Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Local Division Munich
UPC_CFI_15/2023

Decision

of the Court of First Instance of the Unified Patent Court
Local Division Munich

concerning EP 3 646 825
delivered on 15 November 2024

HEADNOTES

1. The Unified Patent Court has jurisdiction over acts of infringement committed before the entry into force of the Agreement on a Unified Patent Court on 1 June 2023. This is in line with Article 3(c) and 32(1)(a) UPCA, in the absence of any conflicting intertemporal provisions.
2. The claimant's choice among the potentially competent German local divisions will ultimately determine the competence of the chosen German local division.
3. In accordance with Article 32(3b) of the UPCA, a referral of the counterclaim for revocation to the central division and a continuation of the action for infringement may be made following a decision to this effect. Once the central division has delivered its ruling and upheld the patent in an amended form, a stay of the action for infringement may be based exclusively on R. 295(c)(i) or (m) RoP.
4. In both instances, the court is at liberty to exercise its discretion as to or not to grant a stay, respectively. In the context of a prior bifurcation decision where the patent had been upheld, the possibility of a stay is limited to instances where there are attenuating circumstances. This is because the agreement explicitly stipulates the possibility for a local or regional division to bifurcate and to stay or not to stay the action for infringement. Consequently, a decision on the infringement action is possible prior to the central division's resolution of the counterclaim referred to it. Subsequent to a decision by the central division on the referred counterclaim, the local or regional division is required to proceed with the next case management step which regularly is a decision on the action for infringement. There are only a few instances in which one might deviate from this default next case management step. These instances occur when the

aggrieved party can demonstrate that the decision made by the central division is manifestly and prima facie erroneous in a formal and/or material way.

5. Art. 34 UPCA stipulates that injunctive relief, and other corrective measures can be ordered with respect to all contracting member states where the European Patent has effect and for which a decision of the Court has been requested as long as an infringing act or the danger of first infringement has been proven for at least one contracting member state.
6. In regard of procedures for implementing corrective measures, Article 64(4) of the UPCA explicitly mentions the interests of third parties. While the Agreement on a Unified Patent Court and the Rules of Procedure for the Unified Patent Court do not explicitly mention the interests of third parties or the public otherwise, these interests may be considered when exercising the discretion stipulated by the "may" in Articles 64(4), A. 63(1) and 64(1) UPCA, respectively.
7. In considering the interests of third parties and the public interest, the court will give due consideration to the possibility of the infringer entering into a license agreement or initiating proceedings for a mandatory license. If proceedings for the issuance of a mandatory license have been initiated, the court shall duly consider the outcome thereof.
8. Although a defendant might be regarded as an unwilling licensee, the Court may nevertheless find that the public interest must be considered as members of the public regularly have no possibility to influence the defendant`s behaviour and still might face serious consequences if access to the attacked embodiment was denied.
9. Those public needs can be adequately addressed through a mechanism which enables individual members of the public to request a single-use licence.

KEYWORDS

Jurisdiction on infringing acts before 1 June 2023; jurisdiction of the German local divisions; decision on infringement after bifurcation; no stay according to R. 295(c)(i) or (m) RoP; Art. 34 UPCA; third parties` interests; public interest; mechanism to address public needs.

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

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 acting as judge-rapporteur, the legally qualified judges Margot Kokke and Tobias Pichlmaier and the technically qualified judge Dr. Stefan Wilhelm.

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Patent infringement

DATE OF THE ORAL HEARING

24 September 2024.

SUMMARY OF FACTS

The Claimant (Edwards) is the globally leading company of the Edwards Lifesciences Group which among other things develops and manufactures artificial heart valves and their corresponding accessories.

The SAPIEN 3 transcatheter prosthetic heart valve, produced by Edwards Lifesciences, is shown below:

The SAPIEN 3 valve is the gold standard in treating patients with aortic valve stenosis. This is a narrowing of the native aortic valve, caused by calcium deposits on the leaflets. This impairs the blood flow to the aorta, preventing the aortic valve from closing and opening properly. The heart must work harder to continue supplying the organs with oxygen. A sustained overload of the heart muscle or a resulting undersupply of oxygen to the body will have life-threatening consequences for patients, such as shortness of breath and even cardiac death.

Prior to the market introduction of TAVI (Transcatheter Heart Valve Implantation) technology, aortic valve stenosis was typically treated through surgical removal of the native heart valve and implantation of an artificial valve. This surgical procedure requires general anaesthesia, stopping of the heart functions for the duration of the procedure, and connecting the patient to a heart-lung machine. The patient will require a longer period of rehabilitation following surgery. Open-heart surgery has significant disadvantages and side effects so that minimally invasive procedures are often the preferred option today.

Such minimally invasive procedure is embodied by TAVI which involves implanting a prosthetic heart valve via a catheter. In a TAVI procedure, the prosthetic heart valve (THV) is catheterised and implanted in the native annulus via the femoral artery or femoral vein. The artificial valve is then compressed, or "crimped" in technical terms, onto the catheter to a small diameter. Once the THV has been successfully navigated to the heart, it is implanted in the native annulus. In the case of a balloon-expandable valve such as Edwards' SAPIEN 3, the valve is expanded using a balloon catheter and secured in the native valve, pushing it aside as it expands. Once implanted, the THV replaces the native heart valve and regulates the blood flow from the heart.

At this stage, Edwards` "SAPIEN" valves are the most widely used valves for TAVI procedures worldwide. The SAPIEN 3 valve is the gold standard in safety and reliability. It has been approved in Europe for high-risk, intermediate-risk, and inoperable patients. It is now the first valve to be approved in Europe for use in low-risk patients, as well.

Defendant 2 is an India-based global medical device company with a strong presence in various medical fields. In the field of vascular intervention devices, the Defendant offers a wide product portfolio that ranges from drug-eluting stents, bioresorbable vascular scaffolds, balloon catheters to peripheral vascular, as well as the here disputed transcatheter aortic valve replacement systems (TAVI System).

Defendant 1 is a Bonn, Germany-based subsidiary of Defendant 2. Defendant 1) is responsible for the distribution of the Indian parent company's products across Europe. It offers the "Octacor" prosthetic heart valve and the associated delivery systems within the scope of the UPCA.

For the sake of simplicity, both defendants will be referred to as "Meril".

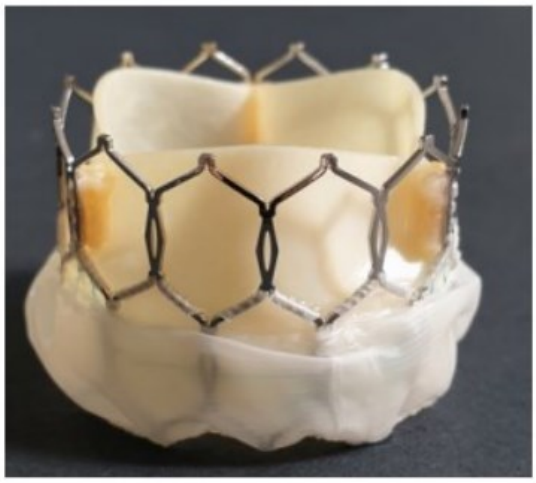
In 2019, Meril launched a transcatheter heart valve, Myval, shown below, along with the Navigator delivery system and the Val-de-Crimp (neo) crimper in Europe.

These products have been the subject matter of various infringement proceedings and cease-and-desist-undertakings in Europe.

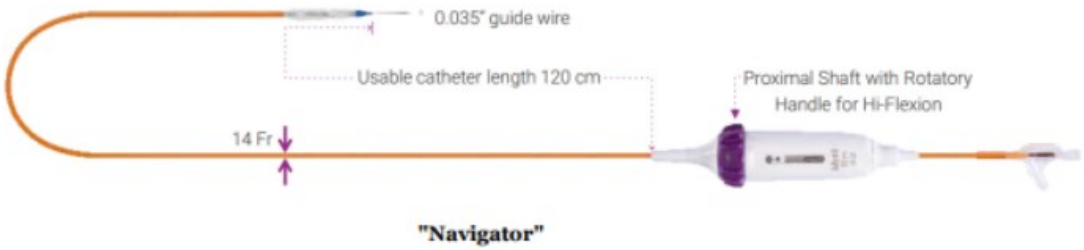
However, for patients with extra-large annuli, the XL-sized "Myval" valve from Meril sometimes still seems to be the best option. Edwards has established a system allowing doctors to request the use of an XL valve of the "Myval" type if they consider it clinically necessary, even though Edwards is not legally obliged to do so. This is done via an online portal set up for this purpose, the so-called "Medical Request Portal" (MRP). The attending physician can upload relevant patient data via this portal. A team of highly qualified doctors at Edwards immediately reviews this data. If this team determines that a SAPIEN 3 valve is not an option in this case, an exception to the injunction or seize-and-desist undertaking can be granted. The physician will receive a response to the request without delay.

Meril is now entering the European market with a modified transcatheter heart valve, the "Octacor" valve, and the associated delivery systems with the designations "Navigator" and

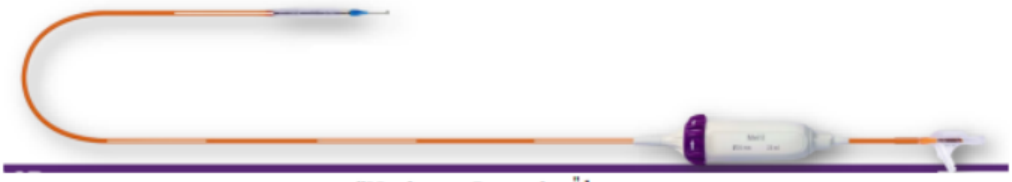
"Navigator Inception" (hereinafter referred to individually or collectively as "infringing



embodiment").



"Navigator"



"Navigator Inception" [1]

Edwards is the registered owner of European Patent 3 646 825 (referred to above and below as the patent, patent at issue or patent-in-suit) which concerns a prosthetic valve and a delivery catheter.

The patent at issue is a divisional application of EP 3 205 309 (parent application) which in turn had been filed as a divisional application of EP 2 731 552 (grandparent application). The grandparent application was filed on 16 July 2012, as an international application which was published as WO 2013/012801 (WO '801). The patent at issue claims priority from two patent applications of 15 July 2011 (US 201161508456, P1) and 13 July 2012 (US 201213549068, P2).

The patent relates to prosthetic heart valves with a sealing mechanism that prevents or minimises perivalvular leakage. The independent claim, as granted, reads as follows:

> *"A system comprising:*
>
> *a prosthetic valve (100) comprising:*
>
> *a collapsible and expandable annular frame (102), configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body;*
>
> *wherein the frame (102) comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114), the angled struts (114) joined to each other so as to form a plurality of rows of hexagonal cells,*
>
> *wherein the frame (102) is made up entirely of hexagonal cells, and wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:*
>
> *two opposing side struts (144) extending parallel to a flow axis of the valve (100),*
>
> *a pair of lower angled struts (146), extending downwardly from respective lower ends of the side struts (144) and converging toward each other, and*
>
> *A pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and*
>
> *a delivery catheter comprising an inflatable balloon;*
>
> *wherein the prosthetic valve (100) is crimped in its radially compressed state on the balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic valve (100) at the desired deployment location, preferably within a native aortic valve."*

On 1 June 2023, Edwards filed an infringement action against Meril before the Local Division Munich (LDM), registered as No. ACT_459987/2023 UPC_CFI_15/2023.

On 4 August 2023, Meril Italy Srl (Meril Italy) filed a revocation action against Edwards concerning the patent at issue before the Central Division, Paris seat (CDP), registered as No. ACT_551308/2023 UPC_CFI_255/2023.

On 1 September 2023, Meril lodged a preliminary objection in the infringement proceedings. This was filed in the workflow of the main proceedings as a "statement of defence". Edwards replied in the main proceeding's workflow as "reply to the defence." On 29 September 2023, the judge-rapporteur (JR) of the LDM informed the parties that the preliminary objection will be dealt with in the main proceedings, registered under No. ORD_576853/2023, in accordance with Rule 20.2 RoP.

On 2 November 2023, Meril filed separate counterclaims for revocation of the patent at issue with the LDM, registered as No. CC_584916/2023 and No. CC_585030/2023, respectively, under the UPC number UPC_15/2023.

By order issued on 13 November 2023, the JR of the CDP rejected the preliminary objection in the revocation proceedings, as well as the request for security for the legal costs submitted by Edwards. This was on the grounds that Meril Italy cannot be considered the same party as those sued before the LDM, and therefore Article 33 (2) UPCA does not apply. The order was not appealed.

On 28 March 2024, the LDM issued an order (ORD_1340/2024) referring the counterclaims for revocation to the CDP for decision in accordance with Article 33 (3) (b) UPCA and 37 (2) RoP.

The JR of the CDP ordered the consolidation of these counterclaims for revocation with the revocation action in accordance with Rule 302 RoP. A single oral hearing was held on 7 June 2024 for both the revocation action and the counterclaims for revocation.

On 19 July 2024, the CDP delivered a decision.

> *"The Court,*
>
> *a) rejects the revocation action filed by Meril Italy Srl on 4 August 2023 and the counterclaims for revocation filed by Meril GmbH and Meril Life Sciences Pvt Ltd on 2 November 2023;*
>
> *b) maintains EP '825 as amended by auxiliary request II submitted on 12 April 2024;*
>
> *c) orders that the Registry shall send a copy of this decision to the European Patent Office and to the national patent office of any Contracting Member States concerned, after the deadline for appeal has passed;*
>
> *d) orders that the costs of the proceedings shall be borne by the claimant and the counterclaimants, jointly, in the amount of 60%, and by the defendant for the remaining fraction."*

Auxiliary request II submitted on 12 April 2024 as exhibit K-A2 reads as follows:

EP 3 646 825 B1 - auxiliary request II

1. A system comprising:
a prosthetic heart valve (100) comprising:
a collapsible and expandable annular frame (102), configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body;
wherein the frame (102) is made of a nickel-cobalt-chromium-molybdenum alloy and comprises a plurality of rows (112a, 112b, 112c, 112d) of angled struts (114), the angled struts (114) joined to each other so as to form a plurality of rows of hexagonal cells, wherein the frame (102) is made up entirely of hexagonal cells, and wherein each of the hexagonal shaped cells is defined by six struts (144, 146, 148), including:
two opposing side struts (144) extending parallel to a flow axis of the valve (100),
a pair of lower angled struts (146), extending downwardly from respective lower ends of the side struts (144) and converging toward each other, and
a pair of upper angled struts (148) extending upwardly from respective upper ends of the side struts (144) and converging toward each other; and
a delivery catheter comprising an inflatable balloon;
wherein the prosthetic heart valve (100) is crimped in its radially compressed state on the balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic heart valve (100) at the desired deployment location, preferably within a native aortic valve,
wherein the frame (102) of the prosthetic heart valve (100) does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from an inflow end (108) or an outflow end (110) of the frame (102) for mounting the frame (102) to the delivery catheter.

2. The system (100) of claim 1, further comprising a leaflet structure comprising a plurality of leaflets (104), and a sealing skirt (106).

3. The system (100) of claim 2, wherein each leaflet (104) has a scalloped lower edge portion (134) that is secured to the frame (102) and/or the skirt (106) by sutures.

4. The system (100) of any of claims 2 to 3, wherein each leaflet (104) has a tab portion (116) adjacent an upper free edge of the leaflet (104).

5. The system (100) of any of claims 2 to 4, wherein the skirt (106) is made of a fabric, the fabric preferably made of PET or UHMWPE.

The CDP's decision has been appealed. The cases are registered as No. UPC_CoA_457/2024, UPC_CoA_458/2024 and UPC_CoA_464/2024. The appeal hearing will be held at a later date.

The LDM panel has rejected Edwards' application to add Meril Italy as defendant 3) to the infringement proceedings (App_5588/2024).

A videoconference was held on 14 March 2024 (App_11151/2024) in the infringement action. The following order was issued in accordance with Rule 105.5 RoP:

> *1. The language of the proceedings is changed to English*
>
> *2. The parties are invited to submit available (computer) translations into English of their pleadings within one month from the date of this order, as specified in 9. above*
>
> *3. Edwards request (App_11151/2024) to file a further submission on Meril's public interest argument, is rejected. The other requests in the same application (regarding experts and regarding the allegedly infringing product Octacor) will be addressed at a later stage (the IC).*
>
> *4. Edwards request (App_12541/2024) to reject Meril's submission of 29 February 2024 (App_11028/2024) is granted. This submission will not be part of the (written) proceedings.*

The interim conference was held on 5 September 2024. The following order (ORD_598441/2023) was issued in accordance with Rule 105.5 RoP.

> *1. Requests no. 1-4 and 12 (physical objects; 3D model; PowerPoint; leave to change claim, video conference) are granted. The physical objects are to be submitted to the Sub-Registry of the Local Division Munich by 16 September 2024 and can be inspected there after having made an appointment on 17 September 2024 or on the date of the oral hearing. The submissions must be accompanied by respective CMS workflows.*
>
> *2. Requests no. 5 (stay; re-schedule) are referred to the panel for decision. Pending a decision by the panel no stay is ordered and the oral hearing stays to be scheduled for 24 September 2024.*
>
> *3. Requests no. 6-9 (experts) are denied with exception to requests concerning the same effect which are referred to the panel for decision during the oral hearing.*
>
> *4. Requests no. 10 (third party access) will be considered after parties have filed their additional submissions.*
>
> *5. Requests no. 11 (dismissal; condition) are referred to the panel for decision during the oral hearing.*
>
> *6. Parties are summoned to the oral hearing on 24 September 2024, 9.00 a.m., Local Division Munich, room 212, Denisstr. 3 in Munich.*

The parties submitted the physical objects in accordance with the requirements set out in item 1 of the aforementioned order.

The oral hearing took place on 24 September 2024.

ARGUMENTS SUBMITTED BY THE PARTIES

Edwards is asserting that the attacked embodiment is using claims 1, 2, 4 and 5 of the patent in suit as upheld by the CDP.

Edwards is asserting that the cells in the attacked Myval Octacor valve are hexagonal in shape corresponding to what is disclosed in Fig. 6 of the patent in suit (Fig. to the left below). The Fig. to the right below is an enlarged view of a cell of the heart valve of Fig. 6 as marked and annotated by Edwards.

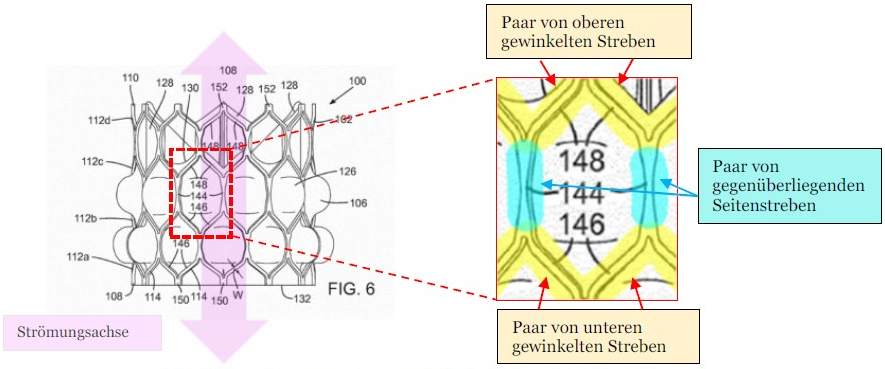


Abbildung 50 – Fig 6. des Klagepatents [Hervorhebungen hinzugefügt]

According to Edwards the upper and lower pairs of angled struts of the attacked Myval Octacor heart valve are connected by side struts that are convexly shaped with a hole in the middle what Edwards refers to as a spindle shaped side strut. Each cell of the attacked Myval Octacor valve therefore have six struts including two side struts that extend in the axial direction. The side struts in the upper row of cells would be formed in three instances by commissure struts which allow for a secure anchoring of the valvular leaflet structure. Edwards submits that it is clear that the Myval Octacor valve displays the contested features.

