**Local Division Munich**
**UPC_CFI_1160/2026**

# Order
# of the Court of First Instance of the Unified Patent Court
# Local Division Munich
# issued on 11 August 2026

CLAIMANT/APPLICANT:

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

represented by: Bryce Matthewson, Siddharth Kusumakar, Adam Rimmer, Daniel Down, Carolina D'Amato (Powell Gilbert)

DEFENDANTS/RESPONENTS:

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 Gujarat - Vapi – IN

3. **Meril Italy S.r.l.,** Piazza Tre Torri 2, 20145, Milan, IT

represented by: Dr. Andreas von Falck, Dr. Roman Würtenberger, Beatrice Wilden, Chia Ching Chuong (Hogan Lovells)

PATENT AT ISSUE:

European patent n° 3 669 828

PANEL/DIVISION:
Panel 1a of the Local Division Munich.

DECIDING JUDGE:
This order has been issued by Presiding Judge Dr. Matthias Zigann acting as judge-rapporteur.

LANGUAGE OF THE PROCEEDINGS:
English

SUBJECT OF THE PROCEEDINGS:
APPLICATION FOR THE DETERMINATION OF DAMAGES (Art. 68 UPCA, R. 125, R. 126 and R. 131 RoP) WITH REQUEST TO LAY OPEN BOOKS (R. 131.1(c) and R. 141 RoP) here: Order pursuant to R 105.5 RoP following the interim conference

PROCEDURAL BACKGROUND AND APPLICATIONS:

1. With decision of the Munich Local Division issued on 4 April 2025 and served on the parties on the same day (UPC_CFI_501/2023, ORD_598588/2023 in Action Number ACT_597277/2023 and ORD_69128/2024 in Action Number CC_23112/2024, the Decision1) this Court held, inter alia, that Meril GmbH (Meril Germany), Meril Life Science Pvt. Ltd (Meril India) and Meril Italy S.r.l. (Meril Italy), (together, Meril or the Defendants):

> (i) infringed EP 3 669 828 B2 (EP 828) owned by Edwards Lifesciences Corporation (Edwards) with respect to the Myval Transcatheter Heart Valve (the Myval THV) and the assembly that comprises the Myval THV and the Navigator THV delivery apparatus (the Myval System), (together, the Infringing Products);2 and therefore
>
> (ii) are jointly and severally obliged to compensate Edwards for the damage (including interest) that Edwards has suffered and will suffer as a result of their infringing acts committed since 5 May 2021.

The Decision has not been appealed and has thus become final.

2. With brief dated 2 April 2026 Edwards filed an application for the determination of damages (the Application), which includes a request for an order to lay open books:

> *Therefore, with the present Application for the determination of damages (the Application), which includes a request for an order to lay open books, Edwards requests the Court to:*
>
> *I. order the Defendants to lay open their books within 20 (twenty) days from the order, or within such other time period deemed appropriate by this Court, and in particular to provide Edwards with the information specified in section D below, pursuant to R. 131.1(c) and 141(c) RoP (Request I); and*

*II. (after the procedure for the laying open of books is complete) determine the damage - in an amount to be specified following said procedure - suffered by Edwards since 5 May 20215 as a result of the infringing acts committed by Meril, together with interest thereon, pursuant to Art. 68 UPCA and R. 125, R. 126 and R. 131.2 RoP (Request II).*

*In relation to each Defendant, for the relevant period (i.e., from 5 May 2021) and in respect of each country within the Territory for Relief, Edwards requests access to the following additional information to determine the damage suffered by Edwards due to the infringement of EP 828:*

*(i) in respect of the Other Relevant Devices, information regarding the extent to which the Defendants and each of them have offered, placed on the market, used, or imported or stored for the said purposes, each of these devices and their related accessory devices within the Territory for Relief;*

*(ii) any reports or policies in relation to discounts, rebates, returns, credit-note practices, with allocation by customer and country, to determine the effective net revenues earned by each of the Defendants from the sale of All Relevant Devices (separately per device);*

*(iii) an indication of the variable/incremental costs attributable to All Relevant Devices (separately per device), which are necessary to establish the unfair profits and the contribution margin gained by the Defendants (profits being calculated by deducting from net revenues only the so-called variable/incremental costs, i.e., the costs directly attributable to the infringing devices27). These costs include, for example, costs of raw materials, and costs of manufacturing and distributing the infringing devices;*

*(iv) a detailed breakdown of any indirect and fixed costs that the Defendants intend to seek to deduct and the specific accounting and allocation methodologies used to apportion such overheads to All Relevant Devices (separately per device);*

