

Procedural Order of the Court of First Instance of the Unified Patent Court Local Division Munich issued on 3 June 2025

CLAIMANT

Edwards Lifesciences Corporation, 1 Edwards Way - 92614 - Irvine - US

- represented by: Boris Kreye, Elsa Tzschoppe (Bird & Bird)
- assisted by: Bernhard Thum, Dr. Jonas Weickert (Thum & Partner); Siddharth Kusumakar, Tessa Waldron and Bryce Matthewson (Powell Gilbert)

DEFENDANTS

1) Meril GmbH Bornheimer Straße 135-137 - 53119 - Bonn – DE

2) Meril Life Sciences Pvt Ltd.

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

3) Meril Italy S.r.l.

Piazza Tre Torri 2 - 20145 - Mailand – IT

represented by: Dr. Andreas von Falck, Dr. Roman Würtenberger, Dr. Lukas Wollenschlaeger, Beatrice Wilden, Dr. Alexander Klicznik, Dr. Felipe Zilly (Hogan Lovells)

Patent at Issue

European patent n° 3669828

PANEL/DIVISION

Panel 1 of the Local Division Munich

DECIDING JUDGE/S

This order has been issued Presiding Judge, Dr Matthias Zigann, acting as Judge-Rapporteur, the legally qualified Judge, Margot Kokke, LLM MSc, the legally qualified Judge, Tobias Pichlmaier, and the technically qualified Judge, Dr Stefan Wilhelm, LL.M.

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Rectifications of decision and orders – R. 353 RoP App_21220/2025 and App_21221/2025 clarification APP_22808/2025

Requests

Meril requests in the two identical applications:

the decision of the Court of First Instance (Munich Local Division) of 4 April 2025, ORD_598588/2023 in ACTION NUMBER: ACT_597277/2023 and ORD_69128/2024 in ACTION NUMBER: CC_23112/2024 in the proceedings UPC CFI 501/2023 be rectified in accordance with the below:

1. Page 3 of the Decision:

Defendants ask that the following statement at page 3 of the Decision:

"Edwards alleges that Meril's "Myval" THV and its "Navigator" THV delivery device infringe independent claims 1 and 12 and dependent claims 2-11 and 13-14 of EP 3 669 828 ("the patent") titled "Prosthetic Heart Valve" and granted on 5 May 2021 (B1) and published in amended form (B2) on 26 June 2024."

be rectified as follows (proposed amendments indicated in red in the original):

"Edwards alleges that Meril's "Myval" THV and its "Navigator" THV delivery device infringe independent claims 1 and independent claim 12 of EP 3 669 828 ("the patent"), titled "Prosthetic Heart Valve" and granted on 5 May 2021 (B1) and published in amended form (B2) on 26 June 2024, as upheld (claim 13 of the patent as granted), and dependent claims 2-811 of the patent as upheld (claims 2-8 of the patent as granted), dependent claims 10 and 11 of the patent as upheld (claims 11 and 12 of the patent as granted), and dependent claim 13-14 of the patent as upheld (claim 14 of the patent as granted) of EP 3 669 828 ("the patent") titled "Prosthetic Heart Valve" and granted on 5 May 2021 (B1) and published in amended form (B2) on 26 June 2024."

The amendment corresponds to a correction of obvious errors. Claimant did only assert the aforementioned claims (see Claimant's Statement of Claim of 27 December 2023, request no. I., cf. further p. 5 of the Reply of 1 July 2024).

2. Page 5 of the Decision:

Defendants ask that the following statement at page 5 of the Decision:

"An opposition to the patent was filed on 4 February 2002 by a third party, Abbott Cardiovascular Systems, Inc. of Santa Clara, USA."

be rectified as follows (proposed amendments indicated in red in the original):

"An opposition to the patent was filed on 4 February 2002 <u>2022</u> by a third party, Abbott Cardiovascular Systems, Inc. of Santa Clara, USA."

The notice of opposition was filed on 4 February 2022. The amendment represents the correction of an obvious clerical error.

