

Local Division Munich UPC_CFI_15/2023

Order

of the Court of First Instance of the Unified Patent Court Local Division Munich concerning EP 3 646 825 delivered on 17 February 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 (APPLICANTS)

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

represented by: Dr. Andreas von Falck, Dr. Roman Würtenberger, Dr. Lukas

Wollenschlaeger, Beatrice Wilden, Dr. Alexander Klicznik, Dr. Felipe Zilly

(Hogan Lovells)

assisted by: Peter-Michael Weisse, Ole Dirks, Dr. Eva Maria Thörner (Wildanger)

PATENT AT ISSUE

European patent n° 3 646 825.

PANEL/DIVISION

Panel 1 of the Local Division Munich.

DECIDING JUDGES

This decision has been delivered by the presiding judge Dr. Matthias Zigann, also 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.

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Rule 353 RoP - Rectification of decision and orders

PARTIES' REQUESTS

Meril seeks

the decision of the Court of First Instance (Munich Local Division) of 15 November 2024, order no. ORD_598479/2023, issued in case UPC_CFI_15/2023 (ACT_458897/2023) be rectified in accordance with the below:

1. Page 13 of the Decision: Defendants ask that the following statement at page 13 of the Decision:

"According to Meril it is therefore clear that the allegedly infringing "Myval Octacor" heart valve does not exhibit the features set out in claim 1 of EP '825 as upheld, namely features 3. 4 and 5a."

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

"According to Meril it is therefore clear that the allegedly infringing "Myval Octacor" heart valve does not exhibit the features set out in claim 1 of EP '825 as upheld, in particular namely features I.3, I.4 and I.5a."

Defendants objected to the allegation of patent infringement not only on the basis of that features I.3, I.4 and I.5.a) of patent claim 1 of EP 825 according to the feature structure at page 25 of the Decision were not realised. Defendants argued already in, for example, their Statement of Defence of 2 November 2023 (p. 55) that inter alia features I.5)b) and c) of patent claim 1 of EP 825 according to the feature structure at page 25 of the Decision were also not realised.

2. Page 14 of the Decision: Defendants ask that the following statement at page 14 of the Decision:

"Furthermore, the LDM had no jurisdiction with respect to the Düsseldorf based Meril GmbH. Edwards should have chosen the Local Division Düsseldorf."

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

"Furthermore, the LDM had no jurisdiction with respect to the DüsseldorfBonn-based Meril GmbH. Edwards should have chosen the Local Division Düsseldorf."

As correctly recorded at page 3 of the Decision, Meril GmbH (Defendant 1)) is based in Bonn.

3. Page 28 of the Decision Defendants ask that the following statement at page 28 of the Decision that was made with reference to Dr. Mayer's expert opinion (Exhibit HL 12):

"The connections to neighboring struts are characterized as plastically and to a certain (low) extent elastically deformable and can thus be provided, for example, as welding points."

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

"The connections to neighboring struts are characterized as plastically and to a certain (low) extent elastically deformable and can thus be provided, for example, as welding points."

Dr. Mayer did not state in his expert opinion that "connections" could be provided, for example, as welding points, but stops with that the connections to neighbouring struts are plastically and to a certain (low) extent elastically deformable. We display the relevant passage to which the Division seems to be referring at page 28 of the Decision and which we took from page 6 of Dr. Mayer's expert opinion (Exhibit HL 12) below:

"Streben als Teil eines Prothesenrahmens Obertragen Kräfte und verbinden sich mit anderen Streben zu einem Gitter. Die Verbindungen zu benachbarten Streben sind dabei plastisch und zu einem gewissen (geringen) Teil elastisch verformbar. Die Dicke der Streben (Stegbreite) richtet sich vor allem nach den mechanischen Erfordernissen der Zellenstruktur, um zusammen mit dem Gewebe ausreichend Komprimierbarkeit zur Minimierung des Profils beim Einführen der Prothese in den Patienten zu erzielen und vor allem um ausreichend Radialkraft für eine sichere und dauerhafte Verankerung der Prothese im Patienten zu gewährleisten."

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

"Mayer also refers to a definition of the term "strut" as provided, e.g., by the Webster dictionary."

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

"Mayer also refers to a definition of the term "strut" as provided for at https://www.encyclopedia.com/literature-and-arts/art-ndarchitecture/architecture/strut, e.g., by the Webster dictionary."

Dr. Mayer does not refer to the dictionary of Merriam Webster with regard to the term "strut", but states at page 6 of Exhibit HL 12:

"Eine Strebe ist ein Stab oder eine Stange, der/die Teil eines Rahmens ist und der Kompression standhalten soll (https://www.encyclopedia.com/literature-and-arts/art-nndarchitecture/architecture/strut)."