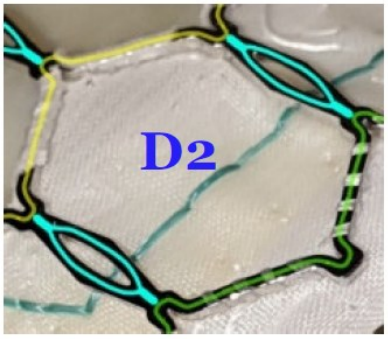


Abbildung 55 – Vergrößerung einer hexagonalen Zelle der Verletzungsform

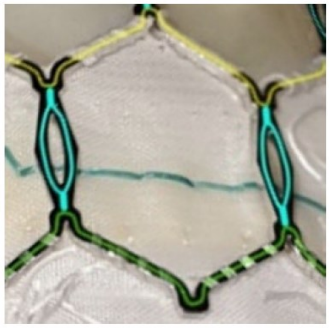
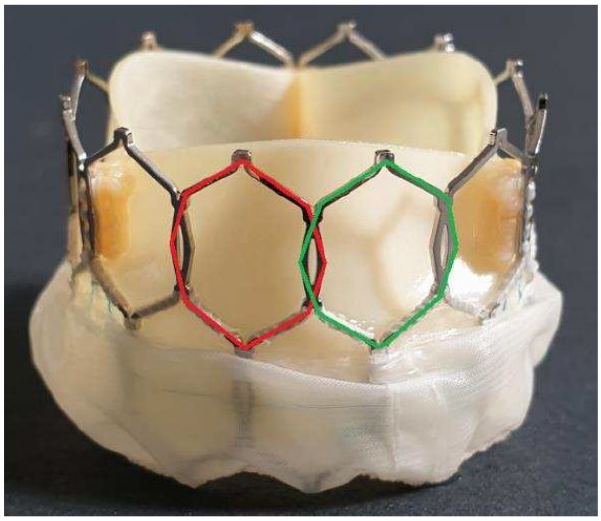


Abbildung 59 – Ausschnitt der Verletzungsform

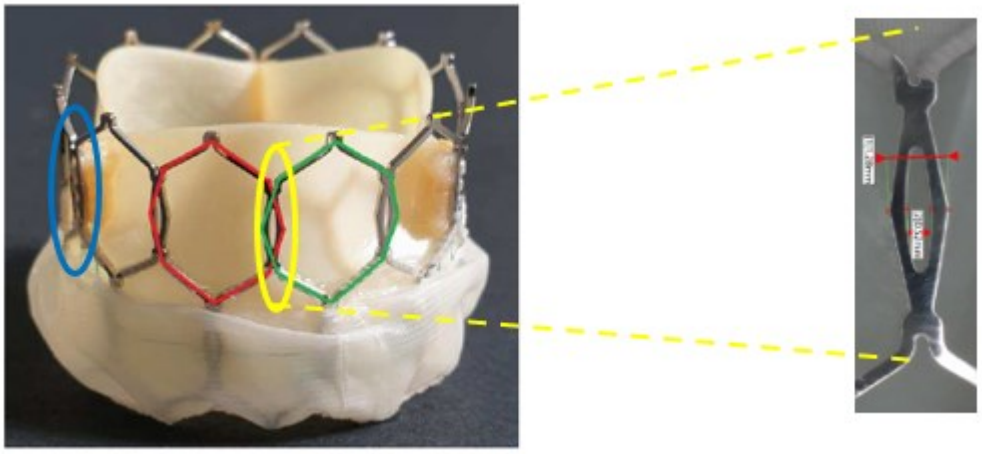
Edwards submits in conclusion that in any case the court must find for equivalent infringement.

Meril is contesting an infringement, whether literal or with equivalent means, as is illustrated by the following figure:



Meril asserts that the frame of the "Myval Octacor" heart valve is composed of octagonal cells (marked in red and green in the figure above) that partially overlap to form rhombic cells in the overlapping zone (marked in yellow in the left Fig. below and shown enlarged in the right Fig. below).

In three cases, the rhombic cells in the upper row would be substituted by commissure posts (highlighted in blue in the Fig. below) that do not form struts.



This is because the posts are different from the struts. 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.

Furthermore, allegedly, there is no equivalent infringement either. In any case, the arguments regarding an equivalent infringement must be rejected since they were filed too late.

Meril asserts that third parties' interests and the public interest (in particular, the life and health of patients with severe heart disease (aortic valve stenosis)) require a denial of injunctive relief. Meril's product offered significant advantages over Edwards' product, and it was essential to practitioners that they have a range of options for treatment.

In any case, the injunction must not be ordered regarding the system comprising the "Myval Octacor" and the "Navigator Inception" in the sizes in which Edward’s "Sapien 3" and the "Sapien 3 Ultra" are not available.

The intermediate sizes, i.e.

- 21.5mm, 24.5mm, 27.5mm for the "Myval Octacor" and
- 21.5mmx30mm, 24.5mmx30mm, 27.5mmx30mm, 27.5mmx35mm for the "Navigator Inception",

and the XL sizes, i.e.

- 30,5mm and 32mm for the "Myval Octacor" and
- 30.5mmx35mm and 32mmx35mm for the "Navigator Inception",

were, in any case, to be exempted from any injunction. The "Myval Octacor" valve (and Meril’s previously developed "Myval" heart valve which has been injuncted by various national courts and is therefore not available without restrictions) met the size spectrum desired by the medical community and offered patients with large annuli of more than 30mm the possibility of a TAVI procedure. According to Meril this was not possible with Edwards` products or other self-expanding transcatheter heart valve prostheses available on the market.

Therefore an alternative is to refuse an injunction and grant compensation instead, or to limit the injunction by granting a grace period.

Meril also argued that the proceedings must be rescheduled or stayed until the appeal against the CDP decision is heard. Meril is convinced that the CDP infringed their right to be heard by failing to mention some of their main arguments in the written decision. However, it is not in disputed that those arguments were discussed during the oral hearing in Paris.

In its preliminary objection, Meril confidently asserted that the UPC was not competent to adjudicate claims based on activities commenced before 1 June 2023. Furthermore, the LDM

had no jurisdiction with respect to the Düsseldorf-based Meril GmbH. Edwards should have chosen the Local Division Düsseldorf.

Edwards counterargued with confidence that the preliminary objection was unfounded and that no re-scheduling and no stay were warranted. Edwards was certain that the decision by the CDP was correct and that all the "missing" arguments could be found in the written decision. Furthermore, Edwards made it clear why the CoA will not reverse the decision by the CDP based on the arguments presented.

The claims for injunction, recall and destruction are proportionate in Edwards' view. Third parties' interests and public interests must not be taken into account. The UPC would have no authority to consider public interest because that issue was deliberately left to the national courts to decide. In any case, the accused Myval Octacor heart valve allegedly is not superior to Edwards' product. There also was no need for intermediary sizes. Practitioners could use the Medical Request Portal to get an XL-sized Octacor valve for a specific patient. The same portal is used for XL-sized Myval valves.

Furthermore, the observations and exhibits submitted by the parties, along with the orders and decisions cited, are referenced.

PARTIES`REQUESTS

Edwards seeks that the Court

I. orders Defendants to cease and desist with respect to a system comprising: a prosthetic heart valve comprising: a collapsible and expandable annular frame configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body; wherein the frame is made of a nickel-cobalt-chromium-molybdenum alloy and comprises a plurality of rows of angled struts, the angled struts joined to each other so as to form a plurality of rows of hexagonal cells, wherein the frame is made up entirely of hexagonal cells, and wherein each of the hexagonal shaped cells is defined by six struts, including:

two opposing side struts extending parallel to a flow axis of the valve, a pair of lower angled struts, extending downwardly from respective lower ends of the side struts and converging toward each other, and a pair of upper angled struts extending upwardly from respective upper ends of the side struts and converging toward each other; and a delivery catheter comprising an inflatable balloon; wherein the prosthetic heart valve is crimped in its radially compressed state on the balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic heart valve at the desired deployment location, preferably within a native aortic valve, wherein the frame of the prosthetic heart valve does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from an inflow end or an outflow end of the frame for mounting the frame to the delivery catheter.

(independent claim 1 of the Patent-in-Suit),

from offering, placing on the market, using, or importing or storing it for the said purposes within the territory of the Agreement on a Unified Patent Court at the time of the oral hearing – except in Malta–, in the alternative in Belgium, Bulgaria, Denmark, Germany, Estonia,

Finland, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Portugal, Sweden and Slovenia

especially if

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

(dependent claim 2 of the Patent-in-Suit),

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 the Patent-in-Suit),

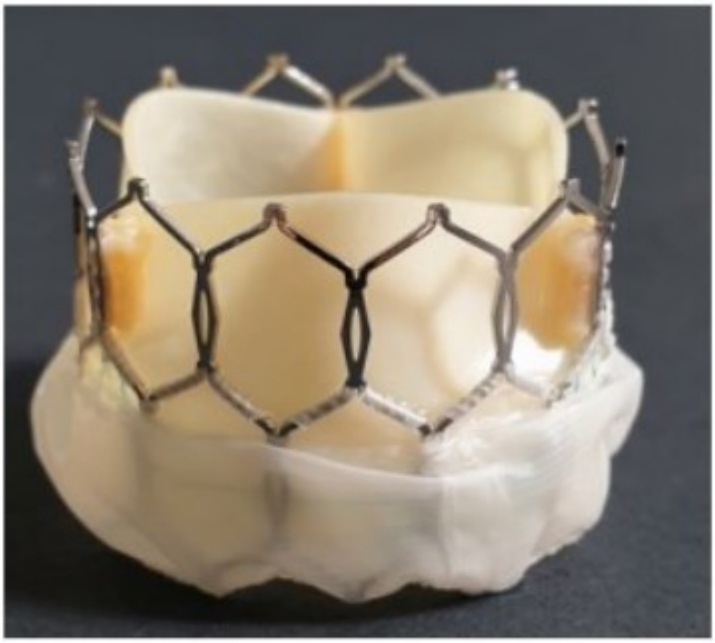
and/or

a system of any of claims 2 and/or 4 and/or 12, wherein the skirt is made of a fabric, the fabric preferably made of PET or UHMWPE;

(dependent claim 5 of the Patent-in-Suit),

especially if the system contains

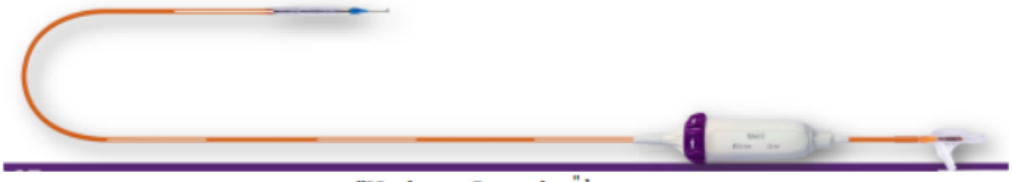
a) a transcatheter heart valve prosthesis with the designation "Myval Octacor" as shown below



and/or

b) a delivery apparatus of the type "Navigator" and/or "Navigator Inception" as shown below

"Navigator"



"Navigator Inception" [1]

II. In the alternative,

orders Defendants to cease and desist with respect to a system comprising: a prosthetic heart valve comprising: a collapsible and expandable annular frame configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body; wherein the frame 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;

(independent claim 1 of the Patent-in-Suit),

from offering, placing on the market, using, or importing or storing it for the said purposes within the territory of the Agreement on a Unified Patent Court at the time of the oral hearing – except in Malta–, in the alternative in Belgium, Bulgaria, Denmark, Germany, Estonia, Finland, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Portugal, Sweden and Slovenia

especially if

the frame is made of a plastically-expandable material, preferably selected from a group comprising stainless-steel, a nickel-based alloy, a nickel-cobalt-chromium alloy, polymers or a combination thereof;

(dependent claim 5 of the Patent-in-Suit),

and/or

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

(dependent claim 6 of the Patent-in-Suit),

and/or

a system of claim 6, wherein each leaflet has a tab portion adjacent an upper free edge of the leaflet;

(dependent claim 11 of the Patent-in-Suit),

and/or

a system according to the dependent claim 11, further comprising at least one reinforcement strip that covers the tab portion of a respective leaflet;

(dependent claim 12 of the Patent-in-Suit),

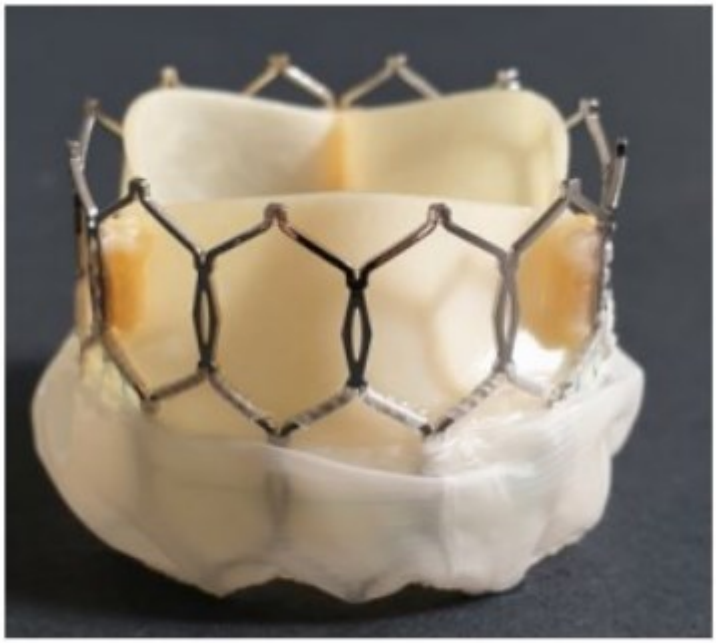
and/or

a system of any of claims 6 and/or 11 and/or 12, wherein the skirt is made of a fabric, the fabric preferably made of PET or UHMWPE;

(dependent claim 13 of the Patent-in-Suit),

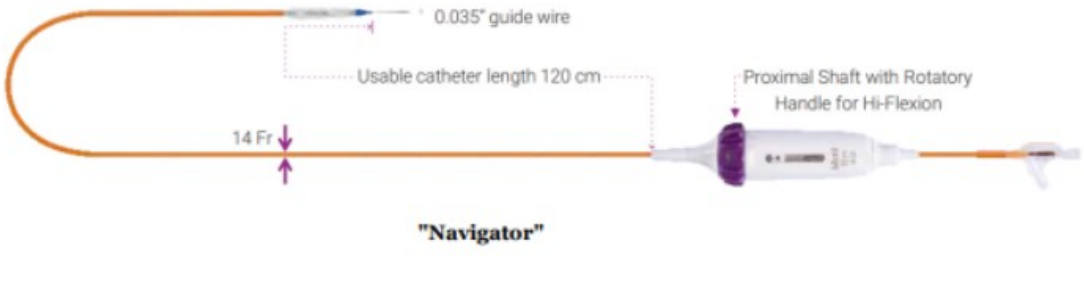
especially if the system contains

c) a transcatheter heart valve prosthesis with the designation "Myval Octacor" as shown below



and/or

d) a delivery apparatus of the type "Navigator" and/or "Navigator Inception" as shown below



"Navigator"

"Navigator Inception" [1]

III. orders Defendants for each case of violation of the order according to Item I. or II., to make penalty payments to the Court, to be determined by the Court in reasonable proportion to the importance of the order to be enforced, whereby an amount of EUR 20,000 for each case of non-compliance and per infringing product is suggested;

IV. finds that the Patent-in-Suit was infringed by Defendants in respect to the products described above under Item I. or II.;

V. orders Defendants, under penalty of a periodic fine of EUR 1,000 for each day of delay, within a period of three weeks from the date of service of the decision, to provide Claimant with information on the extent to which Defendants have committed the acts referred to in Item I. or II. since 17 March 2021, specifying:

1) the origin and distribution channels of the infringing products,

2) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products, and

3) the identity of any third person involved in the production or distribution of infringing products;

VI. orders Defendants, under penalty of a periodic fine of EUR 1,000 for each day of delay, within a period of one week from the date of service of the decision, to recall from the commercial customers the products described above under Item. I. or II. that have been placed on the market since 17 March 2021, with reference to the infringement of the products determined by the Court and with the binding promise to pay any fees and necessary packaging and transport costs, as well as customs and storage costs associated with the return, and to take back the products to have them finally removed from the distribution channels;

VII. orders Defendants, under penalty of a periodic fine 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 referred to above in Item I. or II. and/or materials in their direct and/or indirect possession and/or ownership (including any products and/or materials that come into their direct and/or indirect possession and/or ownership pursuant to Item IV VI. above or otherwise) or, at its option, to hand them over to a bailiff to be appointed or commissioned by Claimant for the purpose of destruction;

VIII. allows Claimant to publish the Court's decision in whole or in part, including the announcement of the decision, in five public media including industry journals of its choice;

IX. orders Defendants to publish the operative part of the Court's decision on their websites

X. finds that Defendants are obligated to reimburse Claimant for any damages (including interest) incurred by Claimant since 17 March 2021 due to the actions described above under Item I. or II. as well as those yet to be incurred;

XI. orders Defendants to pay preliminary damages, with the amount of the security at the discretion of the Court, where at a minimum Claimant's projected costs of the damages and compensation proceedings must be covered and an amount of at least EUR 663,000.00 is suggested;

XII. orders Defendants to pay the costs of the proceedings, including those relating to the measures requested in Item I. to VIII. above;

XIII. attaches to the decision an order for its immediate enforceability;

alternatively,

in the event a security is ordered, permits Claimant to provide it by bank or savings institution guarantee and determine the amount of the security separately for each claim granted and for the decision of costs,

alternatively,

permits Claimant to avoid compulsory enforcement with respect to the costs against provision of security;

XIV. issues a decision by default in the event that Defendants fail to take action within the time limit foreseen in these Rules of Procedure or set by the Court or fail to appear at an oral hearing after having been duly summoned.

Meril seeks

I. the infringement action be dismissed.

II. the Claimant is ordered to bear the costs.

In the alternative:

II. the infringement proceedings (ACT_459987/2023) be stayed pending a final decision of the Court of Appeal in cases UPC_CoA_457/2024, UPC_CoA_458/2024 and/or UPC_CoA_464/2024 on the (in)validity of EP 825;

In the alternative:

III. the oral hearing scheduled for 24 September 2024 be postponed until a date after a final decision of the Court of Appeal in cases UPC_CoA_457/2024, UPC_CoA_458/2024 and/or UPC_CoA_464/2024 on the (in)validity of EP 825;

In the alternative:

IV. a decision – if in Claimant's favour – be rendered under the condition subsequent pursuant to Art. 56(1) UPCA that the patent is not held to be wholly or partially invalid by the final decision in the revocation proceedings, whereby the requests under items no. II. to IV. are conditional on Claimant being granted leave to amend its claims asserted in the infringement proceedings. Otherwise, the action would have to be dismissed already because it is based on an invalid patent.