3. Page 12 of the Decision:

Defendants ask that the following statement at page 12 of the Decision:

"VI. order the Defendants, under threat of a recurring penalty payment of EUR 1,000 for each day of delay, within a period of one week after service of the Decision, to immediately disclose and hand over the products and/or the relevant materials described in Section I. above and/or the relevant materials (including any products and/or materials that come into its direct and/or indirect possession and/or ownership pursuant to Clause IV or otherwise) or, at its option, to surrender them to a bailiff to be named or appointed by the plaintiff for the purpose of destruction;"

(request under item no. VI.)

be rectified as follows (proposed amendments indicated in red in the original):

"VI. order the Defendants, under threat of a recurring penalty payment of EUR 1,000 for each day of delay, within a period of one week after from the date of service of the Decision, to immediately disclose and hand over destroy the products described in Item I. above that are in their direct and/or indirect possession and/or ownership and/or the relevant respective materials described in Section I. above and/or the relevant materials (including any products and/or materials that come into their its direct and/or indirect possession and/or ownership pursuant to Clause-Item IV or otherwise) or, at their its option, to hand surrender them over to a bailiff to be named or appointed by the Claimant plaintiff for the purpose of destruction;"

The amendment represents the correction of an obvious error. Claimant, with its Statement of Claim filed on 27 December 2023 in German, requested (see request under item no. VI., p. 8):

"VI. die Beklagten dazu verurteilt, unter Androhung eines für jeden Tag der Verzögerung wiederholt zu zahlenden Zwangsgeldes in Höhe von EUR 1.000, innerhalb eines Zeitraums von einer Woche nach Zustellung der Entscheidung die in ihrem unmittelbaren und/oder mittelbaren Besitz und/oder Eigentum befindlichen, vorstehend unter Ziff. I. bezeichneten Erzeugnisse und/oder der betreffenden Materialien (einschließlich aller Produkte und/oder Materialien, die gemäß Ziff. IV oder anderweitig in ihren direkten und/oder indirekten Besitz

und/oder ihr Eigentum gelangen) zu vernichten oder nach ihrer Wahl an einen von der Klägerin zu benennenden oder zu beauftragenden Gerichtsvollzieher zum Zwecke der Vernichtung herauszugeben;"

This is to be translated as follows:

"VI. to order the Defendants, under threat of a recurring penalty payment of EUR 1,000 for each day of delay, within a period of one week from the date of service of the Decision, to destroy the products described in Item I. above that are in their direct and/or indirect possession and/or ownership and/or the respective materials (including any products and/or materials that come into their direct and/or indirect possession and/or ownership pursuant to Item IV or otherwise) or, at their option, to hand them over to a bailiff to be named or appointed by the plaintiff for the purpose of destruction;"

As far as Defendants are aware, Claimant did not request with its Statement of Claim that "products and/or materials be immediately disclosed and handed over" as stated in the

4. Page 50 of the Decision:

Defendants ask that the following statement at page 50 of the Decision:

"Finally, with respect to claim 14, Meril argues that this claim depends on claims 12 or 13, so that the objections raised for those claims apply mutatis mutandis. Meril also argues that the tapered shape of the frame can result from various effects, such as frames comprising lower cells with larger openings compared to intermediate cells with smaller openings (paragraph [061]) or the valve comprising V-shaped leaflets (paragraph [085]). Neither of these features is present in claim 14."

be rectified as follows (proposed amendments indicated in red in the original):

"Finally, with respect to claim 14, Meril argues that this claim depends on claims 12 or 13, so that the objections raised for those claims apply mutatis mutandis. Meril also argues that the tapered shape of the frame can result from various effects, such as frames comprising lower cells with larger openings compared to intermediate cells with smaller openings (paragraph [061]) or the valve comprising V shaped leaflets (paragraph [085]). Neither of these features is present in claim 14. Meril also argues that paragraph [008] cannot provide a basis as it requires that the prothesis is mounted on the shaft in a radially compressed configuration. Furthermore, paragraph [085] cannot provide a basis as it refers to the specific embodiment of Fig. 56 which comprises features that were omitted from claim 14."

The amendment is based on page 38 of the Counterclaim (referring to claim 15 as granted which corresponds to claim 14 of the patent as maintained by the Opposition Division) and page 32 of the Reply to the Defense to the Counterclaim. Defendants did not argue that the tapering could be achieved by other means that the V-shaped leaflets. Defendants referred to the omission of features disclosed in connection with the embodiment of Fig. 56.