5. Page 40 of the Decision Defendants ask that the following statement at page 40 of the Decision:

"This is in line with the findings by the OD and the BoA of the EPO in the opposition proceedings against EP '920, another divisional of WO '801. The EPO did not regard Levi as novelty-destroying for a set of claims similar to that of ARII of EP825."

be deleted.

Levi was not discussed by the EPO's Opposition Division in its decision of 15 December 2022 and only submitted at a later stage. The decision of the EPO's Board of Appeal of 1 December 2023 is also silent on Levi and there is no finding in that decision with regard to novelty in light of Levi. Novelty in light of Levi was only addressed by the EPO's Board of Appeal in the context of its preliminary opinion of 21 November 2023.

6. Page 39 and 41 of the Decision Defendants ask that the following statements at page 39 and 41 of the Decision:

"In para 106 of the decision reference is made to a declaration by patent attorney Leo Jessen made in infringement proceedings in DK based on Edward's EP'828 (that is another divisional of WO '801 and therefore has the same disclosure as EP '825)."

"Meril also refers to the expert opinion of Mr. Jessen, Edwards' patent attorney in a related Dutch infringement proceedings based on EP '828. (another divisional of WO '801). Meril submits in that regard:"

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

"In para 106 of the decision reference is made to a declaration by patent attorney Leo Jessen made in infringement proceedings in DK the Netherlands based on Edward's EP'828 EP'928 (that is another divisional of WO '801 and therefore has the same disclosure as EP '825)."

"Meril also refers to the expert opinion of Mr. Jessen, Edwards' patent attorney in a related Dutch infringement proceedings based on EP'828 EP'928 (another divisional of WO '801)."

The proposed amendments are based on

- that the opinion of Mr Jessen (submitted as Exhibit HLNK 40) was submitted in infringement proceedings in the Netherlands,
- that these proceedings are not related to the present proceedings, that they were based on European Patent EP 3 494 928 B1 (and not on "EP '828"), and
- that EP 3 494 928 B1 and "EP '828" are both not divisionals of WO'801.

We refer – by way of example – to Exhibit HLNK 40 (page 1) and Defendants' Reply to the Defence to the Counterclaim for Revocation (p. 48).

7. Page 53 of the Decision: Defendants ask that the following statement at page 53 of the Decision:

"The total axial length (height) of the Myval Octacor valve is between 17.35 -21.15 mm (i.e. 19.25 mm on average)3 as can be taken from K 27 which is a presentation on the Myval Octacor valve submitted by Meril or on its behalf, respectively."

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

"The total axial length (height) of the Myval Octacor valve is between 17.35 -21.15 mm (i.e. 19.25 mm on average) as can be taken from K 27 which is a presentation on the Myval Octacor valve submitted by EdwardsMeril or on its behalf, respectively."

Exhibit K 27 was submitted by Claimant with its Statement of Claim (see p. 44). The average height, if adding the measurements at page 24 of Exhibit K 27 and dividing them by 9, is 19.2mm.

8. Page 59 of the Decision: Defendants ask that the following statements at page 59 of the Decision:

"Approximately 1.5 years later, in November 2022, they approached Edwards with a license request regarding the XL sizes of the "Myval" valve."

"Regarding the infringing embodiments in question, namely the Myval Octacor, Meril approached Edwards in October 2023 with a license request, which Edwards responded to on 21 November 2023."

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

"Approximately 1.5 years later, in November 2022, they approached Edwards with a license request regarding inter alia the XL sizes of the "Myval" valve."

"Regarding Myval Octacor and Navigator Inception the infringing embodiments in question, namely the Myval Octacor, Meril approached Edwards in October 2023 with a license request, which Edwards responded to on 21 November 2023."

Defendants' license request of November 2022 also related to the products NavigatorTM (in sizes 30.5x35mm and 32.0x35mm), Val-de-CrimpTM and Val-de-CrimpTM Neo and was not confined to the heart valve MyvalTM in XL-sizes (see p. 134 of the Statement of Defence). Defendants' license request of October 2023 related to the products MyvalTM Octacor and NavigatorTM Inception (see, for example, Exhibit HL 51). It was not confined to MyvalTM Octacor.

Edwards responded:

Page 13 of the Decision

Claimant does not object to Defendants' request regarding the correction requested on page 13 of the Decision, i.e. to replace the word "namely" with "in particular" when referring to the disputed features I.3, I.4 and I.5. Claimant however notes that the word "namely" can be used as a synonym for "in particular". Hence, the wording chosen by the Court in the Decision does not imply that the listed features I.3, I.4 and I.5 are exhaustive, and that Defendants have not disputed additional features.