*(v) accounting books and records relating to All Relevant Devices (separately per device), including VAT registers, inventories, annual financial statements, stock/warehouse registers, management and accounting statements (general ledger, sub-ledgers, trial balances), as well as tax statements;*

*(vi) inter-company financial data and flows, to avoid the risk of "profit shifting" through artificial transfer prices, internal royalties, or management fees. To determine the true aggregate profits derived from the infringing activities, documentation relating to financial flows between the Defendants is required, including inter-company agreements, transfer-pricing policies, and records of royalty, service, or fee*

*payments connected with All Relevant Devices (separately per device);*

*(vii) all executed or draft licence agreements entered into by Meril relating to All Relevant Devices (separately per device), to the technology at issue or to comparable technologies, including (a) the identity of the products considered comparable; (b) the royalty rates or licence fees agreed by Meril for those products; (c) the basis on which those royalties or fees were calculated (e.g., percentage of sales, lump sum); and (d) the duration and territorial scope of such licences;*

*(viii) any notes, memos or other documents detailing the projected and actual sales of All Relevant Devices (separately per device) in each jurisdiction within the Territory for Relief, including for the period in which each of these products was launched (i.e. including periods prior to 5 May 2021);*

*(ix) details of any approvals, tenders, reimbursement agreements or other such agreement in which one of the Other Relevant Devices has been "substituted" for the Infringing Products; and*

*(x) notes, memos or other documents detailing how the Other Relevant Devices' approval process has been carried out, and the length of time required for the Infringing Product, and separately, the Other Relevant Devices, to obtain CE mark approval.*

3. With brief dated 10 June 2026 Meril filed a DEFENCE TO APPLICATION FOR THE DETERMINATION OF DAMAGES WITH REQUEST TO LAY OPEN BOOKS:

*I. the Applicant's request to lay open books as defined in section A., item I., of the Application, in connection with section D. (mn. 43, items (i) to (x)), be dismissed to the extent specified below:*

*1. the Applicant's request in mn. 43, item (i) in its entirety;*
*2. the Applicant's requests in mn. 43, item (ii) to (viii) insofar as they relate to "All Relevant Devices" other than "Infringing Devices/Products";*
*3. the Applicant's request in mn. 43, item (ii), further insofar as it relates to "policies" and "reports" as further specified in mn. 148 et seq. below;*
*4. the Applicant's request in mn. 43, item (v), further insofar as it refers to "VAT registers, inventories", "stock/warehouse registers, management […] statements (general ledger, sub-ledgers, trial balances)";*
*5. the Applicant's request in mn. 43, item (vi), further insofar as it relates to "inter-company agreements, transfer-pricing policies";*
*6. the Applicant's request in mn. 43, item (vii), further insofar as it relates to "draft licence agreements", "comparable technologies, including (a) the identity of the*

*products considered comparable" and "c) the basis on which those royalties or fees were calculated (e.g., percentage of sales, lump sum)";*
*7. the Applicant's request in mn. 43, item (viii), further insofar as it relates to "any notes, memos", "projected sales";*
*8. the Applicant's request in mn. 43, item (ix) in its entirety;*
*9. the Applicant's request in mn. 43, item (x) in its entirety;*

*II. it be ordered that the Defendants be granted a reasonable period of no less than twelve (12) weeks to comply with the order to lay open books;*

*III. it be ordered that information to be provided under the order be classified as "confidential information" pursuant to Art. 58 UPCA, Rule 144.1(a) RoP and Rule 190.1, .4 RoP and that appropriate measures for the protection of the information to be provided be implemented, in particular by ordering:*

*1. that access to the information be restricted, on part of the Applicant, to the following persons only:*

*a) one employee of the Applicant's accounting team not involved in the prosecution of patents for the Applicant;*

*b) the following representatives of the Applicant:*

*- Mr. Siddharth Kusumakar*
*- Mr. Bryce Matthewson*
*- Mr. Adam Rimmer*

*and two additional named persons at Powell Gilbert LLP, actively involved in these proceedings, which may be other lawyers, patent attorneys or support staff;*

*2. that the information and documents referred to under III. be treated as confidential by the persons referred to under III.1.; that such information must not be used outside of these court proceedings or for purposes unrelated thereto, especially not for commercial, strategic or competitive purposes; that the information must not be disclosed to any person other than the persons identified under III.1., except to the extent that it has lawfully come to the knowledge of such receiving party outside of these proceedings, provided that the receiving party has obtained it on a non-confidential basis from a source other than the Applicant or its affiliates, provided that such source is not bound by a confidentiality agreement with the Applicant or its affiliates;*