On page 38 of the Counterclaim it reads as follows:

"Claim 15 as granted adds subject-matter. Again, paragraph [008] of HLCC 3 discloses that rosthetic heart valve is mounted on the shaft in a radially collapsed configuration for delivery into the body while claim 13 as granted, on which claim 15 as granted depends, specifies that the prosthetic value is "adapted to be mounted" on the shaft in a radially collapsed configuration for delivery into the body. Hence, also paragraph [008] cannot provide a basis. Additionally, paragraph [085] specifically refers to the embodiment shown in Fig. 56. However, the further features of this embodiment are not specified in claim 15 as granted".

5. Page 53 of the Decision:

Defendants ask that the following statement at page 29 of the Decision:

"Prior art references HL-CC 15 and HL-CC 16 were filed late. Meril filed these references with the reply to the defence dated 2 September 2024, without giving any reason for the late filing. The Court therefore disregards the late filed prior art references and the arguments relating to them (Rule 9.2 RoP)."

be rectified as follows (proposed amendments indicated in red in the original):

"Prior art references HL-CC 15 and HL-CC 16 were filed late. Meril filed these references with the reply to the defence dated 2 September 2024, without giving any reason for the late filing. in response to the Claimant's objections against the means of evidence for showing that primary and secondary tabs belonged to the common general knowledge. The Court therefore disregards the late filed prior art references and the arguments relating to them (Rule 9.2 RoP)."

The amendment is based on that fact that the Defendants highlighted in their brief dated 2 September 2024 that documents HL CC 15 and HL CC 16 are filed in response to the Claimant's objections. On page 17 of the brief it reads as follows:

"1. The Claimant does not dispute that the cited documents disclose primary and secondary tabs (cf., section E. of the Counterclaim for Revocation).

2. The Claimant's only argument is that the patent documents (which disclose primary and secondary tabs) do not form part of the common general knowledge."

Based on these two sentences it becomes clear that the following pleading is in direct response to the Claimant's pleading in the context of the common general knowledge. Specifically, the Claimant objected against the view that certain documents qualified as evidence of the common general knowledge. This was countered by reference to supporting case law (cf. pages 17 and 18 of the Reply to the Defense to the Counterclaim), and additional prior art documents HL CC 15 and HL CC 16. It was highlighted that HL CC 15 is referenced in the patent specification of the patent in suit and therefore qualifies as evidence of the common general knowledge (cf. page 18 of the Reply to the Defense to the Counterclaim). HL CC 16 was filed to show that the commercially available CoreValve has primary and secondary tabs (cf. pages 20 to 21 of the Reply to the Defense to the Counterclaim).

From all this it becomes apparent that the Defendants provided reasons for the filing of HL CC 15 and HL CC16.

6. Page 80 of the Decision:

Defendants ask that the following statement at page 80 of the Decision:

"Meril has not provided any motivation for the skilled person to combine Lobbi with Nguyen."

be rectified as follows (proposed amendments indicated in red in the original):

"Meril has not <u>detailed why Nguyen</u> provided <u>a</u> any motivation for the skilled person to combine Lobbi with Nguyen (<u>cf., e.g., pages 68 and 69 of the Counterclaim and pages 44 and 45 of the</u> <u>Reply to the Defense to the Counterclaim</u>), namely the improved strength and durability of the <u>leaflets."</u>

Defendants provided detailed reasoning on the cited pages of the Reply to the Defense to the Counterclaim and the Counterclaim as to why the skilled person would have been motivated to combine the documents and would have arrived that the claimed subject matter. For example, Defendants stated on page 68 of the Counterclaim:

"The skilled person starting from HL-CC 8 would consider HL-CC 5. Both documents relate to the durability of the heart valve".

On page 45 of the Reply to the Defense to the Counterclaim it is stated:

"The teaching of Nguyen provides the skilled person with a strong incentive to implement the secondary tabs according to claim 1 in the embodiment of Lobbi."

We refer to section H.II.8 of our Counterclaim for Revocation. In particular, in paragraphs [0038] and [0053], Nguyen discloses that the folding of the secondary tabs and thereby the formation of a double layer enhances the strength and durability of the leaflets".