Page 14 of the Decision

Claimant does not object to Defendants' request regarding the requested correction on page 14 of the Decision, since Defendant 1), i.e. Meril GmbH, is based in Bonn and not in Düsseldorf.

Page 28 of the Decision

With respect to the requested rectification on p. 28 of the Decision, it is our view that the reference to "welding points" is an insertion by the Court. The Court expressed its own opinion that the connection of neighbouring struts could also be provided as welding points. Therefore, the requested rectification to delete the reference to "welding points" is not appropriate. Rather, the section in question could read as follows (proposed insertion indicated by underlining):

"The connections to neighbouring struts are characterized as plastically and to a certain (low) extent elastically deformable and can thus, in the view of the Court, be provided, for example, as welding points."

Page 29 of the Decision

Claimant objects to Defendants' request regarding the requested "rectification" on page 29 of the Decision referring to the definition of the term "struts". 5. Claimant understands that the Court has referred to the Webster dictionary as an example of a dictionary which includes a definition of the term strut which corresponds to the definition proposed by Dr. Mayer. This does not appear to be a clerical mistake, error in calculation or obvious slip.

Page 40 of the Decision

With respect to the requested rectification on p. 40 of the Decision, Claimant notes that the EPO did not regard Levi as novelty destroying and thus the proposed "rectification" is inappropriate. While it is correct that novelty over Levi was not addressed by the EPO Opposition Division in proceedings relating to EP '920 (as Levi was only introduced into the proceedings after the Opposition Division issued its decision), Levi was addressed in the proceedings before the EPO Technical Board of Appeal. Levi was expressly addressed by the EPO Technical Board of Appeal in its preliminary opinion (where it expressly concluded that the claims were novel over Levi) and the Technical Board of Appeal did not find that EP '920 lacked novelty. Accordingly, Claimants submit that, at most, the reference to "the OD" in this paragraph constitutes an 'obvious slip' and thus may be deleted.

Pages 39 and 41 of the Decision

Claimant does not object to Defendants' request regarding the correction requested on pages 39 and 41 of the Decision, which refer to a declaration of Mr. Leo Jessen (Exhibit HLNK 40). As mentioned by Defendants, said declaration was submitted in proceedings in the Netherlands in relation to EP '928 (which is not a divisional of WO '801). 10. With respect to the section on page 41 of the Decision, which reads that Mr. Jessen would be "Edwards' patent attorney", Claimant notes that Mr. Jessen is indeed a patent attorney. However, Mr. Jessen was not representing Claimant in the Dutch proceedings in question (or any other proceedings), but served as an expert who, although retained by Claimant, drafted his declaration on EP '928 based on his own knowledge and opinion.

Page 53 of the Decision

Claimant does not object to Defendants' request regarding the correction concerning the average height of the infringing embodiment "Myval Octacor". With respect to the requested rectification, whereby Defendants seek to clarify that the presentation (Exhibit K 27) was

"submitted by Edwards or on its behalf, respectively" and not, as stated in the Decision, "submitted by Meril or on its behalf, respectively", Claimant notes that it is indeed correct that Claimant submitted Exhibit K 27. However, Exhibit K 27 was prepared by "Meril or on its behalf, respectively". Therefore, Claimant submits that the Decision should clarify that although the Exhibit K 27 was filed by Claimant, it was prepared by Meril.

Page 59 of the Decision

Claimant does not object to Defendants' request to rectify the Court's statement with respect to the license discussions between Claimant and Defendants. With respect to the first statement, Defendants reached out to Claimant and sought a license regarding the XL-sizes of "Myval" and its components "Navigator" "Val-deCrimp" and "Val-de-Crimp Neo" in November 2022. However, the wording in the Decision ("they approached Edwards with a license request regarding the XL sizes of the "Myval" valve") is, according to Claimant, not incorrect since it doesn't exclude that the license request also included the further components listed above. Nevertheless, Claimant does not object to specify that the license request "inter alia" referred to the "Myval XL".

Meril responded:

To the extent Claimant's submissions are to be understood as an independent request for rectification of the decision of the Munich Local Division of 15 November 2024, order no. ORD_598479/2023 (hereinafter the "Decision"), such request is inadmissible. It was not filed within the one-month deadline according to Rule 353.1 RoP which expired on 16 December 2024 (Rule 301.1 RoP).