In the oral hearing **Edwards** applied to be allowed to amend the requests as follows (APP_53312/2024):

- include Romania and

- (VII_{new}) orders Defendants, under penalty of a periodic fine of EUR 1,000 for each day of delay, within a period of three weeks from the date of service of the decision, to provide Claimant with information on the extent to which Defendants have committed the acts referred to in item I. since 17 March 2021, specifying:

1) the origin and distribution channels of the infringing products,

2) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products, and

3) the identity of any third person involved in the production or distribution of infringing products;

<u>whereby the list with the data has to be additionally transmitted electronically in a form that can be evaluated by means of EDP (e.g. Excel table), and copies of the relevant purchase documents (namely invoices, alternatively delivery bills, alternatively customs documents) are to be submitted by Defendants as proof of the information, whereby confidential details outside the data subject to disclosure information may be redacted;</u>

(changes from Request V. in the Submission of 13 August 2024 are underlined)

Meril demanded that these late amendments be dismissed.

After the closure of the Oral Hearing, with a brief dated 16 October 2024 **Meril** (App_56354/2024) requested:

On behalf and in the name of Defendants, we ask the Division to

I. ask the European Commission to transmit information about the status of the investigations into the potential violation by Claimant of EU antitrust law that prohibits the abuse of a dominant market position, the reasons for the initiation of these investigations and the timing for the next steps;

II. ask the European Commission to provide a copy of any decisions that have been adopted so far, in particular, of any decisions that relate to or concern Claimant's patent filing strategy, Claimant's Global Unilateral Pro-Innovation (AntiCopycatting) Policy and/or Claimant's patent litigation strategy against Defendants, distributors distributing products of the Defendant company and/or companies of the Defendant group;
and request that

III. leave be granted for the parties to submit further written pleadings and the oral hearing be reopened, if necessary, after the European Commission has provided the information requested.

Edwards requested with brief dated 21 October 2024:

Claimant requests that Defendants' Request is dismissed.

By order of 15 November 2024 (App_56354/2024), which is hereby referred to, Panel 1 of the LDM dismissed the defendant's application.

GROUNDS FOR THE DECISION

The request to amend the claim (Romania and details of the information to be provided) is rejected. The preliminary objection and the request for rescheduling or for a stay pending the appeal decision are rejected outright. The attacked embodiment makes direct and literal use of the patent, as upheld by the CDP. As a result, the relief sought is granted. The proportionality defence is rejected almost entirely.

A. Request to amend the claim

The request for leave to change the claim (to add Romania to the list of countries for that relief is sought and details of the information to be provided) is rejected.

I. During the oral hearing Edwards requested leave to make a late claim amendment to include Romania and to specify how the information is to be provided by Meril.

II. Meril firmly objected to this late request.

III. According to R 263.1 RoP a party may at any stage of the proceedings apply to the Court for leave to change its claim or to amend its case, including adding a counterclaim. Any such application shall explain why such change or amendment was not included in the original pleading. According to paragraph 2 leave shall not be granted if, all circumstances considered, the party seeking the amendment cannot satisfy the Court that: (a) the amendment in question could not have been made with reasonable diligence at an earlier stage; and (b) the amendment will not unreasonably hinder the other party in the conduct of its action.

IV. The amendment regarding the information to be provided by Meril should have been filed much earlier, if not with the statement of claim. Edwards did not provide a reason for requesting the amendment so late.

V. Romania effectively joined the system on 1 September 2024, so that the amendment could not have been made with the statement of claim. However, it should have been made prior to the date of the oral hearing (24 September 2024). In any case, Edwards failed to prove at the oral hearing that the renewal fee for Romania had been paid in time and the patent is valid in Romania. The online register entries available on the date of the oral hearing are silent on that. Edwards requested the court to proceed with the proceedings, thereby eliminating the possibility of an adjournment to verify the timely payment of the renewal fee. The request to amend is therefore rejected.

B. Preliminary objection

The preliminary objection is basically rejected.

I. Meril contended that the Court lacked jurisdiction (Rule 19.1(a) RoP) with regard to all claims, given that the claimant was seeking a decision that would be "within the area of application of the Unified Patent Court Agreement as of the date of the hearing, excluding Malta".

1. Meril's request is to be understood as meaning that, if between the filing of the Statement of Claim on 1 June 2023 and the date of the oral hearing, additional member states in which the patent in suit is validated ratify the UPCA, there will be an "automatic" extension of the action, which Meril considers inadmissible.

2. This question can remain unanswered as the request from Edwards is incorrectly worded and therefore invalid. It is the responsibility of the claimant to specify the exact territories for which they are seeking relief. The court will then determine whether this request can be granted. In contrast with the aforementioned rule, Edwards' request leaves it to the court to determine which member states meet the requirements at the time of the oral hearing.

The auxiliary request, which explicitly states the territories in question (Belgium, Bulgaria, Denmark, Germany, Estonia, Finland, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Portugal, Sweden and Slovenia), is, however, admissible. The request to add Romania is rejected (outlined above).

II. Meril also contended that the Court lacked jurisdiction (R. 19.1(a) RoP) with respect to the claims, particularly those in Sections IV, V, VI, IX and X, which pertained to periods preceding 1 June 2023.

1. Meril's request is to be understood as meaning that the Unified Patent Court does not have jurisdiction to decide on acts of infringement committed before the entry into force of the Agreement on a Unified Patent Court on 1 June 2023.

2. This interpretation is incorrect. The Unified Patent Court has jurisdiction over acts of infringement committed before the entry into force of the Agreement on a Unified Patent Court on 1 June 2023. This is in line with Article 3(c) and 32(1)(a) UPCA, in the absence of any conflicting intertemporal provisions. This conclusion is further supported by the fact that the concurrent competence of the UPC and the courts of the member states on European patents will cease after the interim phase. Subsequently, the UPC will have exclusive jurisdiction over all European patents. The courts of the member states will no longer have competence in this matter. If Meril's argument were to be accepted, it would mean that no court, whether the UPC or those of the member states, would have the authority to adjudicate claims for damages for infringements committed prior to 1 June 2023. This is not a viable proposition, even if the statute of limitations is taken into account. This is because the statute of limitations only applies if the defendant raises it in a timely manner.

III. Meril also contended that the LDM (R. 19.1(b) RoP) lacked jurisdiction over all claims pertaining to an alleged infringement of the patent [EP 3 646 825 B1] by a system comprising the transcatheter heart valve 'Myval Octacor™' and the delivery system 'Navigator™'.

1. Meril's request is to be understood as meaning that the question of jurisdiction must be answered on a case-by-case basis, taking into account the specific products or combinations of products involved.

2. This interpretation is incorrect. In the context of Article 33.1(b) UPCA: the question is whether the same allegation of infringement is involved. This necessitates an interpretation of Edward's claim. The claim requests the court to prohibit the defendants from continuing to utilize the technical teaching of the patent in question. This is evidenced by the repetition of the wording of the granted patent claims in the statement of claim. The reference to specific products or sets alleged to be infringing, as well as the explanations provided in the statement of claim, are for illustrative purposes only. Therefore, all products or sets specifically mentioned relate to the same allegedly infringing attacked embodiment within the meaning of Article 33(1)(b) of the UPCA. Accordingly, the LDM has jurisdiction over the first defendant, given that it is domiciled in Bonn and thus in the Federal Republic of Germany.

IV. Meril additionally contested that the plaintiff's choice determines the competent German local division. Rather, national law applies to determine which German local division is competent, due to a lack of provisions in the UPCA. Pursuant thereto, the LDM has no competence regarding the first defendant.

1. In the absence of UPC legislation regarding the distribution of local jurisdiction between the four local divisions of the Court of First Instance of the Unified Patent Court in Germany, Meril's request is to be understood as a call for the application of national (German) laws governing the competence of courts.

2. This line of reasoning is untenable. It is evident that this approach would be unable to address the question of local jurisdiction for defendants domiciled in the German *Länder* without a local division, as is the case in particular in eastern Germany. In light of the aforementioned, the LDM also has jurisdiction over the second defendant, at least in accordance with Article 33.1 b) UPCA. This is because the second defendant has a permanent business relationship with the first defendant with respect to the attacked embodiments and the same infringement is at issue, namely the infringement of the patent in suit. The first defendant is a wholly owned subsidiary of the second defendant. The first defendant serves as the European headquarters of the group of companies and is supplied with the accused products by the second defendant.

C. Claim construction

I. Background of the patent at issue

The patent in suit comprises 13 claims, of which claim 1 is an independent claim and claims 2 to 13 are dependent on claim 1. Claim 1 pertains to a system comprising a prosthetic valve and a delivery catheter.

The patent description states that prosthetic cardiac valves have been used for many years to treat cardiac valvular disorders. Traditionally, the definitive treatment for such disorders was surgical repair or replacement of the valve during open heart surgery. However, a trans vascular technique has been developed for introducing and implanting a prosthetic heart valve using a flexible catheter in a manner that is less invasive than open heart surgery (para. [0002]).

The new technique involves mounting a prosthetic valve in a crimped state on a flexible catheter and advancing it through a patient's blood vessel until it reaches the implantation site. At this point, the valve is expanded to its functional size by inflating a balloon or by a self-expanding frame.

As the native valve annulus in which the expandable prosthetic valve is deployed typically has an irregular shape, mainly due to calcification, small gaps may exist between the expanded frame of the prosthetic valve and the surrounding tissue. These gaps can allow for regurgitation (leaking) of blood flowing in a direction opposite to the normal flow of blood through the valve. To reduce perivalvular leakage, a range of sealing devices have been developed (see paragraph [0004]).

In light of the above, one of the key objectives of the patent at issue is to provide a prosthetic valve that has a minimal impact on the overall crimp profile. This is achieved through the honeycomb structure of the frame, which provides stability during crimping and subsequent expansion, is less sensitive to variations in strut width, and provides increased radial strength (para. [0039]).

II. Feature analysis

According to claim 1 of the patent at issue as upheld by the CDP this problem is to be solved by the following system (the features under dispute are highlighted):

A system comprising:

I. a prosthetic heart valve (100) comprising:

1) a collapsible and expandable annular frame (102), configured

a) to be collapsed to a radially collapsed state for mounting on a delivery apparatus

b) and expanded to a radially expanded state inside the body;

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

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

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

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

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

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

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

II. a delivery catheter comprising an inflatable balloon;

1) wherein the prosthetic heart valve (100) is crimped in its radially compressed state on the balloon of the delivery apparatus,

2) and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic heart valve (100) at the desired deployment location, preferably within a native aortic valve,

III. wherein the frame (102) of the prosthetic heart valve (100) does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from an inflow end (108) or an outflow end (110) of the frame for mounting the frame (102) to the delivery catheter.

III. Construction of the claim features

In order to correctly interpret the claims, it is essential to consider the following: The patent claim is not only the starting point, but also the decisive basis for determining the protective scope of the European Patent. It is important to note that the interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. The description and drawings must always be used as explanatory aids for the interpretation of the patent claim. However, this does not mean that the patent claim serves only as a guideline and that its subject matter may extend to what the patent proprietor has contemplated from a consideration of the description and drawings. These principles for the interpretation of a patent claim apply equally to the assessment of the infringement and to the validity of a European patent. This is in line with the order of the Court of Appeal issued on 26 February 2024, case UPC_CoA_335/2023.

In order to make an accurate assessment, it is necessary to consider the perspective of a person skilled in the relevant field. In this case, this may be defined as a group comprising a

medical device engineer with expertise in prosthetic heart valves and an interventional cardiologist.

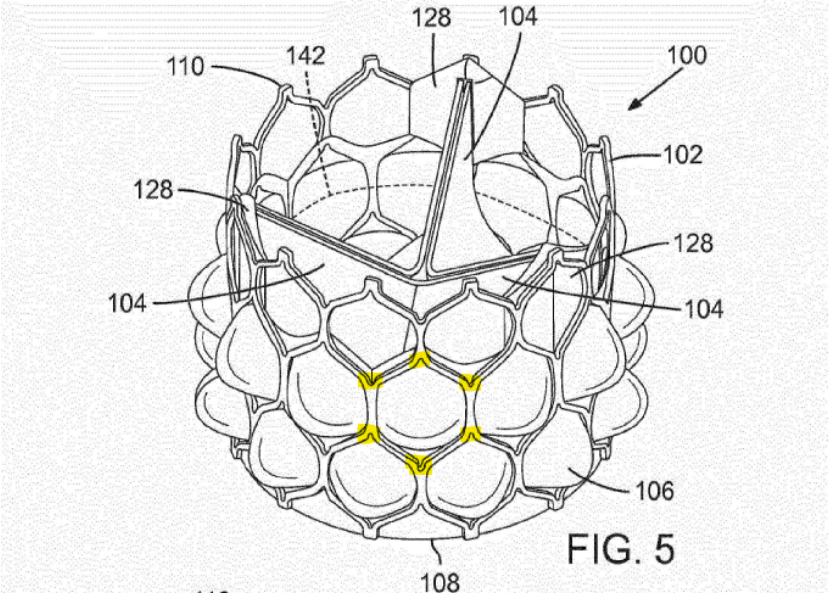
1. “strut”

According to feature I.3 the angled struts are joined to each other so as to form a plurality of hexagonal cells. According to feature I.4 there are 6 struts in total comprising

- two side struts extending in 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 to each other, and
- a pair of upper angled struts extending upwardly from respective upper ends of the side struts and converging to each other.

In col. 11, para [0037] it is disclosed that the pairs of upper and lower angled struts, respectively, converge towards each other and intersect with each other.

This is further illustrated in Fig.5 of EP ’825 below that schematically shows that neighboring struts are joined in apices at the topmost and lowermost row of angled struts, respectively, and in correspondingly shaped connection areas (junctions) or apices such as, e.g., welding points otherwise.



Based on this the term strut is understood in the patent at issue to mean an individual, distinct piece that is connected to neighboring struts in connecting areas or apices.

The struts form the perimeter of the cells of the frames shown in EP ‘825 what is in line with the claim construction provided in the decision of the CDP that states:

> *There is also disagreement between the parties regarding the meaning of the terms ‘cell’ and ‘opening’. The claimant argues that they should be understood as synonyms. However, the panel holds the opposing view that ‘cell’ refers to the entity defined by the struts, while ‘opening’ refers to the open space within the cell, as evident from the content of paras. [0040] and [0041], where the term ‘opening’ is clearly used to refer specifically to an opening within the cell.*

EP ‘825 also comprises subject matter that is not claimed such as the embodiment of Fig.’s 1-4 that is made up exclusively of rhombic cells. These rhombic cells comprise upper and lower pairs of angled struts only that are joined to each other via connection areas and apices, respectively. They do not comprise side struts, though, and therefore do not represent claimed subject matter.

Fig.’s 1 and 2 show a frame with rhombic cells in the expanded state (Fig. 1) and in the crimped (compressed) state (Fig. 2), respectively. It can be seen from the Figs. that the angled struts are compressed so that the angle between the struts is decreased. It can furthermore be seen that the struts are not deformed, they are just turned towards each other around the connection points or nodes. Upon compression, the height of the frame is increased. The compression is essentially reversible, and the frame can be expanded again by mounting it on a balloon catheter and expanding the balloon whereby the height of the frame decreases. This effect is also referred to as “foreshortening.

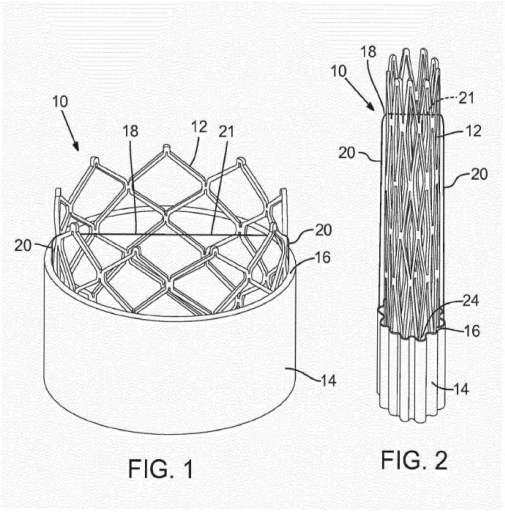


FIG. 1 FIG. 2

A compressed state is not shown in the patent at issue for the frame of Figs. 5-9 that represents an embodiment that is claimed. However, since the compression force is perpendicular to the flow axis of the valve and the side struts extend in the direction of the valve, the side struts are not rotated upon compression but remain aligned with the flow axis. Contrary to that, the orientation of the angled upper and lower struts of the cells of Figs. 5-9 vis a vis the flow axis changes in accordance with what is shown in Fig. 2 for rhombic cells. In the embodiment of Figs. 1-4 all struts can be considered as angled struts that are pushed towards the flow axis.

The thickness or shape of the struts, also of those of the claimed embodiment, is not generally defined in EP ‘825. Figs. 5 and 6 show side struts (reference nr 144 in Fig. 6) that exhibit a concave shape what implies that the shape and width of a strut shape can vary to some extent along its longitudinal extension. This is in line with para [0039] of EP ‘825 stating that “[T]he honeycomb structure … is less sensitive to variations in strut width”.

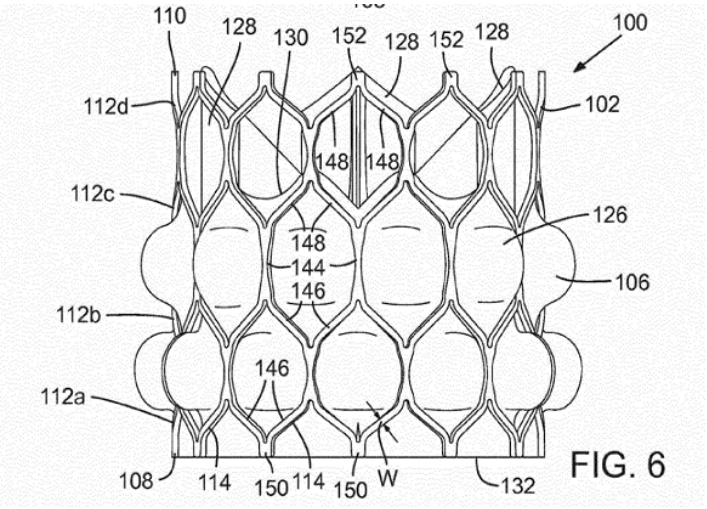


FIG. 6

In the specific example given in para [0039] of EP ‘825 the height of the frame and thus the cumulative length of the struts in the longitudinal direction is distinctly larger than their width and thickness, as is also derivable from the relevant figures. The side struts are different from the connection areas (and from the angled struts 146,148) and extend in the flow direction (claim 1).

> **[0039]** In a specific embodiment, the frame 102 has an overall height (measured from the inflow end 108 to the outflow end 110) of about 20 mm; and the struts have a width W (FIG. 6) of about 0.4 mm and a thickness T (FIG. 8) of about 0.45 mm. The honeycomb structure of the frame reduces the crimping profile of the valve, provides stability during crimping and subsequent expansion, is less sensitive to variations in strut width, and provides increased radial strength.