Accordingly, stating that Defendants had not provided any motivation (suggesting that Defendants remained completely silent on this aspect) represents an obvious error.

7. Page 103 of the Decision:

Defendants ask that the following statements at page 103 of the Decision:

"For all these reasons and after having heard the parties Panel 1 of the Local Division Munich

I. dismisses the preliminary objections and the counterclaim for revocation and

II. orders the three Meril defendants individually and jointly to refrain from offering, placing on the market, using, or importing or storing for the said purposes any product according to claims 1 to 13 of the patent at issue (EP 3 669 828 B2), in particular with the transcatheter prosthetic heart valve called "Myval" as shown below, or an assembly that comprises the "Myval" and a delivery apparatus called "Navigator" (together: the Infringing Products") as shown below:"

be rectified as follows (proposed amendments indicated in red in the original):

"For all these reasons and after having heard the parties Panel 1 of the Local Division Munich

I. dismisses the preliminary objections and the counterclaim for revocation and

II. orders the three Meril defendants individually and jointly to refrain from offering, placing on the market, using, or importing or storing for the said purposes any product according to claims 1 to <u>8</u>, and <u>10 to</u> <u>13</u> of the patent at issue (EP 3 669 828 B2), in particular with the transcatheter prosthetic heart valve called "Myval" as shown below, or an assembly that comprises the "Myval" and a delivery apparatus called "Navigator" (together: the Infringing Products") as shown below:"

The proposed amendment is based on the fact that Claimant's requests concerned claims 1 to 8, and 10 to 13 of the patent as upheld by the Opposition Division (EP 3 669 828 B2).

See, e.g., pages 3 to 7 of the Statement of Claim and page 5 of the Claimant's Reply to the Statement of Defense.

8. Page 104 of the Decision:

Defendants ask that the following statement at page 104 the Decision:

"VII. orders the three Meril defendants individually and jointly, under threat of a recurring penalty payment of up to EUR 1,000 for each day of delay, within a period of one week after service of the Decision, to immediately disclose and hand over the Infringing Products described in item II. above and/or the relevant materials (including any products and/or materials that come into its direct and/or indirect possession and/or ownership pursuant to item VI. or otherwise) or, at its option, to surrender them to a bailiff to be named or appointed by Edwards for the purpose of destruction;"

(order under item no. VII.) be rectified as follows (proposed amendments indicated in red in the original):

"VII. orders the three Meril defendants individually and jointly, under threat of a recurring penalty payment of up to EUR 1,000 for each day of delay, within a period of one week after from the date of service of the Decision, to immediately disclose and hand over destroy the Infringing Products described in item II. above that are in their direct and/or indirect possession and/or ownership and/or the relevant respective materials (including any products and/or materials that come into their its direct and/or indirect possession and/or ownership or, at their its option, to hand surrender them over to a bailiff to be named or appointed by the Edwards for the purpose of destruction;"

The amendment represents the correction of an obvious error. In Defendants opinion, the wording of the order is the consequence of the translation error explained in section 3. above. As is apparent from the Division's comments at page 100 of the Decision (section 5.), the Division sought to order the destruction of the products as is now reflected in the amended wording of the order.

Edwards argues:

Page 3 of the Decision:

Claimant **does not object** to Defendants' request regarding the requested correction on page 3 of the Decision, which refers to the asserted claims of the patent-in-suit. The Decision should be rectified in that Claimant asserted infringement of independent claims 1 and 12 (claim 13 of the patent as granted), dependent claims 2-8 of the patent as upheld and dependent claims 10 and 11 of the patent as upheld (claims 11 and 12 of the patent as granted) as well as dependent claim 13 of the patent as upheld (claim 14 of the patent as granted). This follows from the Statement of Claim of 27 December 2023 (request under item I.) and from the Reply to the Statement of Defence of 1 July 2024 (page 5).

Page 5 of the Decision

Claimant **does not object** to Defendants' request regarding the correction on page 5 of the Decision, as the notice of opposition was filed on 4 February 2022 (Exhibit K9).

Page 12 of the Decision

Claimant **does not object** to Defendants' request with respect to the correction of Claimant's request under item VI. on page 12 of the Decision. As mentioned by Defendants, the amendment represents the correction of an obvious error due to the translation of the Statement of Claim from German into English.

