



Milan Local Division

UPC CFI NO. 202/2025

Act. no. 10936/2025

App. no 30486/2025

DECISION
concerning confirmation of settlement
issued on 5.9.2025

APPLICANT

EDWARDS LIFESCIENCES CORPORATION

represented by Siddharth Kusumakar, Bryce Matthewson and Adam Rimmer

RESPONDENTS

1) SINTEC S.R.L.

2) VALUE MED S.R.L.

represented by Giovanni Ghirardi, Francesco Banterle, Andrea Schettino, Andreas von Falck, Roman Würtenberger and Beatrice Wilden

PATENT AT ISSUE

EP 3 646 825 B1

PANEL AND DECIDING JUDGES

Pierluigi Perrotti	presiding judge and judge rapporteur
Alima Zana	legally qualified judge
Margot Kokke	legally qualified judge

LANGUAGE OF THE PROCEEDINGS

English

SUMMARY OF FACTS

On 6.3.2025 Edwards Lifesciences Corporation (hereinafter Edwards) filed an application for provisional measures based on EP 3 646 825 B1 against Sintec s.r.l. and Value Med s.r.l. before the Milan Local Division of the Unified Patent Court.

On 24.4.2025 Respondents filed their objection to the application.

Exercising the case management powers provided for in rule 332 RoP, by order of 5.5.2025 the judge-rapporteur invited the Parties to enter into negotiations and proposed some possible contents of a settlement.

On 25.6.2025 Edwards filed an application informing the Court that the parties reached a settlement - signed on 23.6.2025 - and requesting the Court (i) to confirm the settlement agreement by decision of the Court and (ii) to grant the reimbursement for 60% of the Court fees.

Sintec and Value Med did not oppose Edwards' requests, as clarified in their most recent submissions filed on 30.7.2025.

PARTIES' REQUESTS

The Parties jointly request that the Court (i) confirm the Settlement Agreement (Exhibit EDW-App-1) by decision of the Court, pursuant to Art. 79 UPCA and rule 365.1 RoP; (ii) publish the redacted copy of the Settlement Agreement in the form of Exhibit EDW-App-2 with its decision.

In addition, pursuant to rules 370.9(c) and 370.11 RoP, Edwards requests that the Court reimburse it for 60% of the Court fees, namely EUR 6,600.00.

GROUND FOR THE DECISION

Art. 79 UPCA states that *"The parties may, at any time in the course of proceedings, conclude their case by way of settlement, which shall be confirmed by a decision of the Court. [...]"*.

Rule 365.1 RoP states as follows: *"Where the parties have concluded their action by way of settlement, they shall inform the judge-rapporteur. The Court shall confirm the settlement by decision of the Court, if requested by the parties, and the decision may be enforced as a final decision of the Court."*

Rule 11.2 RoP states that *"Pursuant to rule 365 the Court shall, if requested by the parties, by decision confirm the terms of any settlement or arbitral award by consent (irrespective of whether it was reached using the facilities of the Centre or otherwise), including a term which obliges the patent owner to limit, surrender or agree to the revocation of a patent or not to assert it against the other party and/or third parties. The parties may agree on costs to be awarded or may request the Court to decide on costs to be awarded in accordance with Rules 150 to 156 mutatis mutandis"*.

In the case at hand, the Parties entered into a settlement agreement on 23.6.2025 ending the litigation between them.

The Court has no objection to confirming this settlement agreement, which is attached to this decision. Pursuant to rule 365.2 RoP, certain parts of the Settlement Agreement shall be kept confidential according to the Parties' request.

Rule 365.4 RoP states that *"The judge-rapporteur shall give a decision as to costs following the terms of the settlement or, failing that, at his discretion."*

Rule 11.2 RoP states that: *"The parties may agree on costs to be awarded or may request the Court to decide on costs to be awarded in accordance with Rules 150 to 156 mutatis mutandis"*.

The Parties agreed on costs and requested no decision relating thereto.

As to the claim for reimbursement of court fees, according to Edwards, the parties reached a settlement agreement prior to the exchange of all written submissions - and thus before the closure of the written procedure, pursuant to rule 370.9(c)(i) RoP - because, in order no. 21229/2025, the Court had already announced that in the event that the parties were unable to reach a settlement, it would have been necessary to authorise the exchange of further written submissions.