To the extent and in case Claimant's submissions are to be understood merely as a suggestion for an alternative wording, Defendants submit the following comments:

Pages 13 and 14 of the Decision

Claimant does not object to Defendants' requests for rectification at p. 3 (item no. 1.) and pp. 3 et seq. (item no. 2.) of the Rectification Request (see mn. 1, 2 of Claimant's Comments). The Decision is to be rectified as requested by Defendants that maintain the view that the term "namely" – as opposed to "in particular" – is limiting in that context.

Page 28 of the Decision

Claimant is of the opinion that the Division expressed at p. 28 of the Decision its own view when stating that the connection of neighbouring struts could be provided as welding points (see mn. 3 of Claimant's Comments). If the Division indeed only intended to express its own view and did not want to imply that Dr. Mayer would have stated in his expert opinion that "connections" could be provided, for example, as welding points, Defendants do not object to the insertion proposed by Claimant (ibid). If this was not the case, however, the Decision would need to be rectified in accordance with Defendants' request (see p. 4, item no. 3. of the Rectification Request).

Page 29 of the Decision

Defendants maintain their request at p. 5 (item no. 4.) of the Rectification Request regarding the statement at p. 29 of the Decision that "Mayer also refers to a definition of the term "strut" as provided, e.g., by the Webster dictionary".

Page 40 of the Decision

Defendants maintain their request at p. 5 (item no. 5.) of the Rectification Request that the statement at p. 40 of the Decision cited there is to be deleted (contrary to mn. 6 to 8 of Claimant's Comments). As Claimant itself notes (in mn. 7 of Claimant's Comments), Levi was not addressed by the Opposition Division and the reference to the "OD" is to be deleted already for that reason. While Levi was addressed by the Board of Appeal in its preliminary opinion of 21 November 2023, it remains the case that the relevant statement at p. 40 of the Decision, i.e.

"This is in line with the findings by the OD and the BoA of the EPO in the opposition proceedings against EP '920, another divisional of WO '801. The EPO did not regard Levi as novelty-destroying for a set of claims similar to that of ARII of EP825",

is incorrect. It suggests that the Board of Appeal (and the Opposition Division) took a corresponding decision. However, the Board of Appeal expressed only its preliminary conclusions in that opinion and stated that these "may not be considered as binding in any sense" (p. 2, item 1 of the preliminary opinion). Also, the Board of Appeal did not decide on novelty at the oral hearing. Rather, any novelty discussions were postponed until after the discussion of lack of inventive step. But since the subject matter of EP 920 in accordance with auxiliary request 21 was found to be obvious and the patent as granted was revoked on other grounds, lack of novelty (inter alia in the light of Levi) did not play a role.

Pages 39 and 41 of the Decision

Claimant does not object to Defendants' request for rectification at p. 5 et seq. (item no. 6.) of the Rectification Request (see mn. 9, 10 of Claimant's Comments). The Decision is to be rectified at least to the extent requested by Defendants

Page 53 of the Decision

Claimant does not object to Defendants' request for rectification at p. 6 (item no. 7.) of the Rectification Request (see mn. 11, 12 of Claimant's Comments). The Decision is to be rectified as requested by Defendants. Defendants do not see a need to introduce a clarification as proposed by Claimant (but not requested by it in a timely manner!) because there is no error or even an "obvious slip" (and Claimant does not show that there would be such) without a further clarification being added.

Page 59 of the Decision

Claimant does not object to Defendants' request for rectification at p. 7 (item no. 8.) of the Rectification Request (see mn. 13, 14 of Claimant's Comments). Defendants maintain the view that the phrase "inter alia" should be introduced as proposed.

GROUNDS

The application is admissible, in particular it was filed on 16 December 2024 and thus within the deadline pursuant to R. 353 RoP, but partly unfounded

I. According to R. 353 RoP, the Court may upon an application by a party made within one month of service of the decision or order, rectify clerical mistakes, errors in calculation and obvious slips in the decision or order. Besides clear factual errors "obvious slips" can be rectified. "Obvious slips" within the meaning of R. 353 RoP are 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 (UPC_CFI_177/2023, Order dated 30 June 2023, under II.1. – myStromer/Revolt Zycling).

II. On the basis of these principles, the following requests for rectification are justified:

- Page 13

The word "namely" can be used as a synonym for "in particular". Hence, the wording chosen by the Court in the Decision does not imply that the listed features I.3, I.4 and I.5 are exhaustive, and that Defendants have not disputed additional features. However, as there is doubt about this between the parties a rectification shall be done.

- Page 14

The request is justified as Meril GmbH is based in Bonn and not in Düsseldorf.