Page 50 of the Decision

Claimant **objects** to Defendants' request regarding the requested "rectification" on page 50 of the Decision, as it is unjustified based on the requirements set out in R. 353 RoP. According to R. 353 RoP, the Court may upon an application made by a party within one month of service of the decision, after hearing the parties, rectify clerical mistakes, errors in calculation and obvious slips in the decision. The circumstances listed in R. 353 RoP for rectification of a decision are exhaustive in nature (Local Division Brussels, Order of 8 May 2025, UPC_CFI_582/2024, YEALINK (XIAMEN) NETWORK TECHNOLOGY Co. Ltd. v. BARCO NV, mn. 4).

Based on the case law of several local divisions of this Court (Düsseldorf LD, Order of 30 June 2023, UPC_CFI_177/2023, myStromer v. Revolt Zycling, under II.1, Munich LD, Order of 17 February 2025, UPC_CFI_15/2023, Edwards v. Meril, under I., Mannheim LD, Order of 13 May 2025, UPC_CFI_359/2023, FUJIFILM Corporation v. Kodak et al, page 3), "obvious slips" within the meaning of R. 353 RoP are to be understood as:

"[..]all incorrect or incomplete statements of what the Court actually intended in the order or decision. In other words, the declaration of the Court's intention in the decision or order must deviate from the intention that existed when the decision was made."

The Paris Central Division also confirmed a narrow application of R. 353 RoP in its order of 31 March 2025 (UPC_CFI_412/2023, BMW AG v. ITCiCo Spain S.L., mns. 6-8):

"[...] According to this panel the circumstances contemplated by Rule 353 'RoP' (clerical mistakes, errors in calculation, obvious slips) all consist of a discrepancy between the judge's intended decision and its material representation and this discrepancy must be deduced from a comparison between the part affected by the error and the considerations contained in the reasoning, from which it can be inferred that the error is due to an oversight or a lack of attention. These kinds of errors are the ones that do not concern the identification and evaluation of the relevant elements of the case and the subsequent formation of the judgment, but rather the external expression of the judgment itself. As such, they can be rectified through an administrative-type intervention that restores the correspondence between what the judgment intended to declare and what it formally declared. It follows that an error subject to rectification is solely that consisting of a mere oversight by the judge which has resulted in the non-expression or inaccurate expression of a judgment that was, however, already formed and can be inferred from the context of the ruling. Errors that constitute the expression of a lacking or at least deficient judgment do not fall into this category."

Based on these principles, there is no room for rectification in the present case. The amendment requested by Defendants contains neither an "obvious slip" nor any other clerical mistake. The amendment concerns an alleged error in evaluating the arguments raised by Defendants with respect to claim 14 of the patent-in-suit. However, this type of "error" cannot be rectified through an administrative-type intervention and is therefore not subject to rectification pursuant to R. 353 RoP.

Page 53 of the Decision

Claimant also **objects** to Defendants' request with respect to the statement on page 53 of the Decision regarding the Court's finding that the prior-art references HL-CC 15 and HL-CC 16 were late-filed by Defendants, who did not present any reason or excuse for filing them late.

Based on the scope of application of R. 353 RoP and the standard presented above (mns. 5-7), the requested amendment does not reflect an alleged "mere oversight" of the Court but has to be seen as a legal assessment of a procedural matter.

It is undisputed that Defendants filed the prior-art references HL-CC 15 and HL-CC 16 with the Reply to the Defence in the counterclaim for revocation proceedings and thus not within the regular procedural timetable as set out in R. 25 RoP. After establishing that both prior-art references were late-filed and that Defendants had not provided any reason for this late-filing, the Court exercised its discretionary power pursuant to R. 9.2 RoP and decided to disregard both documents. It is obvious from the explicit reference to R. 9.2 RoP that the Court's finding is based on its discretionary powers and not an incorrect or incomplete statement of what the Court actually intended to state inthe decision.

Furthermore, the requested addition to the Decision addresses what issue these late filed documents go to, but does not address the reasons why they were late filed. Also for this reason the requested rectification should not be allowed.

Therefore, there is no room for the applicability of R. 353 RoP.