The Court finds that rule 370.9(c)(i) RoP is not applicable to applications for provisional measures, either directly or by analogy (see UPC CFI no. 500/2025, order 28 August 2025, LD Mannheim).

The wording of the provision refers only to actions. Furthermore, the stages of the proceedings referred to in rule 370.9(c) RoP are not applicable in proceedings concerning applications for provisional measures. In particular, there is no interim procedure and oral hearings do not take place in every case. Furthermore, the court fees for applications filed pursuant to rule 206 RoP is already significantly reduced compared to that for actions. Against this background, no further reductions are provided for or required.

An appeal against this decision may be lodged with the Court of Appeal, by any party who has been unsuccessful, in whole or in part, in its submissions, within two months of the date of its notification (Art. 73.1 UPCA, rules 220.1(a) and 224.1(a) RoP).

DECISION

At the request of the parties, the Court confirms, pursuant to rule 365.1 RoP, that the parties have reached the following settlement

SETTLEMENT AGREEMENT

between

Edwards Lifesciences Corporation, incorporated under the laws of the State of Delaware, USA,
and having its registered office at One Edwards Way, Irvine, California, 92614, USA,

– referred to as "**Edwards**" –

a n d

Sintec S.r.l., incorporated under the laws of Italy and having its registered office at Via Santa Lucia,
62 – 80132 Naples, Italy (and offices at via della Resistenza 121B – 20090 Buccinasco MI, Italy),

– referred to as "**Sintec**" –

a n d

Value Med S.r.l., incorporated under the laws of Italy and having its registered office at Piazzale
Medaglie d'Oro 1 – 20135 Milan, Italy.

– referred to as "**Value Med**" –

– together referred to as the "**Parties**" –

PREAMBLE

1. WHEREAS, on 6 March 2025, Edwards filed an application for provisional measures with the Milan Local Division of the Unified Patent Court (hereinafter the "**UPC**") against Sintec and Value Med based on European Patent EP 3 646 825 (hereinafter "**EP '825**") concerning a system comprising the transcatheter heart valve prosthesis Myval™ Octacor and the transcatheter heart valve delivery system Navigator™ Inception. The proceedings are registered under case no. UPC_CFI_202/2025, ACT_10936/2025 (hereinafter the "**Proceedings**");
2. WHEREAS, on 19 July 2024, the Paris Central Division of the UPC issued a decision (ORD_598365/2023, ORD_598366/2023, ORD_598367/2023) in the counterclaim

proceedings initiated by Meril GmbH and Meril Life Sciences Pvt. Ltd. (case no. UPC_CFI_15/2023, CC_584916/2023, CC_585030/2023) and in the central revocation proceedings initiated by Meril Italy S.r.l. (case no. UPC_CFI_255/2023, ACT_551308/2023), upholding EP '825 in amended form, which was appealed by Edwards, Meril GmbH, Meril Life Sciences Pvt. Ltd. and Meril Italy S.r.l. The appeal proceedings are pending;

3. WHEREAS, on 15 November 2024, the Munich Local Division of the UPC issued a decision (ORD_598479/2023) in the infringement proceedings initiated by Edwards against Meril GmbH and Meril Life Sciences Pvt. Ltd. (case no. UPC_CFI_15/2023, ACT_459987/2023), concluding that a system comprising the transcatheter heart valve prosthesis Myval™ Octacor and/or the transcatheter heart valve delivery system Navigator™ Inception and/or Navigator™ infringed EP '825 as upheld by the Paris Central Division of the UPC, which was appealed by Edwards, Meril GmbH and Meril Life Sciences Pvt. Ltd. The appeal proceedings are pending;
4. WHEREAS, on 24 April 2025, Sintec and Value Med filed an objection to the application for provisional measures referred to in Section 1. of the Preamble, opposing Edwards' application;
5. WHEREAS, with order no. 21229/2025 dated 5 May 2025, the presiding judge and judge-rapporteur in the Proceedings before the Milan Local Division of the UPC invited the Parties to enter into negotiations with a view to reaching an amicable settlement of the Proceedings for the ultimate purpose of temporarily freezing the Proceedings until the appeals referred to in Sections 2. and 3. of the Preamble have been decided on and with the consequence that the Parties' subsequent conduct shall be consistent with the final outcome of the appeal proceedings;
6. WHEREAS the Parties desire to settle the Proceedings amicably to avoid further costs and efforts by concluding this settlement agreement;

