant Member States. The Munich Local Division was correct to dismiss this request for a lack of clarity. It is the responsibility of the claimant to clearly define its requests, including the geographical scope of the orders it seeks. As a general rule, this will require listing the countries in which the requested order is to be applicable, as Edwards did in its auxiliary request. Such a specification ensures that the defendant, the Court and – if the order is granted – the national authorities involved in the enforcement of the order can unambiguously and without further research determine the geographical scope of the order.

Claim amendment

215. Edwards' appeal against the decision of the Munich Local Division to deny leave to change Edwards' auxiliary request by adding Romania to the list of countries is not successful either.

216. Under R. 263.2 RoP, leave to change a claim shall not be granted if, all circumstances considered, the party seeking the amendment cannot satisfy the Court that:
a) the amendment in question could not have been made with reasonable diligence at an earlier stage; and
b) the amendment will not unreasonably hinder the other party in the conduct of its action.

217. Edwards failed to demonstrate that the amendment in question could not have been made with reasonable diligence at an earlier stage. On 31 May 2024, Romania ratified the UPCA. Pursuant to Art. 89(2) UPCA, the ratification took effect on the first day of the fourth month after the deposit of the instrument of ratification, i.e. on 1 September 2024. Accordingly, the Court announced that Romania would accede to the UPCA on 1 September 2024 in a communication published on its website on 4 June 2024. However, Edwards delayed the filing of its request for leave to amend claim until the oral hearing on 24 September 2024. Even in the interim conference of 5 September 2024, it did not mention that it would seek such a claim amendment.

218. Moreover, by raising the claim amendment at such a late stage, it unreasonably hindered Meril India and Meril Germany in the preparation of their defence against the claim amendment. An extension of the

geographical scope may require some investigation and argumentation, as the facts of the present case illustrate. At the oral hearing before the Munich Local Division, it emerged that Edwards could not provide evidence that it had paid the annuities and that the patent at issue had been validated in Romania.

219. Edwards' reference to the Court of Appeal's order in the case of Syngenta v Sumi Agro (UPC_CoA_523/2024, order of 3 March 2025) cannot alter that assessment. In that case, the UPCA's entry into force in Romania took place after the Court of First Instance issued its order. In that situation, R. 222.2 RoP does not preclude allowing a claim amendment adding Romania to the territorial scope of the order. In the present case, however, the UPCA entered into force in Romania before the oral hearing in the first instance proceedings. Edwards could therefore have filed the amended claim with the Munich Local Division and should have done so before the oral hearing.

Conclusion

220. It follows that the appeals against the impugned revocation decision, claim amendment order and competence order must be rejected. Edwards' appeal against the impugned infringement decision is not successful either. The appeal by Meril India and Meril Germany against the impugned infringement decision must be rejected, except for the grant of the injunction and corrective measures regarding XL devices that had not already been scheduled for implementation and the order to pay interim damages in the amount of € 663,000. The Court of Appeal will set aside that latter part of the impugned infringement decision and uphold the remainder of the decision. It will grant the injunction and corrective measures regarding XL devices that had not already been scheduled for implementation in an individual patient by 15 November 2025 in amended form. It will order an interim award of costs in the amount of € 363,000. For reasons of efficiency, it will do so by setting aside the impugned infringement decision to the extent that Meril India and Meril Germany were ordered to pay preliminary damages of more than € 363,000.

221. Where multiple appeals against an order or decision in an action are decided together, the Court of Appeal may give a combined decision on the costs of those appeals.

222. In the direct revocation action and the counterclaims for revocation, both parties succeed on appeal only in part. The Court of Appeal will therefore apportion the costs equitably pursuant to Art. 69(2) UPCA. Since the appeals by both Meril and Edwards are rejected entirely, the costs will be apportioned in the same way as the Central Division has done. This means that Meril must bear 60% of the costs that Edwards incurred in these appeal proceedings and that Edwards must bear 40% of Meril's costs.