*3. that the information must be stored securely in accordance with the confidentiality obligations;*

*4. that no copies must be made beyond what is strictly necessary for the proceedings and that any such copies must remain restricted to the persons in III.1. and that any copies and confidential material must be returned or destroyed after the closure of the present proceedings, the destruction to be confirmed in writing;*

*5. that no extraction, summaries, or reproduction of sensitive information outside pleadings to be submitted in the present proceedings is permitted;*

*6. that the obligation to maintain secrecy under III. shall continue to apply after the present proceedings have been concluded;*

*7. that the information and documents referred to under III. shall also be treated as confidential in accordance with the above terms by any person not referred to under III.1. who obtains knowledge of it as a result of his or her involvement in the present proceedings. Such information must not be used or disclosed outside of these court proceedings, except to the extent that it has come to the knowledge of the receiving party outside of these proceedings, provided that the receiving party has obtained it on a non confidential basis from a source other than the Applicant or its affiliates, provided that such source is not bound by a confidentiality agreement with the Applicant or its affiliates;*

*8. that, in the event of a culpable breach of the order pursuant to Request III., an appropriate penalty, to be determined by the Court having regard to the circumstances of each case, be paid to the Court for each culpable breach of that order;*

*9. that if the Applicant's representatives named under III.1.b) make use of the possibility of giving other members of their team access to information classified as confidential, it is their responsibility to ensure that their team maintains the confidentiality of the information. In the event of a culpable breach of the confidentiality obligations, Mr. Siddharth Kusumakar, Mr. Bryce Matthewson and Mr. Adam Rimmer would therefore be liable. This also applies to any breach of the duty of confidentiality by any member of their team to whom they have granted access;*

*10. that, when publishing an order or decision (or any other announcement) in the present proceedings, all confidential information under III. must be redacted to prevent disclosure;*

*11. that Defendants be allowed to redact the confidential details outside the subject of the disclosure information;*

*IV. if any of the Requests I. to III. or V. is rejected, in whole or in part, leave for appeal be granted;*

*V. if any of the Requests I. to IV. is rejected, in whole or in part, it be ordered that the order must not be enforced before the appeal deadline has expired or, if an appeal (or an application for review) is filed, until the end of such proceedings.*

4. With a brief dated 1 July 2026 Edwards filed a REPLY TO DEFENCE TO REQUEST TO LAY OPEN BOOKS (FILED IN RELATION TO APPLICATION FOR THE DETERMINATION OF DAMAGES):

*For the reasons set out below, Edwards Lifesciences Corporation respectfully requests that this Court*

*I. refuse the Defendants' Confidentiality Request (as defined in paragraph 75 below); or in the alternative,*

*II. in the event that the Court grants a confidentiality order in respect of the information, the persons listed in paragraph 83 be entitled to access the information:*

*- up to three members of the Applicant's inhouse legal team;*
*- up to two members of the Applicant's accounting team;*
*- up to four external experts, provided that such experts are subject to reasonable confidentiality restrictions; and*
*- any partner or employee of Powell Gilbert LLP and / or Powell Gilbert (Europe) LLP.*

5. With brief dated 15 July 2026 Meril filed a REJOINDER TO THE REPLY TO THE DEFENCE TO THE APPLICATION FOR THE DETERMINATION OF DAMAGES WITH REQUEST TO LAY OPEN BOOKS.

<u>INTERIM CONFERENCE</u>

6. On 11 August 2026 an interim conference via videoconference was held with the following participants:

<u>for the Court:</u>
Dr. Matthias **Zigann**, Presiding Judge and Judge-rapporteur
Dr. Stefan **Wilhelm**, Technically Qualified Judge

for Edwards:

- Bryce **Matthewson** - Powell Gilbert (Europe) LLP, Representative
- Siddharth **Kusumakar** - Powell Gilbert (Europe) LLP, Representative
- Daniel **Down -** Powell Gilbert (Europe) LLP, Representative
- Carolina **D'Amato** - Powell Gilbert LLP, Additional member of the representative team

for Meril:

- Mr [redacted] (Defendant 2)
- Dr. [redacted] (Defendant 3)
- Dr. Andreas **von Falck**, Rechtsanwalt, Hogan Lovells Cadwalader International LLP
- Dr. Roman **Würtenberger**, Rechtsanwalt, Hogan Lovells Cadwalader International LLP
- Beatrice **Wilden**, Rechtsanwältin, Hogan Lovells Cadwalader International LLP
- Chia **Chuong**, Rechtsanwältin, Hogan Lovells Cadwalader International LLP

7. The following topics had been discussed:

8. Value in dispute

Edwards is proposing 15 million EUR, while Meril only proposes 8 million EUR. Meril's counsel explained that they believe the 'other relevant devices', which are undisputedly not infringing the patent in question, should not be the subject of the open books order, and therefore cannot increase the value in dispute.