It can also be seen from Fig. 6 that the apices 150, 152 in the top and bottom row of cells, respectively, join neighboring angled side struts 146,148, respectively. Likewise, the angled struts 146,148 are joined to the side struts 144 via connection areas such as welding points that correspond to the apices in the upper and lower rows of cells, respectively as can be taken, e.g., from [0037] of the patent at issue.

> to form apices 150 at the inflow end of the frame. The upper angled struts 148 extend upwardly from the upper ends of the side struts 144 and converge toward each other and intersect with each other and the lower end of a strut of another cell in an upper row, except for the angled struts 148 in the fourth row 112d, which intersect with each other to form apices 152 at the outflow end of the frame.

Based on this the term strut is understood in the patent to mean an individual, distinct and rigid piece that is connected to neighboring struts in connecting areas or apices, respectively.

It has also been submitted by Meril’s expert Mayer in his declaration HL12 that struts are joined with other struts to form a grid referred to as frame or stent in the patent at issue. 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. Mayer also differentiates between angled struts and vertical struts, the latter being side struts in the terminology of the patent at issue. Upon compression the angled struts are moved essentially in the connection areas of the flow axis so that the radial diameter of the frame is decreased.

Mayer further states that in contrast the alignment of the vertical strut is not changed upon compression. .

Streben als Teil eines Prothesenrahmens übertragen 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.

Die Streben dienen mithin hauptsächlich der Stabilität und gleichzeitigen Komprimierbarkeit des Prothesenrahmens, während Pfosten hauptsächlich der Befestigung des Klappengewebes mit Nahtmaterial dienen.

Eine *gewinkelte Strebe* ist eine Strebe, die nicht senkrecht, sondern in einem bestimmten Winkel zu einer vertikalen Achse steht. Die vertikale Achse versteht die Fachperson hier als die Achse in Flussrichtung des Blutes, das durch die Klappe fließt. Beispiele für eine gewinkelte Strebe sind unten abgebildet. Im Gegensatz zu einer vertikalen Strebe (in Strömungsrichtung) versteht der Fachmann, dass eine gewinkelte Strebe es ermöglicht, den radialen Durchmesser eines Rahmens durch Kompression zu verringern. Außerdem weiß der Fachmann, dass die für eine solche Änderung des Radialdurchmessers erforderliche Kraft von der präzisen Konstruktion des Rahmens abhängt:

Mayer also refers to a definition of the term “strut” as provided , e.g., by the Webster dictionary. This definition appears to be in line with what has been discussed above.

strut 2 of 3 **noun**

1 : a structural piece designed to resist pressure in the direction of its length

2 : a pompous step or walk

3 : arrogant behavior : SWAGGER

This claim construction is also in line with the interpretation by the CDP. In its decision it is stated:

> *The parties debated the meaning of the term ‘strut’. According to this Court, the term must be understood, in line with the common general knowledge, to mean a single, unitary elongated piece that connects the neighboring struts. This definition is not explicitly disclosed in EP ‘825 but is implied by the claims, which require that each hexagonal cell is defined by six struts (feature 1.6.) including two opposing side struts extending parallel to a flow axis of the valve (feature 1.7), a pair of lower and upper angled struts angled struts extending downwardly or upwardly from respective lower or upper ends of the side struts, respectively, and converging toward each other (features 1.8 and 1.9.) with the angled struts being joined to each other so as to form a plurality of rows of hexagonal cells (feature 1.4.). Reference can also be made to Fig. 6 which shows that neighboring struts are joined at apices 150 and 152 at the topmost and lowermost row of angled struts, respectively, and in correspondingly shaped connecting portions such as welding points or nodes at intermediate rows of angled struts.*

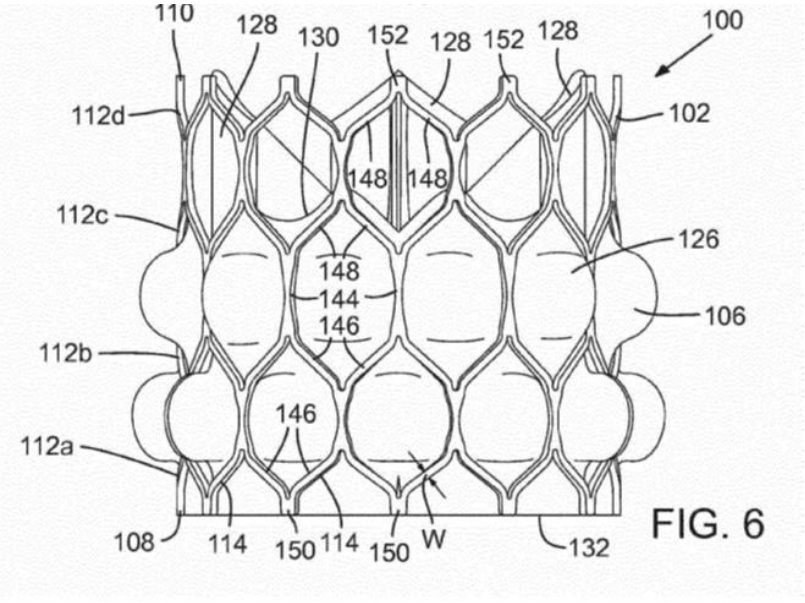


FIG. 6

This claim construction is further in line with the technical understanding as applied by Meril itself in its Indian patent application 202121047196 (IN'196) that was filed on 18 October 2021 (K66).

Reference is made to [00126] of IN'196 that states: "As shown in Figs. 1b-g, the frame 101 of the THV 100 has three circumferentially extending rows of angled struts 10a, 10b, 10c that are interconnected by diamond shaped cells 101c, rhombus bodies 101c' and the commissure areas 101d." This is shown, for example, in Fig. 1c reproduced below.

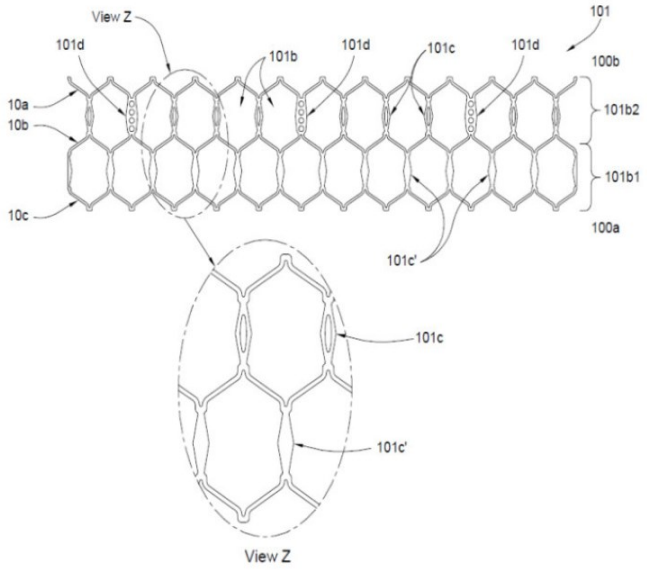


Fig. 1c

Abbildung 53 – Fig 1c. der Patentanmeldung (Anlage K 66)

While the designation of elements 101c, 101c' and 101d was evidently chosen to be in line with Meril's defence strategy in – at the time of filing of IN '196 – potential future patent litigation

relating to the Myvalv Octacor heart valve, a closer evaluation shows that all of these elements actually form side struts within the frame 101 of Fig. 1c.

Elements 101c and 101c' in Fig. 1c above exhibit the same geometry with the only exception that the hole/open space present in the center of 101c is completely filled with material in 101c'. In other words, element 101c' does not comprise an opening and can therefore not possibly be referred to as a rhombic (or diamond) cell.

Element 101c' actually is a side strut the width of which varies to some extent along the flow axis of the frame 101 and the valve. Side strut 101c' furthermore extends in parallel with the flow axis of the valve As was convincingly argued by Edwards in its brief dated 9 January 2024, recital #114 et seq., the crimping behaviours of side strut 101c' and that of element 101c are essentially identical because the frame 101 would otherwise deform upon crimping and would at least be positioned in an obliquely deformed fashion on the balloon of the catheter what would render the implantation of the valve at least very difficult. It can be concluded from this that the hole in element 101c is essentially not compressed upon crimping but maintains its shape.

Therefore it has to be concluded that element 101c also qualifies as a side strut so that the angled side struts 10a, b and c, respectively, and the side struts 101c or 101c', respectively, form hexagonal cells.

The same argument applies with respect to element 101d that is designated as "commissure area" in IN '196. Elements 101d are commissure struts comprising holes for accepting the suturing for anchoring the leaflets wherein the holes maintain their shape upon crimping of the valve. They also qualify as side struts within the meaning of the patent.

As a result, Meril's post-filed and post-published patent application IN '196 supports and is in line with the claim construction outlined above.

2. "Parallel orientation of the side strut relative to the flow axis"

According to claim 1 side struts that form part of a hexagonal cell extend in parallel to a flow axis of the valve, i.e. in the longitudinal direction.

The term "in parallel" must not be understood in a strictly mathematical sense as can be taken from the Figs. that show a slight concave shape. According to para [0039] of EP '825 "the honeycomb structure of the frame …. is less sensitive to variations in strut width …." as was detailed above.

A parallel orientation of a side strut relative to the flow direction/axis of the valve has the technical effects that this alignment with the flow direction is not changed upon crimping. In contrast, if a side strut is arranged obliquely to the flow axis, rotational forces apply to the side strut and change its orientation relative to the flow axis upon crimping.
Accordingly, a parallel orientation of the side strut relative to the flow axis requires that the two end points of the struts be positioned on the longitudinal axis of the valve. It is not required, however, that the thickness of the side strut does not vary along the extension of the side strut in the direction of the flow axis.

This appears to be essentially in line with the declaration of Prof. Buller (K65) who is an expert to Edwards:

43. Exemplary hexagonal shaped cells with these features are illustrated in FIGs. 5 and 6 of the Patent (reproduced above as Figure 4 and Figure 8). The phrase "*extending parallel to the flow axis of the valve*" requires that the two opposing struts must start and finish at locations that are aligned parallel to the flow axis. The Skilled Cardiologist would not however understand this limitation to require that the strut itself is uniform in width. This is illustrated in the exemplary embodiment of FIG. 6 in which the side struts 144 vary in width along their length. It is evident from Figure 6 and Figure 7 above that the hexagonal shaped cells of the frame of the Myval Octacor are made up of six struts and that there are two opposing side struts, lower angled struts and upper angled struts configured in conformity with features 1.2.1 and 1.2.1.1-1.2.1.3 of the Patent.

3. "(hexagonal) cell"

The frame of claim 1 is made up entirely of hexagonal cells that each comprise six struts including two side struts extending in parallel to the axis of low and a pair of upper and lower angled struts, respectively.

The frame has a homogenous pattern of hexagonal cells (see col. 4, lns. 27-31) which means that the

> has what can be referred to as a "homogenous" pattern of hexagonal cells, meaning that the frame is made up entirely of hexagonal cells and does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from the inflow end or outflow end for mounting the frame to a delivery apparatus.

(coll.11, lns 49-55 and features I.4 and III.).

The frame is collapsable and expandable (feature I.1 and col. 4, lns. 23-24) what implies that the cells are collapsable and extendable as well, since the frame is made up entirely of hexagonal cells. The cells comprise pairs of upper and lower angled struts that are pushed towards each other upon compression thereby pivoting around the connection areas (or junctions) and apices 150,152, respectively (see Fig. 6 of the patent at issue). In contrast, the orientation of side struts in parallel to the flow axis is maintained upon compression as was discussed above.

The claim does not exclude that the frame comprises other openings provided that these

(i) do not form cells, i.e. are not collapsible and expendable and
(ii) do not result in the introduction of struts that do not form part of the hexagonal cells.

Examples for this are commissure posts or struts, respectively, that are replacing e.g. side struts in hexagonal cells.

The patent displays a commissure post or strut in Fig. 15 that is not an example according to the claims.

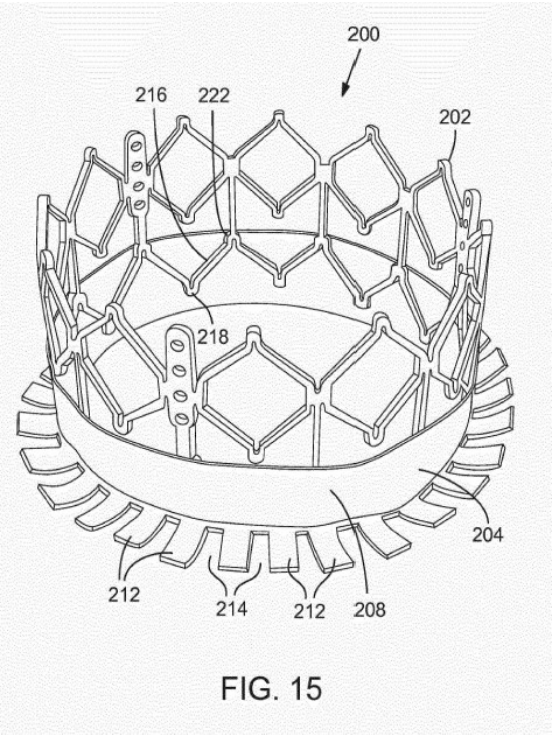


FIG. 15

However, the relevant skilled person knows that commissure posts or struts are commonly used in the art to provide a safe anchoring for the valvular leaflet structure by securing the suturing. The holes in the commissure struts or posts must be stable and must not change their shape upon crimping because they need to safely anchor the leaflets and support/limit their movement. If the holes would change their shape upon e.g. crimping the stability of the suturing might be impaired, and the movement of the leaflets between the closed and open states of the valve, respectively, might become uncontrolled.

This means in other words that the openings or holes in the commissure posts/struts are not collapsible or expandable so that they are not considered as cells. Whether to refer to them as struts or posts, respectively, is a play with words and does not change the technical assessment.

The patent in suit also discloses an alternative anchoring mechanism for the leaflets that is different from commissure posts/struts which employs commissure securement portions that attach the leaflets directly to the frame:

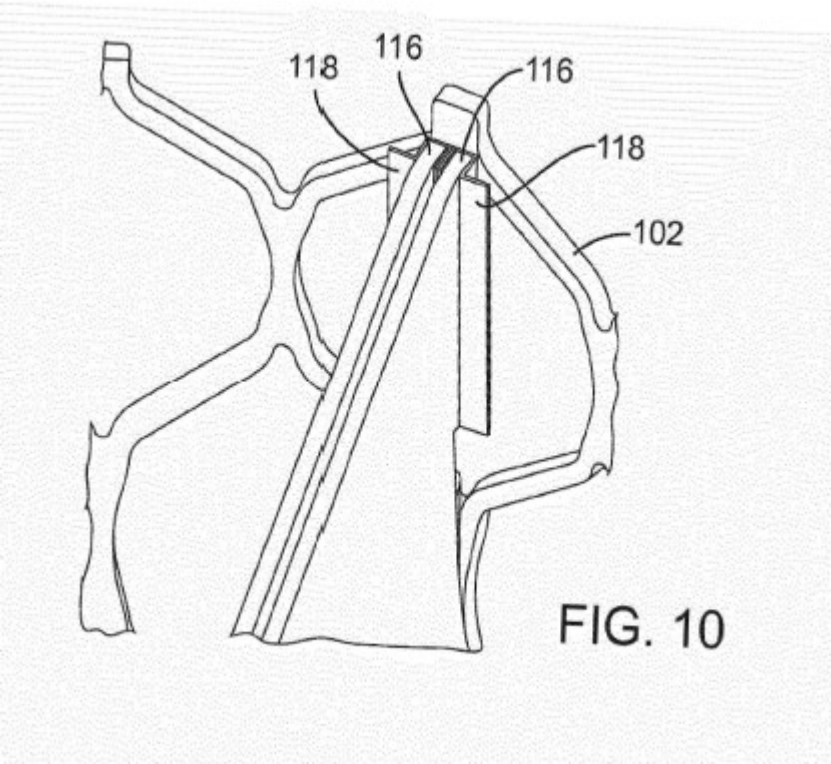


FIG. 10

It cannot be concluded from this that EP ‘825 is restricted to this specific anchoring mechanism because it is not comprised in the main claim.

D. Request to stay pending the appeal decision

The request for re-scheduling or for a stay pending the appeal decision is rejected.

I. Meril argued that their right to be heard had been infringed by the CDP as some of their main invalidity arguments were not mentioned in the written decision and that because of these arguments the patent will be revoked on appeal.

II. In accordance with Article 32(3b) of the UPCA, a referral of the counterclaim for revocation to the central division and a continuation of the action for infringement may be made following a decision to this effect. Once the central division has delivered its ruling and upheld the patent in an amended form, a stay of the action for infringement may be based exclusively on R. 295(c)(i) or (m) RoP.

1. R. 295(e), R. 37.4 RoP mentioned by Edwards are not applicable.

According to R 37.4 RoP the panel – after the panel decided to proceed in accordance with Article 33(3)(b) of the Agreement - may stay the infringement proceedings pending a final decision in the revocation proceedings and shall stay the infringement proceedings where there is a high likelihood that the relevant claims of the patent will be held to be invalid on any ground by the final decision in the revocation proceedings.

With order dated 28 March 2024 (ORD_1340/2024) the panel already decided to proceed with the infringement action.

Irrespective from that there is no high likelihood that the relevant claims of the patent will be held invalid on any ground by the final decision in the revocation proceedings as the CDP has upheld the patent in the form of auxiliary request II and this panel concludes that this decision is correct. Reference is made to the reasoning below in the context of R 295.m RoP.

2. R. 295(c)(i) RoP, R. 295(m) RoP.

According to R 295(c)(i) RoP the court may stay proceedings where an appeal is brought before the Court of Appeal against a decision or order of the Court of First Instance disposing of the substantive issues in part only. According to R 295(m) the court may stay in any other case where the proper administration of justice so requires.

In both instances, the court is at liberty to exercise its discretion as to or not to grant a stay, respectively. In the context of a prior bifurcation decision where the patent had been upheld, the possibility of a stay is limited to instances where there are mitigating circumstances. This is because the agreement explicitly stipulates the possibility for a local or regional division to bifurcate and to stay or not to stay the action for infringement, respectively. Consequently, a decision on the infringement action can be rendered prior to the central division's resolution of the referred counterclaim. After a decision by the central division on the counterclaim referred to it, the local or regional division is required to proceed with the next case management step which regularly is a decision on the action for infringement. There are only a few instances in which one might deviate from this default next case management step. These instances occur when the aggrieved party can demonstrate that the decision made by the central division is manifestly and prima facie erroneous in a formal and/or material way.

These requirements have not been met here.

III. Not erroneous on a formal point

Meril was unable to demonstrate that the decision by the CDP was manifestly and prima facie erroneous in a formal sense. Meril's assertions that the CDP decision would have disposed of the substantial issues in part only, are erroneous and constitute a misrepresentation (R 284 RoP).

1. Oral hearing at the CDP

It is beyond dispute that the arguments in question were indeed discussed during the oral hearing in Paris.