223. Also in the infringement action, both parties succeed on appeal only in part, since the appeal by Edwards and the appeal by Meril India and Germany are rejected entirely or to a large extent. The Court of Appeal will therefore apportion the costs equitably pursuant to Art. 69(2) UPCA. The appeal by Edwards against the impugned infringement decision aimed at adding one Member State to the sixteen Member States covered by its originally filed requests. Edwards will therefore be ordered to bear 1/17 of the costs that Meril India and Meril Germany incurred in the appeal proceedings relating to the infringement action. In respect of the other sixteen Member States the orders imposed by the Munich Local Division in the impugned infringement decision are largely upheld. The amendment of the injunction and corrective measures and the reduction of the payment order is of relatively minor importance for the purpose of the allocation of costs. Meril India and Meril Germany will therefore be ordered to bear 16/17 of the costs that Edwards incurred in the appeal proceedings relating to the infringement action.

224. The value of the actions on appeal is the same as the value of the infringement action, the direct revocation action and the counterclaims for revocation, as determined by the Munich Local Division and the Central Division respectively, i.e. € 8,000,000.

DECISION

In the appeals by Meril Italy and Edwards against the impugned revocation decision, competence order and claim amendment order (UPC_CoA_464/2024 APL_45049/2024 and UPC_CoA_530/2024 APL_ 51701/2024)

I. The appeals are rejected;

II. Meril Italy is ordered to bear 60% of Edwards' costs;

III. Edwards is ordered to bear 40% of Meril Italy's costs;

IV. The value of the direct revocation action on appeal is € 8,000,000;

In the appeals by Meril India and Meril Germany and Edwards against the impugned revocation decision (UPC_CoA_458/2024 APL_44702/2024, UPC_CoA_457/2024 APL_44701/2024, UPC_CoA_532/2024 APL_ 51746/2024, and UPC_CoA_533/2024 APL_ 51748/2024)

V. The appeals are rejected;

VI. Meril India and Meril Germany are ordered to jointly bear 60% of Edwards' costs;

VII. Edwards is ordered to bear 40% of the costs of Meril India and Meril Germany;

VIII. The value of the counterclaims on appeal is € 8,000,000;

In the appeals by Edwards and by Meril India and Meril Germany against the impugned infringement decision (UPC_CoA_27/2025 APL_2205/2025 and UPC_CoA_21/2025 APL_1926/2025)

IX. The impugned infringement decision is set aside to the extent that the orders sub I, V, and VI extend to XL devices (30,5 mm and 32 mm) that have not been scheduled for implantation in an individual patient by 15 November 2024 and that Meril India and Meril Germany were ordered to pay preliminary damages in the amount of more than € 363,000;

X. The orders sub I, V, and VI of the impugned infringement decision do not extend to XL devices that have been the subject of a notification of an intention to use by a physician confirming that the XL device is the only available treatment option for a particular patient in the Medical Request Portal, which Edwards has confirmed will remain operational for the XL devices, or otherwise such a notification is made in writing to Edwards should the Medical Request Portal not be available;

XI. The appeals are rejected in all other respects;

XII. Meril India and Meril Germany are ordered to jointly bear 16/17 of Edwards' costs;

XIII. Edwards is ordered to bear 1/17 of the costs of Meril India and Meril Germany;

XIV. The value of the infringement action on appeal is € 8,000,000.

This decision was issued on 25 November 2025.

KLAUS STEFAN MARTIN Grabinski

Digitally signed by KLAUS STEFAN MARTIN Grabinski
Date: 2025.11.24 15:25:37 +01'00'

Klaus Grabinski, president of the Court of Appeal

Peter Hendrik Blok

Digitally signed by Peter Hendrik Blok
Date: 2025.11.25 09:05:04 +01'00'

Peter Blok, legally qualified judge and judge-rapporteur

EMMANUEL, LUCIEN, RENÉ GOUGÉ

Signé numériquement par EMMANUEL, LUCIEN, RENÉ GOUGÉ
Date : 2025.11.24 15:33:40 +01'00'

Emmanuel Gougé, legally qualified judge

Elisabetta Papa

Firmato digitalmente da Elisabetta Papa
Data: 2025.11.24 15:54:20 +01'00'

Elisabetta Papa, technically qualified judge

Max Wilhelm Tilmann

Digital unterschrieben von Max Wilhelm Tilmann
Datum: 2025.11.24 16:04:55 +01'00'

Max Tilmann, technically qualified judge