However, the judge-rapporteur believes that the value is determined by the underlying claim for damages. Edwards is currently estimating this to be 15 million. Therefore, the current value of the dispute is 15 million. The court reserves the right to revisit this assessment when Edwards has calculated the damages.

9. Legal basis of the application and its enforcement if granted

The judge rapporteur explains that, if this case is not settled or goes to the PMAC, it will require a decision from the Court of Appeal. This is because, for the first time, the UPC will need to define the details of a claim for damages and the accompanying claims to open the books with regard to non-infringing products. Although there is some national case law, the situation at hand has not, it seems, been decided: the replacement of an infringing product by a non-infringing product during the lifetime of the patent, and the patent owner's claim that the profits with this non-infringing product must be taken into account when calculating damages.

Furthermore, it must be determined whether national or UPC law applies. In this regard, the judge rapporteur referred to a decision made by the Mannheim Local Division (decision of 11 March 2025 – UPC CFI 162/2024). Counsel for Edwards endorsed the Mannheim approach, arguing that UPC law should be applied to resolve the case. Meril's counsel argued that national law must be consulted for the period prior to the UPCA's entry into force.

The judge rapporteur suggested that the parties should agree on the applicable law. Both counsels said that they would discuss this with their clients.

Regarding the procedural basis for the application, counsel for Edwards referred to a broad interpretation of Rule 141(c) of the Rules of Procedure (RoP), pointing out that the information to which access is requested is not limited, given that the second part of the sentence begins with 'in particular'. However, counsel for Meril argued that this rule is limited to infringing products in its overall context.

With regard to the potential scope of an 'open the books' application, the judge rapporteur directed the parties to Rule 141(b), which states that the applicant must provide details of the information received from the infringer pursuant to a Rule 191 order. This could imply that information subject to a Rule 141 order is limited to the amount involved. Counsel for Edwards explained that, in his view, information regarding causation can also be requested. Counsel for Meril disagreed.

Regarding the enforcement of a possible 'open the books' order, Edwards' counsel explained that they are considering requesting copies of the relevant documents containing the requested information. Meril may blacken out any additional information that is not subject to the order. Counsel for Meril agreed.

In response to a question from the judge-rapporteur, counsel for Edwards explained that Edwards will not start enforcing a possible order while Meril is appealing against it. In response to a question from Meril's counsel, Edwards' counsel was unsure whether Edwards would start enforcing a partially successful order pending an appeal by Edwards. It was agreed that the two counsels would discuss a possible out-of-court arrangement.

The judge rapporteur instructed Edwards that the court must, in any event, set a time period pursuant to Rule 144.1(b). Therefore, Edwards shall suggest a suitable time period and starting date.

10. Partial withdrawal and partial acknowledgement.
Meril argues that Edwards has partially withdrawn its request in response to their defence of the application. Counsel for Edwards explained that they had simply clarified uncertainties. The parties discussed whether this would have any consequences for the cost decision, and whether this cost decision should be made in the open the books order or the later damages order.

The judge-rapporteur informed Edwards that, if the argument relating to clarification failed, a partial withdrawal pursuant to Rule 263.3 of the Rules of Procedure (RoP) might be permissible, but would require an application to this effect.

The judge-rapporteur left open the question of whether a cost decision would be included in the 'open the books' order. In any case, any unnecessary costs may be subject to an Article 69.3 UPCA decision.

The judge-rapporteur noted that, in any event, it would be beneficial for the parties and the court if Edwards could file two sets of formal pleadings: the first according to what Meril admitted to owing, and the second according to what is still under dispute.

11. Preliminary assessment of the major point(s)

The judge-rapporteur shared his preliminary assessment of the main legal question of whether profits from non-infringing products could be taken into account when calculating damages, and whether they could therefore be subject to an 'open the books' application. He gave an example: A department store advertises an infringing product, 'A'. A customer sees the advertisement and visits the department store to buy the infringing product “A”. However, the product has been taken off the shelves in the meantime due to a court order. The salesperson sells the customer a non-infringing product, "B", instead. In this situation, the profits made from selling product “B” can be attributed to the patent infringement, the patent-infringing offer. In the present case, it may be necessary to take into account the profits made from non-infringing products that replaced the infringing product in open tenders. However, if the link to the sales of the non-infringing products is more tenuous, this might be viewed differently.