2. Written decision by the CDP

The arguments in question, which were purported to be absent, are in fact to be found in the written decision. Accordingly, the decision of the CDP is consistent with the stipulations set forth in R 350.4 RoP.

a. Meril`s allegations

Meril refers to five issues discussed on pp. 7-10 of its brief dated 23 August 2024 filed in its application for a stay (App_48488/2024). Additionally, Meril refers to allegedly not addressed arguments discussed by Meril IT (not a party to the infringement proceedings) in its appeal against the CDP decision (bottom of p.22 of said brief of 23 August 2024). Meril argues that this is a violation of the right to be heard (Arts. 56(2) and 76(2) UPCA) in a manner relevant for the decision of the CDP. The CDP would have violated the fundamental right of a fair trial.

b. Assessment of the allegations

It will be shown below that the arguments that Meril alleges were not addressed by the CDP, were actually considered in the decision. This assessment is performed on the basis of AR II as maintained by the CDP. To facilitate the cross-reference to Meril's request of stay, the same headings as used by Meril in its application are applied here, as well.

aa. Omission of a sealing device not discussed

(1) Meril argues that the decision of the CDP does not address the omission of the feature of a sealing device (skirt) in the main claim of AR II. This would represent added matter (intermediate generalisation) which when properly considered would have resulted in a revocation of EP '825.

(2) This is not correct. The issue has rather been addressed at various passages of the decision:

> • Para 52: "In particular, WO '801 purportedly also .... mentions the presence of a sealing device inside the frame ...."
> • Para 69: "The panel notes that para [013] of WO '801, which forms the basis of claim 1, ..."
> • Para 71: "Since the ground of invalidity concerning the violations of Articles 76(1) and 123(2) EPC is upheld, it is unnecessary to examine the other grounds of invalidity raised with regard to the patent as unconditionally amended".

• Para 96: “This panel first points out that P1[1]does not include the equivalent of para. [013] of EP ‘825. “
• Para 97: in P1 “... the presence of a leaflet structure and a sealing device is mandatory, not optional, as confirmed by Fig. 3-7.”

It is clear from this that the attack of added matter according to Art. 123(2) EPC purportedly resulting from the omission of the feature of a sealing device was addressed in the decision of the CDP.

The Paris panel addressed this in terms of the validity of the priority claim. It concluded that ARII did not validly claim the priority of P1 (US 2011/61/508,456) because it does not comprise the equivalence of [013] of WO ‘801, i.e. P1does not disclose a valve without a sealing device. Therefore, P1 could only rely in terms of the priority claim on the disclosure of its Figs. 3-7 of P1. All these Figs. show heart valves comprising sealing devices so that the priority claim relative to P1 was not accepted by the CDP. If P1 had comprised the equivalence of [013] the priority claim would likely have been acknowledged.

It is therefore implicitly clear in the decision that the feature of a sealing skirt could be omitted in the patent at issue because claim 1 of AR II is based on [013] of WO ’801 (=grandparent to EP ’825). This paragraph does not require the presence of a sealing device (nor the presence of a valvular structure as is extensively discussed in the decision).

The Munich panel furthermore believes that it is unlikely (and at least not highly likely) that the CoA will come to a different assessment of this issue thereby turning around the decision of the CDP. As was already mentioned above claim 1 of AR II is based on the disclosure of [013] of WO ‘801 that does not require the presence of a sealing device. Also, the features of an all-hexagon structure of the frame and the presence of a sealing device are not inextricably linked.

bb. Lack of novelty in light of embodiment 2 of Levi (Figures 44/45) not discussed

(1) Meril argues that the decision of the CDP does not address the novelty attack based on Fig.’s 44 and 45 of Levi. The decision allegedly only addressed the attack based on Fig. 5 of Levi. Meril refers in this regard to section H.I.2 of its CC for revocation and section F.I.2 of its reply to the defence to the CC for revocation. Meril submits that the novelty attack based on Fig.’s 44 and 45 of Levi if considered would have rendered ARII invalid.

(2) This is not correct.

(i) Firstly, and most importantly, the differentiation between Fig. 5 of Levi on the one hand and Figs. 44 and 45 of Levi on the other hand is artificial and technically not justified.

Meril discusses on pp. 48 et seq. of its reply to Edwards’ defence to the CC for revocation an expert opinion by Edwards’ patent attorney Leo Jenssen filed in an infringement action in the Netherlands relating to EP 3,494,928 (HLNK 40).

The Jessen opinion and its coverage in the decision of the PCD will be discussed in section cc. below in detail.

In terms of the alleged differentiation between Figs. 5 and 44 and 45 of Levi reference is made to the following passage on p. 49 of Meril’s reply to the defence against the counterclaim:

[1] P1 is priority document US 2011/61/508,456 having an effective date of 15 July 2011

> (3) Da Figur 5 von Levi eine ähnliche Zellgeometrie wie Figur 45 von Levi aufweist, belegt dies noch einmal mehr, dass es sich bei allen Zellen des Rahmens in Figur 45 von Levi ebenso um hexagonale Zellen mit kurzen Seitenstreben handelt, er also vollständig aus hexagonalen Zellen besteht.
>
> 4. Die Ausführungsformen aus den Figuren 44 und 45 sowie aus den Figuren 1 bis 10 aus Levi nehmen damit den Gegenstand des Anspruchs 1 neuheitsschädlich vorweg.

This passage clearly states that (i) the cell geometries of Figs. 5 and 45 of Levi are similar, and that (ii) the embodiments of Figs. 1-10 and 44-45 of Levi would all be novelty destroying for the subject matter of claim of the disputed patent EP 825.

Meril has not disputed that a novelty attack based on Fig.5 of Levi was addressed in the decision. In view of the similarities of the cell geometries displayed in the embodiments of Figs. 1-10 and 44-45 of Levi the arguments provided in terms of the Fig.5 embodiment simply apply to the embodiments of Figs. 44 and 45, as well. Hence, a novelty attack based on Fig. 45 of Levi is comprised in the decision of the CDP.

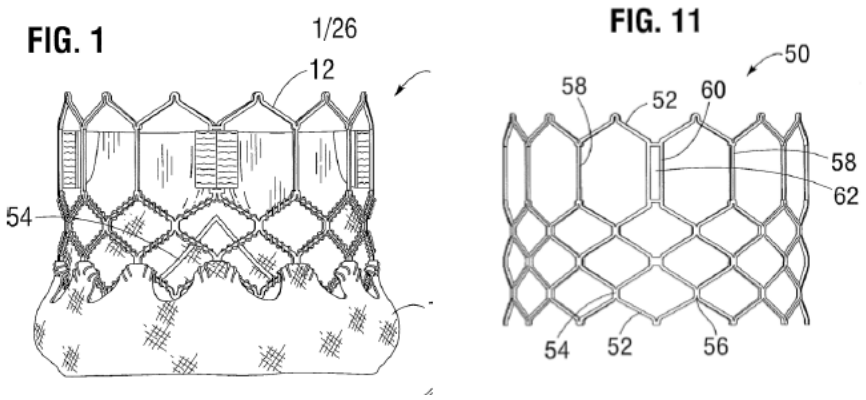
(ii) Secondly, the alleged novelty of ARII in view of Levi is broadly discussed in paras 99 -106 of the decision of the CDP as follows:

- Para 100 of the decision summarizes the novelty attack based on Levi by stating: “The claimant argues that ‘Levi’ discloses all features of claim 1 of auxiliary request II of the patent at issue, in particular, a prosthetic heart valve which includes a collapsible and expandable annular frame .... , where the frame comprises a plurality of angled struts and these angled struts are joined to each other ..... to form hexagonal cells so that the frame only comprises hexagonal cells. The frame disclosed in Fig. 5, for example, ...” (emphasis added).
- The position of the defendant is summarized in para 101: “The defendant denies that ‘Levi’ discloses a frame that is made up entirely of hexagonal cells, pointing out that, as evident from the drawings, ... the cells of the two intermediate rows are each defined by four struts, forming diamond shaped cells.”
- The decision continues by construing the feature of “the frame being made up entirely of hexagonal cells” of the patent at issue EP ‘825 (paras 102 and 103).
- In view of this it is stated in para: 104:

> 104. The wording of ‘Levi’'s claims and description does not disclose this feature. Additionally, contrary to the claimant's argument, the drawings are not conclusive. In fact, they show a distinction between hexagonal cells with side struts and cells without side struts (rhombic or diamond-shape cells) in which the connections between lateral portions must be considered welding nodes and do not consist of separate struts.

This is illustrated by reference to Fig.’s 1 and 11 of Levi in para 105 of the decision as follows:

105. It follows that it is not possible to assert that 'Levi' discloses a prosthetic heart valve with a valve made entirely of hexagonal cells.



- 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). It is stated:

106. The claimant relies on an opinion delivered by Mr. Leo Jessen (Gide 48) in a different judicial proceeding related to a patent of the same family (EP '928). Mr. Jessen reportedly stated that a skilled person would consider the intermediate rows to be hexagonal cells, not diamond-shaped. However, for the reasons explained above, this opinion is not convincing and fails to sustain the claimant's ground of invalidity.

The Paris panel was aware that Levi disclosed a number of frame geometries such as those shown in Fig.'s 1 and 11 that are reproduced in para 105 of the decision.

This is underlined by the summary of claimant's attack in para 100 of the decision which refers to the ".... frame disclosed in Fig. 5, for example, ..." (emphasis added). This implies that the line of arguments specified in the decision in an exemplary fashion for Fig. 5 does likewise apply for the frame geometries shown in Figs. 1-4, 6-10, 44 and 45 of Levi.

The decision concludes in para 104 by way of a summary that all Figs. of Levi "...show a distinction between hexagonal cells with side struts and cells without side struts (rhombic or diamond-shaped cells) in which the connections between lateral portions must be considered welding nodes and do not consist of separate struts."

In view of that the novelty attack based on Fig.'s 44 and 45 of Levi was clearly considered and addressed in the decision of the CDP.

(iii) Meril entirely relies on the Figs. of Levi and ignores that Levi clearly distinguishes between cells that comprise side struts or angularly extending struts (31, 34 in Fig.5) on the one hand and nodes and connection portions (54,56 in Fig. 11) on the other hand. In other words, Levi clearly distinguishes between cells that comprise side struts/axially extending struts that are hexagonal in shape and cells that do not have side struts and are rhombic or diamond-shaped, respectively.

Meril uses enlarged details of the frames coloured (i.e. changed) in a somewhat suggestive way to extract structural information from the Figs. that is not in line with the disclosure of the specification.

When comparing annotated and marked Fig. 5 of Levi

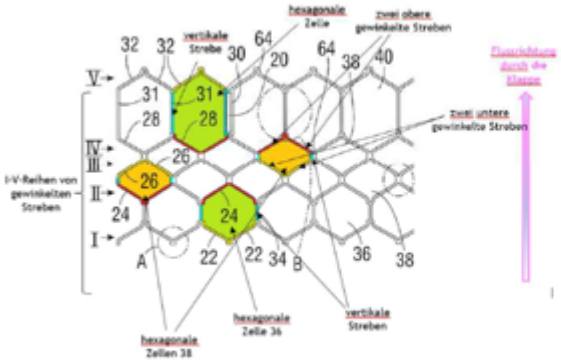


Abbildung 52 - Fig. 5 von Levi

Abbildung 53 – Fig. 5 von Levi

with annotated and marked Fig. 45 of Levi (both sets of Fig.'s taken from Meril's CC for revocation)

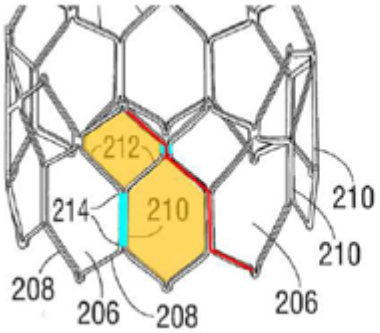


Abbildung 46: Versetzte gewinkelte Streben: Sie verlaufen nicht auf einer Linie.

Abbildung 44 – Fig. 45 von Levi

it is evident that they both show hexagonal cells and rhombic cells and are not novelty-destroying. The differentiation between Fig.5 of Levi on the one hand and Fig.'s 44 and 45 is artificial and made up. In other words, Fig.'s 44 and 45 of Levi do not add anything to what had been alleged by Meril in relation, for example, to Fig. 5 of Levi.

(iv) This is also acknowledged by Meril itself (see, e.g., p. 49 of the reply to the defence against the CC for revocation).

> (3) Da Figur 5 von Levi eine ähnliche Zellgeometrie wie Figur 45 von Levi aufweist, belegt dies noch einmal mehr, dass es sich bei allen Zellen des Rahmens in Figur 45 von Levi ebenso um hexagonale Zellen mit kurzen Seitenstreben handelt, er also vollständig aus hexagonalen Zellen besteht.
>
> 4. Die Ausführungsformen aus den Figuren 44 und 45 sowie aus den Figuren 1 bis 10 aus Levi nehmen damit den Gegenstand des Anspruchs 1 neuheitsschädlich vorweg.

As a result, it must be concluded that the decision of the CDP considering Levi as a whole as not novelty-destroying is correct and will hold water also in the appeal proceedings.

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.

cc. Lack of novelty discussion fails to take account of Fig.'s 1 and 3 of EP '825

(1) Meril argues that the claim construction applied in the CDP decision is incorrect. The connections between the upper and lower pairs of angled struts shown in Fig.'s 1 and 3 of the disputed patent EP '825 would not be connection areas such as welding nodes but side struts. There would be no limitation as to the length of the side struts in EP '825. Fig.'s 1 and 3 of the disputed patent would thus be all-hexagonal and would be covered by claim 1 of AR II.

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

(1) So hat sich die Klägerin im Verletzungsverfahren in den Niederlanden auf der betreffend EP 3 494 928 B1 Äußerungen ihres Patentanwalts (Leo Jenssen) (welche eine auf Levi basierende Teilanmeldung ist) zu eigen gemacht, der erklärte, dass die Zellen des Rahmens von Figur 5, die den Zellen des Rahmens von Figur 44 identisch sind, hexagonale Zellen seien. Das entsprechende Sachverständigengutachten des Herrn Leo Jessen wurde bereits als Anlage HLNK 40 vorgelegt.

(2) Zur Untermauerung dieses Verständnisses blenden wir die nachfolgende Abbildung (dem Original aus dem Gutachten nachgebildet) ein, in der die sechs Ecken des Hexagons in der mittleren Reihe von Figur 5 aus Levi markiert wurden.

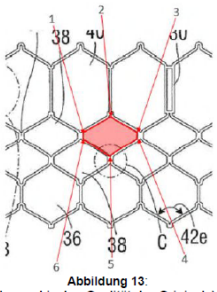


Abbildung 13:
Nachbildung (mangels graphischer Qualität des Originals) einer Abbildung des Sachverständigengutachtens der hiesigen Klägerin und Patentinhaberin (Anlage HLNK 40)

(3) Da Figur 5 von Levi eine ähnliche Zellgeometrie wie Figur 45 von Levi aufweist, belegt dies noch einmal mehr, dass es sich bei allen Zellen des Rahmens in Figur 45 von Levi ebenso um hexagonale Zellen mit kurzen Seitenstreben handelt, er also vollständig aus hexagonalen Zellen besteht.

4. Die Ausführungsformen aus den Figuren 44 und 45 sowie aus den Figuren 1 bis 10 aus Levi nehmen damit den Gegenstand des Anspruchs 1 neuheitsschädlich vorweg.

(pp. 48-49 of Meril's reply to the defence against the CC for revocation).

Meril submits that in view of the above Figs. 1-10 and Figs. 44-45 of Levi would be novelty destroying for AR II of EP'825.

Meril submits that the novelty attack based on Figs. 1 and 3 of EP '825 if considered would have rendered ARII invalid.

(2) This is not correct as is already shown above.

The disputed decision of the CDP provides both a construction of term 'strut' in claim 1 of EP '825 (see para 43) and it also explicitly discusses the Jessen opinion in para 106 of the decision:

106. The claimant relies on an opinion delivered by Mr. Leo Jessen (Gide 48) in a different judicial proceeding related to a patent of the same family (EP '928). Mr. Jessen reportedly stated that a skilled person would consider the intermediate rows to be hexagonal cells, not diamond-shaped. However, for the reasons explained above, this opinion is not convincing and fails to sustain the claimant's ground of invalidity.

The novelty attack based on Fig. 5 of Levi is also discussed in detailed (paras 103 – 105 of the CDP decision).

EP '825 discloses various embodiments. The embodiment disclosed in [013] of WO '801 (= [014] of EP '825) in conjunction with Figs. 5-9 and the corresponding disclosure that is claimed in EP '825 is separate from the embodiment displayed in Figs. 1 – 3, for example.

As was discussed above with respect to Levi the embodiments of Figs. 1 and 3 of EP'825 disclose rhombic cells rather than hexagonal cells and are not subject matter of the claims of EP'825 as maintained.

The Munich panel believes that this assessment will hold water in the appeal proceeding.

dd. Obviousness of subject matter of claim 1 of EP '825 in accordance with AR II attack starting from embodiment 2 (Fig.'s 44 and 45) of Levi not discussed

(1) Meril alleges that its inventive step attack based on Figs. 44 and 45 would not have been addressed by the decision of the CDP, neither in combination with Fontaine nor based on these Figs. alone.

Meril refers in that regard e.g. to section C.VIII.2 of the rejoinder to the application to amend.

Meril submits that the inventive step attack based on Figs. 44 and 45 of Levi alone or in combination with Fontaine, respectively, would have rendered ARII invalid.

(2) This is not correct.

The decision of the CDP provides an extensive discussion of inventive step attacks based on "hexagonal cells in heart valves (paras 129-138)" alone and in combination with "hexagonal cells in stents" (paras 139 -152) and in particular the Fontaine reference, respectively.

(i) Inventive step attacks based on the heart valve references cited alone

Meril's (the claimant's and counterclaimants') position relative to inventive step attacks based on the heart valve art alone, is clearly summarized and addressed in the decision of the CDP The CDP refers to these attacks in general because the arguments are essentially the same for any of the heart valve references cited. Therefor these statements are not restricted to Levi, let alone a specific embodiment of Levi.

131. Both the claimant and the counterclaimants argue that using a frame geometry exclusively made of hexagonal cells would have been an obvious alternative based on the established prior art demonstrating that hexagonal cells had already been used in heart valves and that it would be a mere design choice to extend the length of the side struts (or rather connection portions) without requiring any inventive step. The prior art would sufficiently motivate this approach because it would have been known that hexagonal cells have a low foreshortening and provide a low crimping profile.

Reference is also made to a number of expert opinions that are considered as not convincing:

137. The counterclaimants rely on the expert opinion provided by Prof. Solar (HLNK 38), Prof. Dasi (HLNK 38a) and Prof. Brecker (HLNK 38b). However, these declarations do not appear conclusive, as they fail to convincingly demonstrate that it would be obvious for a person skilled in the art to achieve a favourable crimping profile of the frame by making this frame entirely of hexagonal cells.

The decision concludes in para 138:

138. In conclusion, the prior art teachings on heart valves and, in particular, concerning the structure of the frame do not provide any motivation to alter the shape of (some of) the cells to an all-hexagonal configuration.

It can be taken from this that the decision of the CDP discusses the inventive step attacks based on the heart valve art alone in a general and summary fashion because the arguments provided apply to the heart valve references cited in general.