Page 80 of the Decision

Claimant **objects** to Defendants' request regarding the amendment on page 80 of the Decision. The requested amendment is not a clerical mistake or an obvious slip in the sense of R. 353 RoP, but rather alters the expression of the Court's evaluation of the relevant factual and legal issues of the case and the subsequent formation of the judgment. It further deviates from the Court's intention. Plainly rectification pursuant to R. 353 RoP is not the correct mechanism for challenging such matters.

On an auxiliary basis, Claimant notes that the amendment requested by Defendants would not impact the outcome of the proceedings. The Court considered that the claimed subject-matter is inventive over a combination of Lobbi and Nguyen and confirmed that even if the skilled person would have been motivated to combine the documents, the resulting valve would not show all features of claim 1 of the patent-in-suit (the Decision, page 80):

"Meril has not provided any motivation for the skilled person to combine Lobbi with Nguyen. Even if the skilled person would have combined the two references the resulting valve would not show all features of claim 1. As Nguyen only discloses folding

around folding lines d, e and f that all extend in parallel an axial orientation of creases in the assembled valve as claimed in the Patent will not be obtained."

Page 103 of the Decision

Claimant **does not object** to the proposed amendment on page 103 of the Decision. As pointed out by both parties, Claimant asserted infringement of claims 1 to 8 and 10 to 13 of the patent as upheld by the Opposition Division and published in amended form (B2) (see above under mn. 1).

Page 104 of the Decision

Claimant **does not object** to Defendants' request to rectify the order under item no. VII. on page 104 of the Decision. As explained above (mn. 3), the present wording is the consequence of a translation error and therefore an "obvious slip" within the meaning of R. 353 RoP.

GROUNDS FOR THE ORDER

It was unclear to the court why Meril filed two identical applications. Meril sufficiently explained in App_22808/2025:

When filing a request for rectification under Rule 353 RoP via the CMS, the CMS asks a party (1) to link the request to a specific action number and (2) to provide an order number (if applicable). Since Defendants ask for the rectification of obvious errors relating to both, the infringement action and the counterclaim for revocation, Defendants filed the request for rectification twice, once linked to the infringement action (by indicating action number ACT_597277/2023 and the related order number) and once linked to the counterclaim (by indicating the separate action number CC_23112/2024 and the related order number) in order to comply with the formal requirements of the CMS. Furthermore, Defendants intended to make it clear that the request relates to both "parts" of the decision. Hence, the filing of two identical requests was caused by technical reasons and the intention to avoid any ambiguities.

The applications are founded with regard to items 1, 2, 3, 7 and 8. Edwards did not object to these requests. The court agrees with both parties' reasoning.

However, items 4, 5 and 6 of these requests are unfounded, as Edwards explained above. The court agrees with Edwards' reasoning.

Order

1. The Court of First Instance of the Unified Patent Court, Local Division Munich, rectifies the decision dated 4 April 2025 (ORD_598588/2023 in ACTION NUMBER: ACT_597277/2023 and ORD_69128/2024 in ACTION NUMBER: CC_23112/2024 in the proceedings UPC CFI 501/2023) in accordance with items 1, 2, 3, 7 and 8 of the applications to rectify dated 5 May 2025.

2. The applications to rectify dated 5 May 2025 are otherwise dismissed.

Zigann Presiding Judge and Judge-rapporteur	
Kokke Legally Qualified Judge	
PichImaier Legally Qualified Judge	
Wilhelm Technically Qualified Judge	

DETAILS OF THE ORDER

Order no. ORD_22208/2025 in ACTION NUMBER: ACT_597277/2023 UPC number: UPC_CFI_501/2023 Action type: Infringement Action Related proceeding no. Application No.: 21220/2025 Application Type: Generic procedural Application

Order no. ORD_22209/2025 in ACTION NUMBER: ACT_597277/2023 UPC number: Not provided Action type: Infringement Action Related proceeding no. Application No.: 21221/2025 Application Type: Generic procedural Application

Order no. ORD_26274/2025 in ACTION NUMBER: ACT_597277/2023 UPC number: UPC_CFI_501/2023 Action type: Infringement Action Related proceeding no. Application No.: 22808/2025 Application Type: Generic procedural Application