12. Confidentiality regime

Bearing in mind this preliminary assessment, the judge rapporteur concludes that an arrangement for the protection of confidential information subject to the open-the-books order must be prepared. In the judge-rapporteur's view, this is not premature, as Edwards argues. According to R. 144.1(a) and 190.1 RoP, the order to open the books must be accompanied by suitable arrangements for the protection of confidential information.

Counsel for Edwards explained that Edwards has not yet named the experts or their fields of expertise, as this depends on the exact scope of the disclosure that the court finally orders.

The judge-rapporteur concedes that a two-step approach to confidentiality and the composition of the confidentiality club(s) could be a solution. The first step will be concluded with the order to open the books. The second step could follow at a later stage. The order will explicitly allow for this second step. The judge-rapporteur encourages the parties to reach an out-of-court agreement on the details of the confidentiality regime and the members of the confidentiality club(s), taking into account the two-step proposal.

Both counsels promise to work on this.

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13. Use of the PMAC?

The judge rapporteur encourages the parties to make use of the PMAC. At the PMAC, the parties can agree on even more stringent or innovative confidentiality regimes, including an attorney-eyes-only regime. Furthermore, the PMAC would provide additional confidentiality with regard to the public.

Counsel for both parties promise to discuss this proposal with their clients.

14. Preparation of the oral hearing
The judge rapporteur explained that the oral hearing would be held via videoconference, with at least two of the four panel members participating remotely due to time constraints. The judge rapporteur will be present in the hearing room. Parties and their representatives can join remotely or in person. Members of the public can attend the hearing in person.

Counsel for both parties agree to inform each other prior to the hearing whether they will attend remotely or via videoconference, in order to avoid a mixed situation.

In any case, the parties must inform the court of the names and positions of those participating in the oral hearing, and whether they will participate in person or remotely, by 3 September 2026.

The judge rapporteur allows the use of a PowerPoint presentation, provided that its content is limited to what is present in the CMS at that time, and that it is shared with the court and the other party by 16:00 (Munich time) on 9 September 2026.

The judge rapporteur informs the parties that a major point of discussion at the oral hearing will be the main legal question laid out under items 9 and 11, and which law should be consulted to answer it. The hearing will start at 09:00 and end by 12:00 at the latest. Therefore, the time available to each party to present their case must fit within this schedule.

ORDER

1. The date of the videoconference hearing on 10 September at 9:00 am is confirmed. Those wishing to attend in person, including parties and the public, may do so in Room 212 and Overflow Room 220b at the address Denisstr. 3, Munich. The parties are summoned to attend on this date.

2. The parties are asked to submit the names and roles of those attending the oral hearing, and whether they will attend in person or via videoconference, by 3 September 2026.

3. A PowerPoint presentation may be used during the oral hearing, provided its content is limited to that present in the CMS at the time and it is shared with the court and the other party by 16:00 Munich time on 9 September 2026.

4. Edwards may respond to the formal points raised today by 21 August 2026.

5. Meril may file observations on the Edwards brief by 3 September 2026.

6. The value of the dispute is set at 15 Mio. EUR.

INFORMATION ABOUT REVIEW BY PANEL
Any party may request that this Order be referred to the panel for a review pursuant to R. 333 RoP. Pending review, the Order shall be effective (R. 102.2 RoP)

INFORMATION ABOUT ORAL HEARING HELD IN COURT
The oral hearing shall be open to the public unless the Court decides to make it, to the extent necessary, confidential in the interests of one or both parties or third parties or in the general interest of justice or public order (R. 115 RoP).

INFORMATION ABOUT AUDIO RECORDING
The oral hearing shall be audio recorded. The recording shall be made available at the premises of the Court to the parties or their representatives after the oral hearing (R. 115 RoP).

INFORMATION ABOUT ABSENCE OR DELAY OF A REPRESENTATIVE
A decision by default may be given, upon request, against a party that was duly summoned but fails to appear at the oral hearing (R. 355.1 (b) RoP.

INFORMATION ABOUT DECISION BY DEFAULT
Should a party fail to comply with the present Order within the time period specified, a decision by default may be given in accordance with R. 355 RoP (R. 103.1, last subparagraph and .2 RoP).

Matthias ZIGANN

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Datum: 2026.08.11 16:19:19 +02'00'

Dr. Zigann
Presiding Judge