It is therefore not correct that the decision would only discuss inventive step based on Fig. 5 of Levi but not based on Figs. 44 and 45 of Levi, respectively.

Meril argued in the rejoinder to the reply to the CC for revocation that the person skilled in the art would be motivated to change both embodiments to an all-hexagon cell configuration because the person skilled in the art had sufficient motivation to extend the nodes of the rhombic cells to side struts (see pp. 74-75).

This is illustrated by Meril in the following figures that were taken from this passage:

(3) Die routinemäßige Verlängerung der Seitenelemente und die daraus natürlich folgende hexagonale Zellstruktur wird in der nachfolgenden Abbildung veranschaulicht:

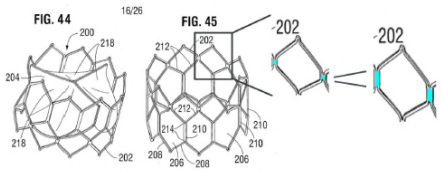


Abbildung 28:
(von links nach rechts) Figuren 44 und 45 aus Levi; Lupenansicht der Seitenstreben im Hexagon (blau eingefärbt) in Figur 45; bearbeitete verlängerte Seitenstreben des Hexagons (blau eingefärbt, so nicht in Levi dargestellt)

(4) Anhand einer konnotierten Abbildung der Figur 5 von Levi lässt sich dies wie folgt darstellen:

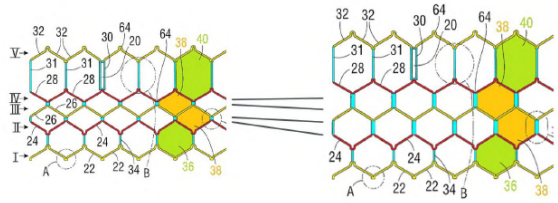


Abbildung 29:
(von links nach rechts) kolorierte Figur 5 von Levi (blaue Seitenstreben und grüne und gelbe Hexagone); bearbeitete verlängerte mittlere Seitenstreben (blaue Seitenstreben und grüne und gelbe Hexagone; so nicht in Levi dargestellt)

Der Fachmann hätte auch einen konkreten Anlass aus Levi gehabt, die Seitenelemente zu verlängern.

It can be seen that Meril argues with respect both to Figs. 44 and 45 of Levi on the on hand and Fig. 5 of Levi on the other hand that the rhombic cells can simply be converted to hexagonal cells by making the connection areas (nodes) somewhat longer.

However, as was already pointed out above Figs. 5 and 44/45 of Levi disclose the same rhombic cells and a very similar frame structure so that the differentiation between these figures is artificial and made up and not in line with the general assessment of the heart valve art provided in the decision..

(ii) Inventive step attacks based on a combination of the heart valve references with Fontaine

While the decision of the CDP acknowledges that a combination of valve references with stent references of the prior art is generally permissible it requires a strong motivation to consider such combination (para 142 of the decision). The CDP decision concluded that a combination of any heart valve reference with the Fontaine reference would not be considered by the person skilled in the art in view of the properties of the Fontaine stent (see paras 147-149 of the decision). These considerations apply to a combination of any heart valve references with Fontaine and are not restricted to the embodiment of Fig. 5 of Levi.

ee. Obviousness of subject matter of claim 1 of EP ‘825 in accordance with AR II based on Alon in Combination with Fontaine not discussed

(1) Meril alleges that the decision of the CDP did not address the inventive step attack based on a combination of Alon and Fontaine relative to AR II although it could be taken from the minutes of the decision of the BoA revoking the sister patent EP ‘920 in its entirety that such combination was assessed as highly relevant by the BoA with respect to inventive step of a set of claims very similar to AR II in the present proceedings.

Meril submits that if such attack would have been considered EP ‘825 would have been nullified in its entirety.

(2) This is not correct.

It is acknowledged by Meril that Alon was explicitly referred to in the inventive step discussion of the CDP decision:

> 121. The counterclaimants contend that the patent at issue also lacks inventive step citing the prosthetic ‘Colibri’ heart valve and US ‘313 (‘Alon’).

The inventive step section of the CDP decision that relates to heart valve references (paras 129 – 138) comprises statements referring to heart valves in general and not just to Levi:

> 132. As previously indicated, frames of heart valves that comprise hexagonal cells were disclosed at the time of the application of the patent at issue but were only used in combination with (intermediate) rhombic cells.
>
> 133. However, the mere use of hexagonal cells in the frame of heart valves does not lead to the conclusion that for the person skilled in the art it would be obvious to employ a frame entirely made of hexagonal cells to address the problem of reducing the crimping profile of a

The reasoning provided in paras 134-137 discusses these statements particularly in terms of Levi but also refers to broader expert opinions (HLNK 38-38b).

As a result, the CDP decision provides a general statement that refers to prior art valve references in general and thus also to Alon:

> 138. In conclusion, the prior art teachings on heart valves and, in particular, concerning the structure of the frame do not provide any motivation to alter the shape of (some of) the cells to an all-hexagonal configuration.

Likewise, in the section of the CDP decision relating to the Fontaine reference (paras 139 - 152), the decision sets out that a combination of valve references with stent references is possible but requires careful consideration:

> 142. In view of this, despite the significant evolution of TAVRs and the distinct requirements for crimping on a balloon of a delivery device and deployment at the implantation site within the heart, which differentiate TAVRs from stents as separate fields, the person skilled in the art would be aware of the vascular stent prior art. This includes in particular familiarity with the relevant references and commercial products in the stent field. However, such person would always bear in mind that stents and heart valves are very different devices with very different requirement profiles. Therefore, a reference to the prior art in the stent field would require careful consideration and a strong motivation for application to heart valve technology.

It is obvious that this section is not specific to Levi but relates to valve references in general.

The decision goes on to discuss Fontaine in detail and concludes that due to the properties of the Fontaine stent it would not have been combined with any heart valve reference; see, in particular:

> 147. In fact, the Fontaine stent exhibits high flexibly, in particular in the partially expanded state (Fig. 7), allowing for "an almost 180° bend" (page 31). Such flexibility is not required for heart valves which are introduced through the femoral artery and would in fact be considered disadvantageous because high flexibility may impede a safe anchoring of the valve in the aortic annulus.
>
> 148. Furthermore, radial strength plays different roles in vascular stents and in aortic valves: in the former devices, it fulfils the technical function of maintaining the opening of the vessel and preventing restenosis, while in the latter, it ensures tight closure and prevents blood reflux. Therefore, achieving a very high radial strength, which in the Fontaine stent is obtained upon full expansion of the stent so that the hexagonal cells "assume a boxlike configuration, with two vertical and two nearly horizontal struts (Fig. 6)", would be undesirable for heart valves as it might damage the valve's leaflet structure and prevent the device from properly fulfilling its function. Hence, Fontaine's article demonstrates how the honeycomb pattern allows for an increase in the device's capability to maintain the opening of the vessel, but there is no indication – neither in this document nor in the prior art – of whether the teaching is also applicable to heart valves.

This reasoning thus also covers the combination of Alon and Fontaine.

(3) It is noted that Meril submitted at the IC held on September 5 that the inventive attack based on Alon had been central to and fundamentally important for its case.

However, the Alon reference was not cited in the CC for revocation relative to the main claim of the requests at all but only in its reply to the defence to the counterclaim. It therefor is a new attack.

Meril referred in that regard to a decision of the BoA of the EPO revoking EP ‘920 in its entirety based on inadmissible broadening that was issued in December 2023. It can be taken from the minutes of the oral hearing that an auxiliary request similar to the AR II in the present proceedings, had been discussed during oral proceedings before the BoA. The BoA had indicated that a combination of Alon, Fontaine and a 3rd reference disclosing the MP35N material (alloy) of the frame might render obvious said auxiliary request without giving any reasons for that. Since Edwards withdrew all auxiliary requests on file and maintained only the main request the patent was revoked because of an inadmissible broadening of claim 1 of the main request.

In view of the BoA’s decision Meril completely switched horses and cited Alon as a major reference in its reply to the CC for revocation for the first time.

(4) Irrespective of that the Munich panel notes that an inventive step attack based on a combination of Alon with Fontaine is unlikely to overturn the CDP decision on appeal.

It should be noted that Alon does not disclose the specific alloy claimed in claim 1 of AR II so that an inventive step attack would need to combine 3 references (Alon plus Fontaine plus a 3rd reference for the alloy) to render claim 1 of AR II obvious.

This is usually not permissible unless the claim is based on partial objects (what is not suggested by the BoA and not the case here anyway because both the geometry and the specific material contribute to the advantageous properties of the claimed frame structure) or the material chosen is based on CGK.

Meril IT cited an overview paper (Gide 38) in that regard that states in section 16, Conclusion:

stent before use. New alloys and materials are likely to take over from stainless steel, allowing further optimisation of physical parameters with thinner strut and stent profiles.

This statement suggests that the use of new alloys including alloys of Co, Cr and Ni is still under investigation and no secure knowledge (no CGK) that would be directly applied by the person skilled in the art without any further ado and without any further investigations or modifications being required.

ff. Objections raised by Meril IT (not a party to the infringement proceedings)

(1) Meril briefly referred to objections raised by Meril IT in its appeal alleging that the following issues would not have been addressed by the decision of the CDP:

- lack of novelty in light of Levi's embodiment two as shown in Figure 44/45 of Levi (Exhibit HLNK 39, submitted as Exhibit Gide 47 in the central revocation proceedings by Meril Italy S.r.l.) (see mn. 23, p. 9 of Exhibit HL-Stay 3), and

- lack of inventive step starting from DiMatteo (Exhibit HLNK 32 in the counterclaim proceedings, submitted as Exhibit Gide 54 in the central revocation proceedings by Meril Italy S.r.l.) which was, instead, considered and assessed as a novelty attack by the Paris Central Division (see mn. 23, p. 9 of Exhibit HL-Stay 3).

(2) The first attack has already been addressed above.

(3) It is correct that the decision of CDP relates to a novelty attack based on DiMatteo raised by the Meril parties in the CC for revocation:

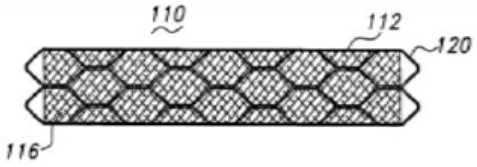
Auxiliary request II: lack of novelty in view of 'Dimatteo'.

111. 'Dimatteo' (Gide 54) is a patent application which discloses an invention in "the field of implantable prostheses. More specifically, the present invention relates to implantable prosthetic cardiac, aortic, and venous valves" (page 1, lines 3-4).

112. The claimant relies on the description contained in page 22, lines 24-26 and on Figs. 18-21, that depict an embodiment "in which the valve leafs of an implantable prosthetic valve 110 are attached to the interior lumenal surface 114 of a second radially collapsible tubular fluid conduit 112" and, therefore, disclose a collapsible and expandable frame. The claimant adds that in 'Dimatteo' the frame may be formed to permit radial expansion at a desired location by a delivery balloon. Furthermore, the claimant points out that 'DiMatteo' discloses feature (1.5), as each cell has a hexagonal shape.

113. The panel considers that a person skilled in the art would understand that 'Dimatteo' discloses two embodiments, depicted in Figs. 1-21 and Figs. 22-29, respectively. The first embodiment (and the related drawings), referred to by the claimant, discloses a venous valve rather than a heart valve. This can be inferred from page 22, lines 27-28 where it is stated that the "[S]econd conduit 112 further maintains the patency of the body lumen to either side of the valve ….". Also, the size of the second conduit and the arrangement of the leaflets 40 within the conduit support the view that the prosthetic valve shown is designed for venous valve replacement. Therefore, it would be unsuitable for the purpose of replacing a heart valve, as asserted by the defendant (see para. 226 of the defence to revocation).

FIG 18



114. The claimant argues that a person skilled in the art would consider the device of Figs. 18-20 to be a prosthetic heart valve and supports this argument by referring to the declaration of Prof. Stephen Brecker (Gide 74). However, this evidence is not convincing.

115. Moreover, 'Dimatteo' does not disclose the nickel-cobalt-chromium-molybdenum alloy as a frame material (as required in claim 1 of auxiliary request II), nor does it offer any information in this regard.

DiMatteo was discussed in detail in the novelty discussion. Based on that it is clear that DiMatteo is not a good starting point for an inventive step attack and that such attack is of minor relevance.

(4) Also, the general points referred to in the consideration of Alon for an inventive step attack apply here likewise.

(5) The decision also comprises a broad salvatory clause relative to arguments that were not specifically addressed.

156. For these reasons, the grounds of invalidity raised by both the claimant and the counterclaimants against the patent at issue, as amended by the auxiliary request II submitted on 12 April 2024, are unfounded and any arguments of the parties which have not been specifically addressed must be deemed absorbed.

While it is acknowledged that such a broad salvatory clause cannot overcome any failure to address major and likely relevant arguments this panel believes that it supports the notion that the decision by the CDP must be read with a mind willing to understand. Thus, arguments that are addressed implicitly are meant to and are in fact covered by the decision, as well.

IV. Not erroneous on a material point

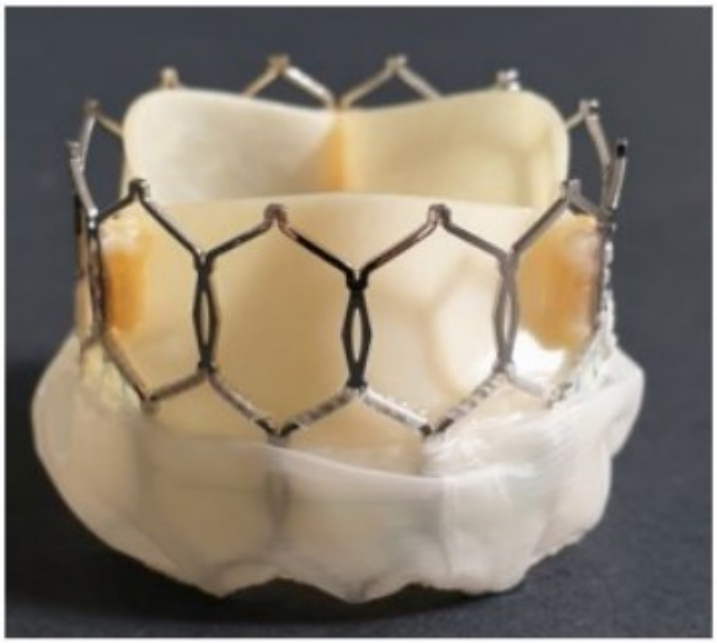
Meril further failed to demonstrate that the decision by the CDP is manifestly and prima facie erroneous in a material way. Indeed, the panel has reached the conclusion that the patent will not be revoked on appeal. This panel concurs with the reasoning put forth by the CDP. In this context, the decision by the CDP and the above additional explanations are referenced.

E. Infringement

The attacked embodiment makes direct literal use of claims 1, 2, 4 and 5 of the patent at issue as upheld by the CDP.

I. Attacked embodiments

The subject matter of the proceedings, as defined by the claims and the reasons brought forward in the statement of claim, concerns a transcatheter heart valve prosthesis and a delivery apparatus that makes use of claims 1, 2, 4 and 5 of the patent which was upheld by the CDP. In particular, the subject matter concerns a transcatheter heart valve prosthesis with the designation "Myval Octacor", as shown below.



and

a delivery apparatus of the type "Navigator" and/or "Navigator Inception" as shown below

"Navigator"

"Navigator Inception"[1]

II. Infringement of Claim 1

The purported differences in the attacked embodiment do not preclude a conclusion of literal infringement in view of the aforementioned claim construction.

1. Commissure posts/struts

In the Myval Octacor valve part of the side struts are replaced with commissure posts/struts. This can be seen, e.g., from Fig. 39 shown on p. 68 of the statement of claim in Edwards' infringement action.

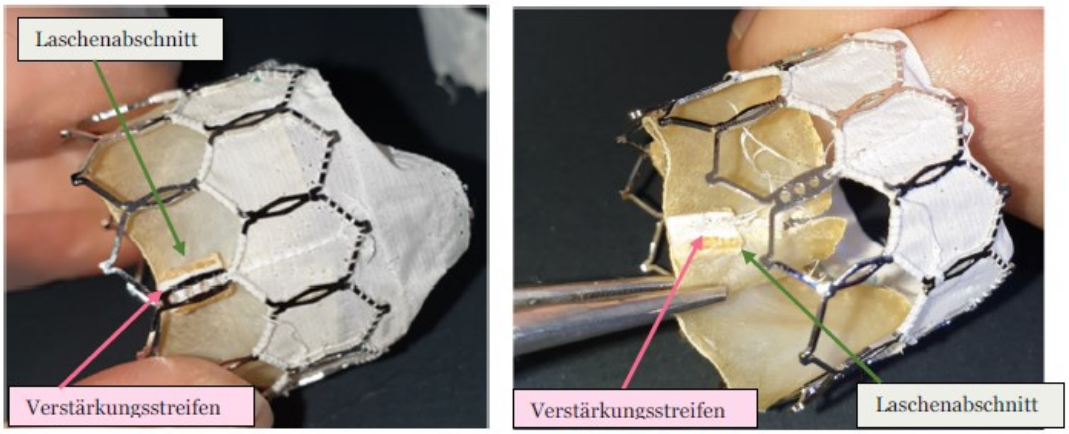


Abbildung 39 – Abbildungen der Verletzungsform (Markierungen hinzugefügt)

The commissure post/(strut) thus functions as

(i) a side strut and
(ii) as a commissure device that is used to safely anchor the leaflets to the frame.

It can be concluded that the frame does not comprise struts other than those forming the hexagonal cells (feature III of claim 1).

2. The Cells of the "Myval Octacor" heart valve behave like hexagonal cells.

The below Fig.'s 56 and 57 are taken from pp. 65 - 66 of Edwards' reply to Meril's defence against the infringement action.

Fig. 56 shows that the "rhombic cells" of the Myval Octacor heart valve are not compressed in the crimped state. This means that the openings do not represent cells as would be

required if the design would be understood as being made of octagonal cells that overlap to form rhombic cells in the overlapping area.

The crimping behaviour of the side elements is that of unitary side struts that comprise a non-compressible opening.

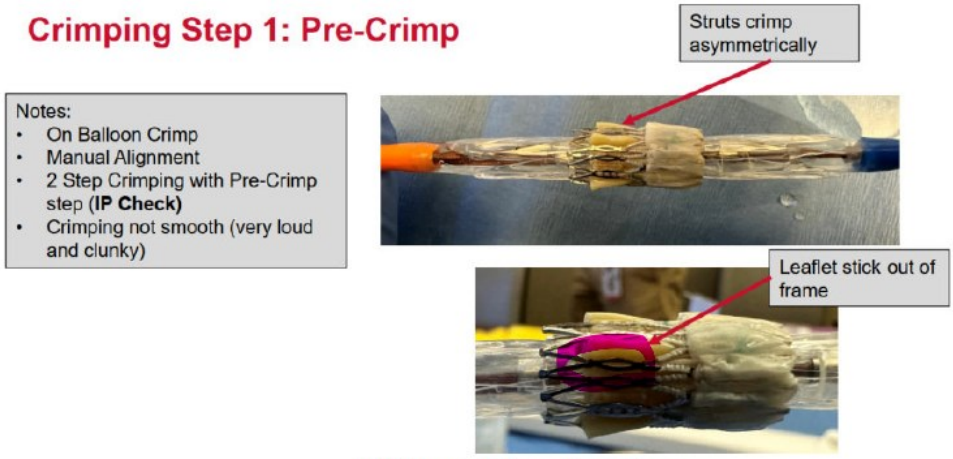


Abbildung 56 – Verletzungsform gecrimpt

Likewise, the commissure posts/struts/elements that replace side struts in the frame of the "Myval Octacor" valve are not compressed upon crimping.