- Page 28

A mind willing to understand will take from this sentence that the Division only intended to express its own view and did not want to imply that Dr. Mayer would have stated in his expert opinion that "connections" could be provided, for example, as welding points. However, as there is doubt about this between the parties a rectification shall be done along the suggestions filed by Edwards.

- Pages 39 and 41

The request is justified as said declaration was submitted in proceedings in the Netherlands in relation to EP '928 (which is not a divisional of WO '801). As Mr. Jessen was not representing Claimant in the Dutch proceedings in question (or any other proceedings), but served as an expert who, although retained by Claimant, drafted his declaration on EP '928 based on his own knowledge and opinion, a further rectification is to be made.

- Page 53

The request is justified as the average height of the infringing embodiment "Myval Octacor". With respect to the requested rectification, whereby Defendants seek to clarify that the presentation (Exhibit K 27) was "submitted by Edwards or on its behalf, respectively" and not, as stated in the Decision, "submitted by Meril or on its behalf, respectively", it is to be noted that it is indeed correct that Claimant submitted Exhibit K 27. However, Exhibit K 27 was prepared by "Meril or on its behalf, respectively". Therefore, it is to be made clear that although the Exhibit K 27 was filed by Claimant, it was prepared by Meril.

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The request is justified. With respect to the license discussions between Claimant and Defendants there is no dispute between the parties. With respect to the first statement, the wording in the Decision ("they approached Edwards with a license request regarding the XL sizes of the "Myval" valve") is not incorrect since it doesn't exclude that the license request also included the further components listed above. However, as there is doubt about this between the parties a rectification shall be done by inserting "inter alia".

III. The other requests for rectifications are to be dismissed:

- Page 29

The Court has referred to the Webster dictionary as an example of a dictionary which includes a definition of the term strut which corresponds to the definition proposed by Dr. Mayer. This is not a clerical mistake, error in calculation or obvious slip.

- Page 40

The EPO did not regard Levi as novelty destroying for a set of claims similar to that of ARII of EP 825. Thus, the finding of the Court is in line with the EPO. And thus, this statement is not a clerical mistake, error in calculation or obvious slip.

ORDER

1. The decision dated 15 November 2024 is rectified as follows:

Page 13

"According to Meril it is therefore clear that the allegedly infringing "Myval Octacor" heart valve does not exhibit the features set out in claim 1 of EP '825 as upheld, in particular namely features I.3, I.4 and I.5a."

Page 14

"Furthermore, the LDM had no jurisdiction with respect to the DüsseldorfBonn-based Meril GmbH. Edwards should have chosen the Local Division Düsseldorf."

Page 28

"The connections to neighbouring struts are characterized as plastically and to a certain (low) extent elastically deformable and can thus, in the view of the Court, be provided, for example, as welding points."

Pages 39 and 41

"In para 106 of the decision reference is made to a declaration by patent attorney Leo Jessen made in infringement proceedings in DK the Netherlands based on Edward's EP'828 EP'928 (that is another divisional of WO '801 and therefore has the same disclosure as EP '825)."

"Meril also refers to the expert opinion of provided by Mr. Jessen, Edwards' patent attorney in a related in Dutch infringement proceedings based on EP'828 EP'928 (another divisional of WO '801)."

Page 53

"The total axial length (height) of the Myval Octacor valve is between 17.35 -21.15 mm (i.e. 19.25 mm on average) as can be taken from K 27 which is a presentation on the Myval Octacor valve prepared by Meril or on its behalf respectively and submitted by Edwards Meril or on its behalf, respectively."

Page 59

"Approximately 1.5 years later, in November 2022, they approached Edwards with a license request regarding inter alia the XL sizes of the "Myval" valve."

"Regarding Myval Octacor and Navigator Inception the infringing embodiments in question, namely the Myval Octacor, Meril approached Edwards in October 2023 with a license request, which Edwards responded to on 21 November 2023."

2. The remaining application for rectification is dismissed.

INSTRUCTIONS TO THE REGISTRY

The correction must be attached to the original and become an integral part of the decision. The original version of the decision on the UPC's webpage must be amended. Any authentic copy of the enforceable decision handed out to the parties must be rectified as well.

DETAILS OF THE ORDER

Order no. ORD 68584/2024 in ACTION NUMBER: ACT 459987/2023

UPC number: UPC_CFI_15/2023
Action type: Infringement Action

Related proceeding no. Application No.: 66551/2024 Application Type: Generic procedural Application

UPC_CFI_15/2023

Done in Munich on 17 February 2025

Zigann Presiding Judge	
Kokke Legally Qualified Judge	
Pichlmaier Legally Qualified Judge	
Wilhelm Technically Qualified Judge	
For the Deputy-Registrar	