NOW THEREFORE, without acknowledgement of any legal obligation to do so, without acknowledgement of any obligation to bear the costs of the Proceedings save as expressly agreed herein, and without acknowledgement of any rights of the other party, the Parties agree as set out in the following (hereinafter the "Agreement"):

1. Subject to Section 3. of this Agreement, Sintec and Value Med undertake to immediately cease and desist from offering, placing on the market, using, or importing or storing for these purposes in Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Romania, Slovenia and Sweden:

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

(independent claim 1 of EP '825 as upheld by the Paris Central Division),

especially when

a system of claim 1, further comprising a leaflet structure comprising a plurality of leaflets, and a sealing skirt;

(dependent claim 2 of EP '825 as upheld by the Paris Central Division)

and/or

a system of claim 2, wherein each leaflet has a tab portion adjacent an upper free edge of the leaflet;

(dependent claim 4 of EP '825 as upheld by the Paris Central Division)

and/or

a system of any of claims 2 and/or 4, wherein the skirt is made of a fabric, the fabric preferably made of PET or UHMWPE;

(dependent claim 5 of EP '825 as upheld by the Paris Central Division)

especially when the system contains

- (1) a transcatheter heart valve prosthesis with the designation Myval™ Octacor as shown below:



Myval™ Octacor

and

- (2) a delivery apparatus with the designation Navigator™ Inception as shown below:



Navigator™ Inception

2. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- 3. Sintec and Value Med retain any and all rights they may have against Edwards in the event that the Court of Appeal orders the revocation of EP '825 in full or in part to the extent that EP '825 is not infringed and/or in the event that the Court of Appeal sets aside the injunction granted by the Munich Local Division (Item I.1 of the decision referred to in Section 3. of the Preamble), and in such circumstances the undertaking in Section 1. of this Agreement shall

cease to have effect. The same applies if, after referral back to the Court of First Instance, the Court of First Instance (a) orders the revocation of EP '825 in full or in part to the extent that EP '825 is not infringed and/or (b) sets aside the injunction granted by the Munich Local Division (Item I.1 of the decision referred to in Section 3. of the Preamble).

4. [REDACTED]
5. [REDACTED]
6. [REDACTED]
7. [REDACTED]
8. [REDACTED]

9.

[REDACTED]
[REDACTED]
[REDACTED]

On behalf of Sintec S.r.l.

Name: [REDACTED]

Position: [REDACTED]

Date: 17.06.2025

Signature:

[REDACTED]

On behalf of Value Med S.r.l.

Name:

Position:

Date:

Signature:

On behalf of Edwards Lifesciences Corporation

Name:

Position:

Date:

Signature:

9.



On behalf of Sintec S.r.l.

Name:

Position:

Date:

Signature:

On behalf of Value Med S.r.l.

Name:



Position:



Date:

16.06.2025

Signature:



On behalf of Edwards Lifesciences Corporation

Name:

Position:

Date:

Signature:

9.

[Redacted]

On behalf of Sintec S.r.l.

Name:

Position:

Date:

Signature:

On behalf of Value Med S.r.l.

Name:

Position:

Date:

Signature:

On behalf of Edwards Lifesciences Corporation

Name:

[Redacted]

Position:

[Redacted]

Date: June 17, 2025

Signature:

[Redacted]

- this decision including only the redacted version of the settlement shall be entered on the register;
- the request for reimbursement of the court fees is dismissed;
- this decision is enforceable as a final decision of the Court.

Milan, 5 September 2025.

Pierluigi Perrotti
presiding judge and judge rapporteur

Alima Zana
legally qualified judge

Margot Kokke
legally qualified judge

for the Deputy Registrar