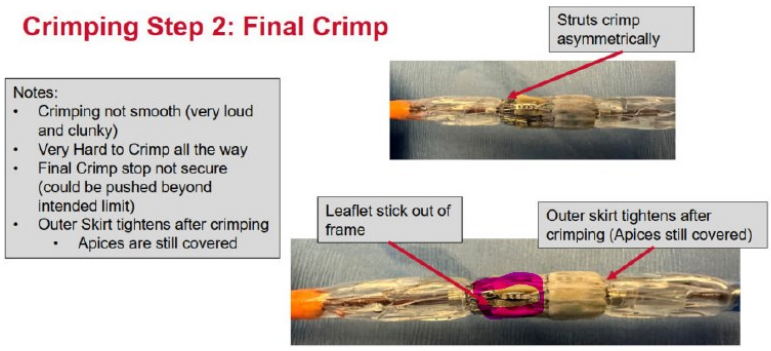


Abbildung 57 – Verletzungsform gecrimpt

143. Die vorstehenden Abbildungen 56 und 57 überreichen wir gesondert als

On p. 49 in its statement of defence Meril shows a comparison between its previous "Myval" valve (on the left) and the presently attacked "Myval Octacor" valve (on the right). Both valves are in the crimped state.

Gewebematerials (Segelprotrusion) – durch **hexagonale** Zellen hindurch – gut zu erkennen (roter Kreis). Rechts abgebildet sind zum Vergleich die (von rhombusförmigen Zellen abgedeckten) Flächen bei der gecrimpten angegriffenen Ausführungsform "Myval Octacor".

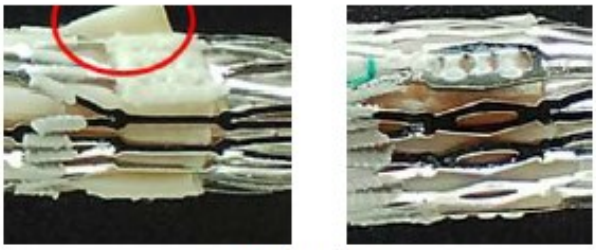
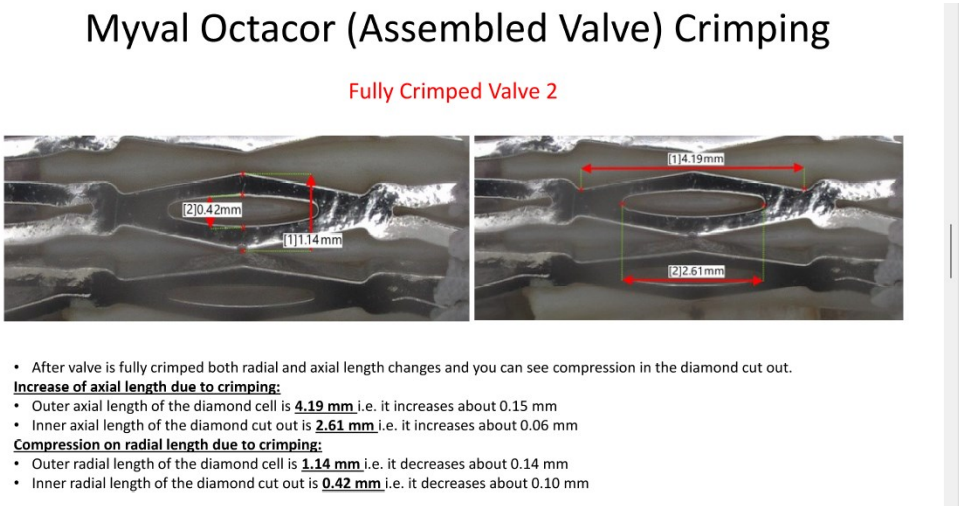


Abbildung 19

It can be seen that the linear side strut in the “Myval” valve is replaced in the “Myval Octacor” valve with a side element that comprises an opening that is not compressed and continues to extend in the longitudinal direction in its crimped state.

3. The “rhombic cells” that are allegedly formed by overlapping octagons are not compressible.

Edwards has introduced data showing the behaviour of the side struts including their opening as reference K69. This panel understands that these data were actually measured by Meril and had been introduced by it in national infringement proceedings brought by Edwards based on EP ‘920 before the Munich Regional Court I. Thus, these data appear to be non-contested. K69 comprises, for example, a slide that shows photos of the side strut of the 2nd out of 3 Myval Octacor valve sample (that were measured) in a crimped state.



It can be qualitatively taken from this slide that the opening in the side strut is maintained upon crimping. The absolute values given for the changes in the outer axial length and the outer radial length are in the µm-range and thus very small.

K69 furthermore comprises a table that summarizes the measurement results of the axial and radial lengths of the side struts, respectively, obtained for 3 samples of the Myval Octacor valve upon crimping and re-expansion, respectively. The results obtained were averaged. The side struts are referred to in the table as “diamond cells” (diamond cells = rhombic cells) what is in line with Meril’s defence arguments.

State of the valve	Parameter	Valve 1 (mm)	Valve 2 (mm)	Valve 3 (mm)	Average (mm)	Average Changes in length
At nominal diameter i.e. before crimping	Outer axial length of the diamond cell	4.01	4.04	4.03	4.03	-
	Inner axial length of the diamond cut out at nominal diameter	2.51	2.55	2.54	2.53	-
	Outer radial length of the diamond cell at nominal diameter	1.30	1.28	1.30	1.29	-
	Inner radial length of the diamond cut out at nominal diameter	0.51	0.52	0.51	0.51	-
Fully Crimped Valve	Outer axial length of the diamond cell	4.17	4.19	4.16	4.17	0.15
	Inner axial length of the diamond cut out at nominal diameter	2.59	2.61	2.60	2.60	0.07
	Outer radial length of the diamond cell at nominal diameter	1.14	1.14	1.17	1.15	-0.14
	Inner radial length of the diamond cut out at nominal diameter	0.41	0.42	0.42	0.42	-0.09
Expanded valve after crimping	Outer axial length of the diamond cell	4.04	4.06	4.05	4.05	-0.12
	Inner axial length of the diamond cut out at nominal diameter	2.53	2.56	2.55	2.55	-0.05
	Outer radial length of the diamond cell at nominal diameter	1.21	1.21	1.23	1.22	0.07
	Inner radial length of the diamond cut out at nominal diameter	0.48	0.49	0.48	0.48	0.07

The measurements were taken in three states – (i) nominal state before crimping (topmost line of the table); (ii) fully crimped valve (middle row of the table); and (iii) expanded state obtained after previous crimping (bottom row of the table). The reference point is in each case the valve in the previous state (i)-(iii). In each state, (i) the outer axial length of the diamond cell; (ii) the inner axial length of the diamond cell; (iii) the outer radial length of the diamond cell; and (iv) the inner radial length of the diamond cell was measured.

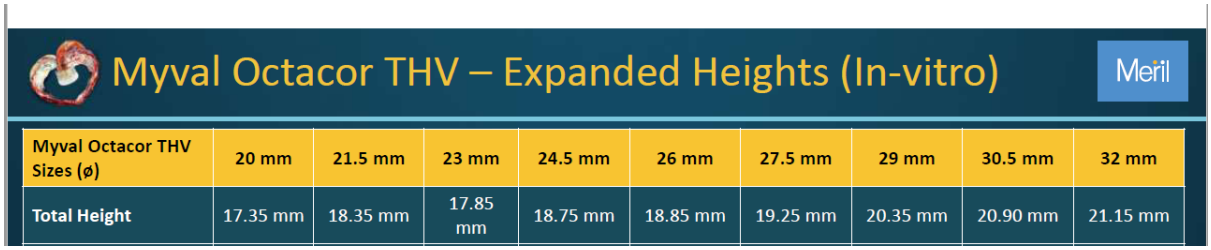
The data show that the “diamond cells” (side struts) of the Myval Octacor valves essentially do not change in their axial and radial length upon crimping and re-expansion, respectively.

The outer axial length of a single cell changes by +0.15 mm (150 µm) upon crimping and by -0.12 mm (120 µm) upon re-expansion, respectively, i.e. by 135 µm on average. These changes are technically insignificant and therefore negligible in comparison to the total axial length of the Myval Octacor valve (even when considering that the Myval Octacor valve comprises two rows of cells so that the change in axial length resulting from the side struts is about 270 µm in total)[2].

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.

[2] It is assumed that the commissure struts that replace side struts in three instances in the upper row of cells exhibit a similar change of the outer axial length as the side struts

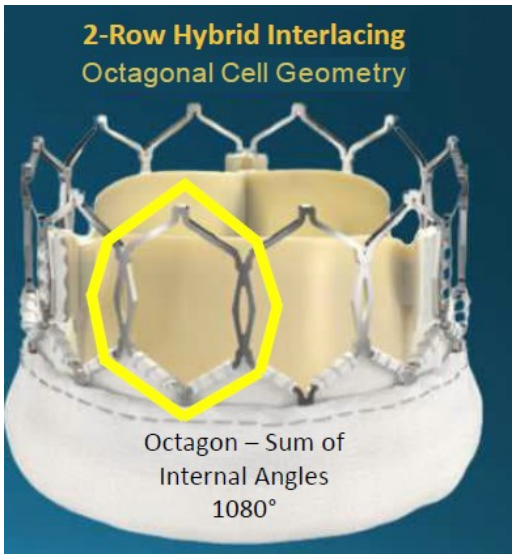
[3] K69 does not indicate the sizes of the Myval Octacor valve samples that were measured



Myval Octacor THV Sizes (ø)	20 mm	21.5 mm	23 mm	24.5 mm	26 mm	27.5 mm	29 mm	30.5 mm	32 mm
Total Height	17.35 mm	18.35 mm	17.85 mm	18.75 mm	18.85 mm	19.25 mm	20.35 mm	20.90 mm	21.15 mm

Accordingly, the foreshortening resulting from the change in the outer axial length of the side struts of the Myval Octacor valve is about 1.4%.

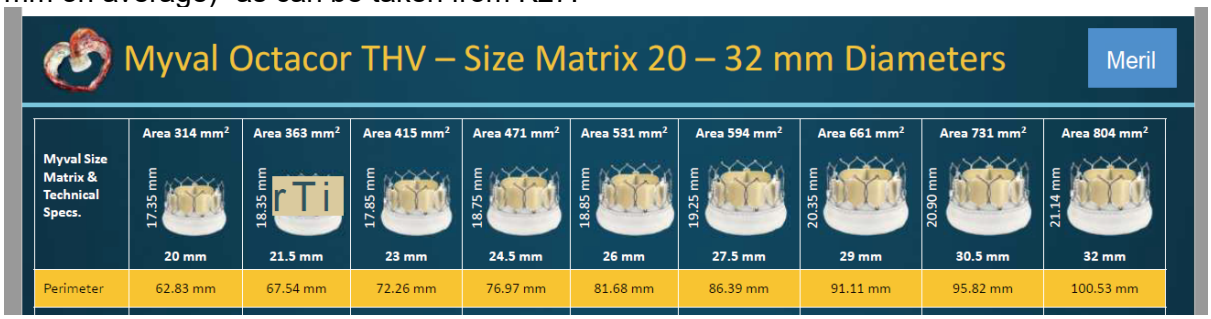
The outer radial length of a cell was measured as -0.14 mm (140 µm) upon crimping and + 0.07 mm (70 µm) upon re-expansion, i.e. 105 µm on average. When taking into account that each row of the Myval Octacor valve comprises 12 cells[4]



(also reproduced from K27)

the total change of the perimeter of the Myval Octacor valve resulting from the change of the outer radial length of the side struts is about 1.26 mm.

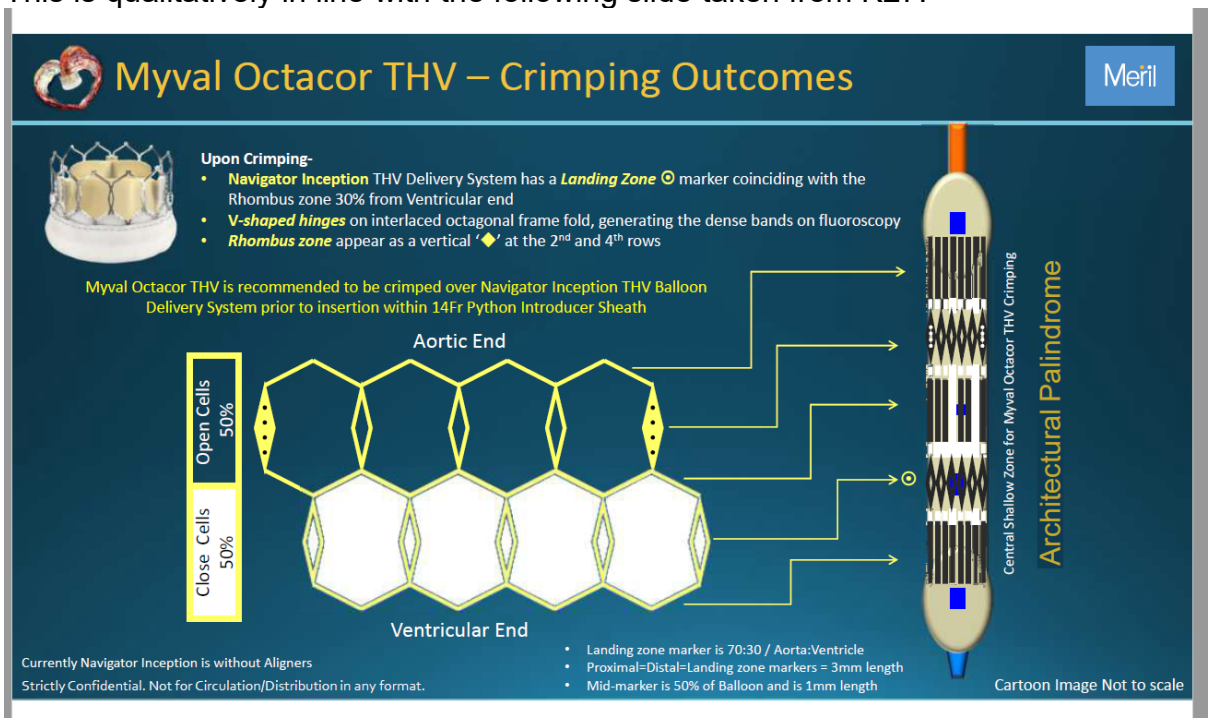
The perimeter of the Myval Octacor valve changes between 62.83 and 100.53 mm (i.e. 81,68 mm on average)[5] as can be taken from K27.



[4] It is assumed that the commissure struts that replace side struts in three instances in the upper row of cells exhibit a similar change of the outer radial. length as the side struts.
[5] K69 does not indicate the sizes of the Myval Octacor valve samples that were measured

Thus the change in perimeter of the Myval Octacor valve resulting from the change in perimeter of all 12 cells of a row of cells of Octacor is about 1.5% and thus technically insignificant and negligible.

This is qualitatively in line with the following slide taken from K27.

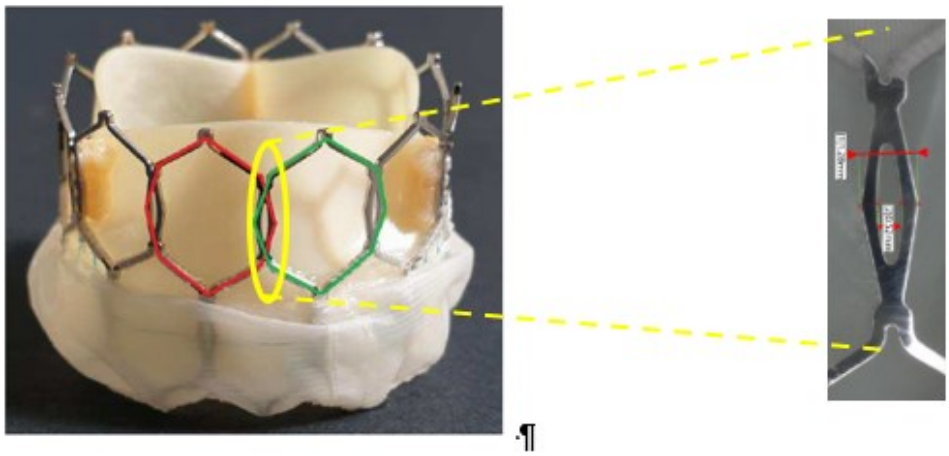


The slide schematically shows the Myval Octacor valve in the expanded state (on the left) and the crimped state (on the right).

The axial length of the valve is substantially expanded upon crimping. The increase of the length results from the movement of the angled struts and their alignment with the longitudinal axis upon crimping. In contrast, the side struts and the commissure (securement) struts remain essentially unchanged in shape and size upon crimping and also maintain their alignment with respect to the longitudinal axis.

4. The side struts that include openings form integral pieces.

The below Fig. was not presented in this form by either party but has been composed by the court from two separately submitted images:



The Fig. shows that the side struts in the Myval Octacor valve are coupled to the upper and lower pairs of angled struts, respectively, via connection portions the shape of which is referred to in other Edwards patents as crown-shaped (see, for example, Hariton) The side strut appears to be a unitary piece comprising an elliptically shaped hole in the middle. The side struts do not comprise junctions between the upper and lower portion of the two side parts what would have to be expected if these were separate struts forming part of an octagonal cell. When the valve is crimped, the angled struts rotate in the crow-shaped connection between the side struts and the angled struts and the apices in the top and bottom of the upper and lower row of cells, respectively, thereby moving (flattening out) towards the flow axis whereas the shape and orientation of the side struts remains essentially unchanged.

5. The side struts extend in parallel to the flow direction

The below Fig. was taken from p.55 of Meril's reply to the infringement action.

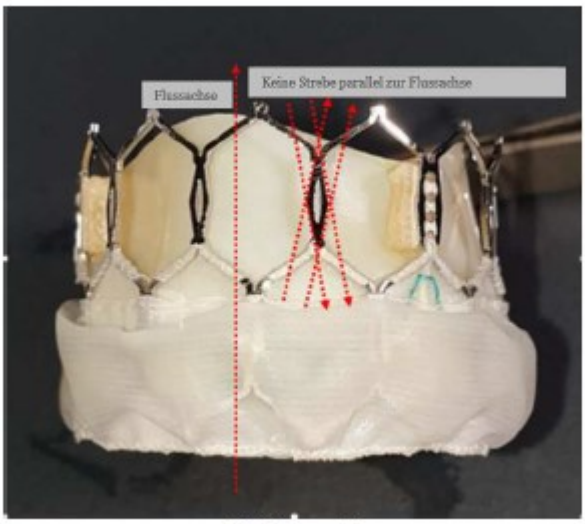


Abbildung 24

Meril submits that the side struts (=the respective upper and lower parts of the two side elements of the overlapping area that are part of the 'octagonal cell and form a rhombic cell in the overlapping area) do not extend into the flow direction.

This is not in line with reality.

It is clear from this Fig. that the upper and lower ends of the side strut are positioned on the flow axis. As a result, the rigid side strut experiences force perpendicular to the flow axis upon crimping and is not, or not to a relevant extent as discussed, deformed but is just pushed into the direction of the flow axis when the upper and lower pairs of angled struts are collapsing upon crimping. Thus, the side strut remains essentially parallel to the flow axis upon crimping.

This is illustrated by the following Fig. taken from p. 49 of Meril's statement of defense:

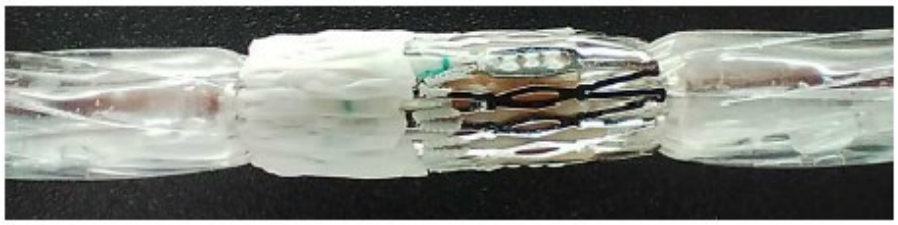


Abbildung 20

6. Conclusion

The "Myval Octacor" heart valve does not display octagonal cells; rather, it comprises and is exclusively made of hexagonal cells. The side elements which comprise an opening in the middle, are side struts that extend in the direction of the flow axis. Upon crimping, the side elements and openings are not compressed. The figures provided by both parties demonstrate that the crimping behavior of the frame of the "Myval Octacor" valve is consistent with that of a frame comprising solely hexagonal cells.

III. Infringement of claims 2, 4 and 5 and by the associated delivery systems

Meril does not contest the infringement of dependent claims 2, 4 and 5 and by the associated delivery systems. As this is also the view of the panel, no further elucidation is required.

F. Final findings

I. Passive legitimation of both defendants

Both Meril defendants have committed infringing acts within the scope of the UPCA.

1. Defendant 2).

a. Companies that are members of a group and play a key role in a distribution network for the infringing product – such as a sole manufacturer or a European sales and marketing hub – may also be considered as infringers if they are located outside the Contracting Member States but supply their products to other members of the group located in the Contracting Member States, while these companies distribute these products on the European market, including in at least one Contracting Member State where the patent in suit is valid (LD Düsseldorf, ACT_18492/2024 UPC_CFI_165/2024).

b. Defendant 2) is based in India and is the manufacturer of the attacked embodiments. It imports, offers and puts on the market - together with the defendant 1) - the attacked embodiments within the territorial scope of the UPCA.

2. Defendant 1).

Defendant 1) is based in Bonn and among other things participates in the Europe-wide distribution of the Indian parent company's products and offers the "Octacor" prosthetic heart valve and the associated delivery systems within the scope of the UPCA.

II. Territory

It is irrelevant for the outcome of this infringement action whether the catheter embodiment “Navigator” is currently not distributed in Germany as Meril claimed with reference to a disclaimer on its website:

> *Myval, Navigator, Python, Mammoth & Val-de-crimp are registered trademarks of Meril Life Sciences Pvt. Ltd. These products are intended for use by or under the direction of a trained healthcare practitioner only. Only qualified medical experts can give you information regarding your individual treatment. Prior to use, refer to the instructions for use/IFU. Data on file at Meril Life Sciences Pvt. Ltd. Illustrations are artist's representation and should not be considered as engineering drawings or photographs. Please check the regulatory approval status of Myval THV in your country. Myval, Navigator, Python, Mammoth & Val-de-crimp are not approved and not available for sale in USA. Myval THV-system is not available for sale in USA, Sweden, Poland, Italy, Denmark. Myval,* ***Navigator*** *and Val-de Crimp, Val-de-crimp Neo* ***are not available for sale in Germany****.*

It is clear from this and undisputed that the “Navigator” catheter is currently offered and put on the market in the other contracting member states mentioned in the statement of claim.

Art. 34 UPCA stipulates that injunctive relief, and other corrective measures can be ordered with respect to all contracting member states where the European Patent has effect and for which a decision of the Court has been requested (Bopp in Bopp/Kircher, Handbuch Europäischer Patentprozess, 2nd ed. 2023, sec. 8 mn. 189) as long as an infringing act or the danger of first infringement has been proven for at least one contracting member state.

III. The proportionality defense is basically rejected.

Meril asserts that third parties' interests or the public interest (specifically, the life and health of patients with severe heart disease (aortic valve stenosis)) necessitate a denial of injunctive relief, recall, and destruction. Edwards argues that this defense was not available and, in any case, would not succeed in light of the circumstances of this case. The panel has essentially rejected the defense.

1. Availability of the defense.

Regarding procedures for implementing corrective measures, Article 64(4) of the UPCA explicitly mentions the interests of third parties. While the Agreement on a Unified Patent Court and the Rules of Procedure for the Unified Patent Court do not explicitly mention the interests of third parties or the public otherwise, these interests may also be considered when exercising the discretion stipulated by the "may" in Articles 63(1) and 64(1) UPCA.

In considering the interests of third parties and the public interest, the court will give due consideration to the possibility of the infringer entering into a license agreement or initiating

proceedings for a mandatory license. If proceedings for the issuance of a mandatory license have been initiated, the court shall duly consider the outcome thereof.

2. Rejection of the defense.

The panel has essentially rejected the defense.

a. The Bundespatentgericht has dismissed Meril's request for a mandatory license for Germany with decisions dated 25 March 2021 (docket nos. 6 Li 1/20 (EP), 6 Li 2/20 (EP), 6 Li 3/20 (EP), 6 Li 4/20 (EP) and 6 Li 5/20 (EP); exhibit K 70a). Meril sought a mandatory license for a set comprising the Myval™ valve and the Navigator™ delivery system. In its decision, the Bundespatentgericht highlighted that following the testimony of a court-appointed expert, a public interest had only been demonstrated for the Myval™ valve prosthesis with sizes 30.5 mm and 32 mm for annuli larger than 30 mm, given that the demand for those XL-sized valve prostheses is not met by Edward's or third parties' products. However, the Bundespatentgericht rejected the request in its entirety on the ground that Meril was an unwilling licensee. This was because Meril had not made sufficient efforts to obtain such a license. Meril had declined to comply with Edwards' reasonable request for access to samples and documentation that would have enabled Edwards to form an impression of the "Myval" valve, particularly regarding its actual quality and effectiveness. To guarantee the confidentiality of this data, Edwards had also consented to enter into a corresponding confidentiality agreement, namely the "Confidentiality and Non-Disclosure Agreement". Nevertheless, a comprehensive evaluation of the product to be licensed by Edwards was imperative to facilitate the continued negotiation of license terms in accordance with the standards expected of a reputable medical device manufacturer (see the decision by the Bundespatentgericht, exhibit K 70a, p. 57).

In the wake of the Bundespatentgericht's ruling, Meril, according to Edwards, initially demonstrated a lack of initiative in pursuing a license to Edwards' patents pertaining to the "Myval" valve. Approximately 1.5 years later, in November 2022, they approached Edwards with a license request regarding the XL sizes of the "Myval" valve. Nevertheless, Edwards retained a legitimate interest in reviewing specific documents and documentation pertaining to the "Myval" valve, particularly for the purpose of assessing the safety and quality of the product to be licensed. Consequently, Edwards requested that Meril provide the pertinent documentation and once more proposed the conclusion of a confidentiality agreement in relation to this matter. However, Meril did not respond to Edwards's legitimate request and letter and terminated the license negotiations. 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. Considering the pivotal role that patient interests play in Edwards' operations, the company highlighted the dearth of data pertaining to the infringing embodiment in its correspondence. To assess the safety and quality of the products to be licensed, Edwards requested the review of certain records and documentation and once more proposed the conclusion of a confidentiality agreement in this regard (Exhibit K71). No reply was forthcoming to the letter dated 21 November 2023.

b. In light of the finality of the Bundespatentgericht's judgment and the absence of an application for a mandatory license pertaining to the patent in question at the time from Meril, both in Germany and in the other Contracting Member States, the findings of the Bundespatentgericht imply a strong assumption against Meril with respect to both the public interest determination and the conclusion that Meril is an unwilling licensee. The Bundespatentgericht had heard expert testimony from a court-appointed expert, Dr. Kim, and based on this testimony delivered a comprehensive evaluation of all facts presented to determine whether there was a public interest in the case. In this context, it is pertinent to cite the reasoning of the Bundespatentgericht. Although different patents and a different product

(Meril's Myval) formed the subject matter of these proceedings, it is agreed between the parties that these findings also apply to the patent in suit, the attacked embodiment (Meril`s Myval Octacor) and the other European States. This is because the patents and products are related and the medicinal situation in the various European Contracting Member States is comparable.

c. During the present proceedings, Meril was unable to dispel this assumption. Considering the aforementioned considerations, this panel concurs with the stance adopted by the Bundespatentgericht, namely that a public interest is only to be recognized in the context of valve prostheses for annuli exceeding 30 mm in diameter. Meril has demonstrated that neither Edwards' nor third parties' products meet the demand for an XL-sized valve prosthesis. Although Meril is still to be regarded as an unwilling licensee, as Meril still rejects Edwards' legitimate request for access to samples and documents that would have allowed the formation of an impression of the Myval Octacor valve (in particular, its actual quality and effectiveness) that would be licensed, this panel finds that the public interest must still be considered. Patients with serious heart problems and an annulus larger than 30 mm have no possibility to influence Meril's behavior and still might face serious medical consequences if access to XL-sized Myval Octacor valves prostheses was denied.

aa. There is a clear and pressing public need for Meril's XL-sized valve prosthesis. Proper sizing is a critical factor in the success of the transcatheter aortic valve implantation (TAVI) procedure. In the event of an imperfect sizing relation between the natural anatomy and the prosthesis diameter, life-threatening complications may ensue. Meril has demonstrated with figure 27 of Exhibit 21 that Edwards`s product is recommended for native valve annulus sizes of a maximum of 28 mm (TEE):

Table 3

Native Valve Annulus Size (TEE)	Native Valve Annulus Size (CT)		THV Size
	Area	Area Derived Diameter	
16 – 19 mm	273 – 345 mm²	18.6 – 21.0 mm	20 mm
18 – 22 mm	338 – 430 mm²	20.7 – 23.4 mm	23 mm
21 – 25 mm	430 – 546 mm²	23.4 – 26.4 mm	26 mm
24 – 28 mm	540 – 683 mm²	26.2 – 29.5 mm	29 mm

Valve size recommendations are based on native valve annulus size, as measured by transesophageal echocardiography (TEE) or computed tomography (CT). Patient anatomical factors and multiple imaging modalities should be considered during valve size selection.
NOTE: Risks associated with undersizing and oversizing should be considered.

Figure 27: Sizing matrix - "Sapien 3"/"Sapien 3 Ultra

Meril`s product is also recommended for a native valve annulus size of up to 31 mm (TEE) as shown in figure 26 of Exhibit K21:

Table 1

Reference/ Catalog Number	THV Size (mm)	Transesophageal Echocardiogram (TEE)* (mm)	Native Annulus Area (mm^2)	Area-derived diameter (mm)
MOCTA2200	20	16 –19	270 – 330	18.5 – 20.5
MOCTA2215	21.5	17.5 – 20.5	314 – 380	20 – 22

Reference/ Catalog Number	THV Size (mm)	Transesophageal Echocardiogram (TEE)* (mm)	Native Annulus Area (mm^2)	Area-derived diameter (mm)
MOCTA2230	23	18 – 22	360 – 440	21.4 – 23.7
MOCTA2245	24.5	19.5 – 23.5	410 – 500	22.8 – 25.2
MOCTA2260	26	21 – 25	460 – 560	24.2 – 26.7
MOCTA2275	27.5	22.5 – 26.5	510 – 630	25.5 – 28.3
MOCTA2290	29	24 – 28	570 – 700	26.9 – 29.9
MOCTA2305	30.5	25.5 – 29.5	630 – 770	28.3 – 31.3
MOCTA2320	32	27 – 31	700 – 840	29.9 – 32.7

Figure 26 - Sizing Matrix - "Myval Octacor

Edwards posited that patients with extra-large annuli could also be treated with the "SAPIEN 3" valve in 29 mm (THV size), citing several meaningful studies that addressed the issue of overexpansion of the 29 mm "SAPIEN 3" valve in extra-large annuli and reported favorable outcomes. It further proposed that the "CoreValve Evolut R" valve in size 34 mm from Medtronic could be a viable alternative. However, this panel remains unconvinced due to the fact that Edwards also referred to the possibility of implanting an XL-sized "Myval" valve from Meril. Edwards has established a system whereby doctors can request the use of an XL valve of the "Myval" type if they consider it to be clinically necessary, despite not being legally obliged to do so. As Edwards highlighted that this option is available via the so-called Medical Request Portal, despite being legally non-binding, this panel believes that there may be patients who can only be adequately treated with Meril's XL-sized Myval valve. Otherwise, Edwards would have defined annulus sizes larger than 28 mm in its recommendations for use of its "Sapien 3" and would not have established the Medical Request Portal. The same argument applies to the Myval Octacor.

bb. This public need is adequately addressed through the existing Medical Request Portal for the Myval valve prosthesis. In the oral hearing, Edwards conceded that the Medical Request Portal will remain operational for the XL-sized Myval valve prosthesis and will also be accessible for XL-sized Myval Octacor products. The Medical Request Portal enables practitioners to request a single-use license to treat a specific patient. As the Medical Request Portal for the Myval valve prosthesis is functioning effectively, it is evident that no further arrangements or limitations with regard to injunctive relief are necessary, apart from the aforementioned limitations in the operational part of this decision.

It is, however, necessary to limit/adjust the orders as to recall and destruction. The aforementioned orders do not extend to XL devices that have been scheduled for implantation in an individualized patient by 15 November 2024. This is to ensure that no patient is placed at risk during the interim period required to disseminate information regarding the applicability of the Medical Request Portal to XL-sized Myval Octacor devices. The XL device may be retained for an individual patient, and the practitioner may apply for an individual exemption for that patient. It is agreed that any applications will be responded to by Edwards without delay if all the relevant information is provided by the practitioner.

cc. It is not evident that intermediate sizes and additional features offer significant advantages that would justify the granting of an exemption from injunctive relief, recall and destruction.

(1) Meril asserts that the availability of different models was crucial from a clinical standpoint, as it permitted the selection of an appropriate model tailored to the individual patient's needs.

Notwithstanding the aforementioned, this position was endorsed by the court expert, Dr. Kim, during the proceedings at the Bundespatentgericht.

"From a clinical perspective, it is helpful that different models with different properties exist on the market because, in this way, one can make choice tailored to the individual patient."

However, it is not sufficient for a public interest to be legally justified on the grounds that it would be advantageous for the treating physician to have a variety of treatment methods at their disposal. Consequently, in order to justify a public interest in the availability of the infringing embodiment, it is essential to demonstrate that this is the sole available treatment method or that it represents an improvement upon a known treatment method, resulting in a notable enhancement in patient care.

(2) Meril further asserts that the Myval Octacor exhibited additional features that were advantageous or even superior to those of Edwards' "Sapien 3" and "Sapien 3 ultra" and other manufacturers' products. These include a variety of sizes, including intermediate sizes; an even more precise positioning of the valve; a reduction in the typical risks associated with this procedure, including paravalvular insufficiency and conduction disturbances; a low-profile introducer sheath with the ability to retrieve the transcatheter heart valve prosthesis before it expands; and a protection of the leaflet structure as well as the so-called OctaAlign technique.

In this regard, Meril was unable to surmount the presumption established by the decision of the Bundespatentgericht. Edwards demonstrated that the aforementioned features do not result in a notable enhancement of patient care, as evidenced by the findings of the LANDMARK Clinical Trial. It can be concluded, at best, that Meril's products are not inferior. Nevertheless, the concept of "non-inferiority" is not a suitable criterion for evaluating the public interest defense in the course of the weighing of proportionality. In the absence of any further comment from Meril on Edwards' submissions dated 4 September 2024 (46733/2024) in the oral hearing, it must be concluded that the public interest defense is also unsuccessful in this regard:

- On 22 May 2024, the Journal “The LANCET” published an article by Baumbach et al. entitled “LANDMARK comparison of early outcomes of newer-generation Myval transcatheter heart valve series with contemporary valves (SAPIEN and Evolut) in real-world individuals with severe symptomatic native aortic stenosis: a randomized noninferiority trial” (the “LANDMARK Publication”). A copy of the LANDMARK Publication was submitted together with Edwards R. 36 Request as Exhibit K-B 1. Copies of the “Supplementary appendix 1” and “Supplementary appendix 2” were submitted as Exhibits K-B 2 and K-B 3. The LANDMARK Publication reports on the “early outcomes” of the LANDMARK clinical trial. This clinical trial, which is sponsored by Defendant 2), compares Meril’s “Myval” valve series (including the infringing embodiment) with the “SAPIEN Series” valves of Edwards and the “Evolut Series” valves of Medtronic (the “LANDMARK Clinical Trial”). According to the LANDMARK Publication, the LANDMARK Clinical Trial is a “prospective, multinational, randomized, open-label, non-inferiority trial” and “aimed to show non-inferiority of” Meril’s valves to the “SAPIEN 3” valves of Edwards and the “Evolut” valves of Medtronic. The design of the LANDMARK Clinical Trial was initially reported in February 2021 in a publication by Kawashima, H. et al. entitled “Rationale and design of a randomized clinical trial comparing safety and efficacy of Myval transcatheter heart valve versus contemporary transcatheter heart valves in patients with severe symptomatic aortic valve stenosis: The LANDMARK trial’” (Exhibit K-B 4). Kawashima, H. et al. reported that that the LANDMARK Clinical Trial was a randomized head-to-head trial comparing “Myval” THV series to commercially available THVs (see ‘Summary’ on pg. 23). It was further reported that

“[t]he primary objective of this study is to prove that Myval THV is noninferior to contemporary THV series (SAPIEN THV series and Evolut THV series). Subsequently, the secondary objective is to show that Myval THV is noninferior to SAPIEN THV series and Evolut THV series” (see ‘Statistical Analysis’ on pg. 3o). At that point, the trial was limited to a comparison between Defendants’ first generation THV (i.e. the “Myval” THV) and Claimant’s “SAPIEN” THV series, on the one hand, and Medtronic’s “Evolut” THV series on the other hand. At some point after publication of the study design by Kawashima, H. et al., the trial design appears to have been amended to introduce the infringing embodiment into the “Myval” THV arm of the trial. Shortly before the publication of the LANDMARK Publication, in April 2024, in a Letter to the Editor published in the American Heart Journal, further updates were made to the study protocol. In particular, it was reported that the secondary end point was removed, such that the trial would no longer assess non-inferiority of the “Myval” THV series (now including the infringing embodiment) against each of Claimant’s “SAPIEN” THV series and Medtronic’s “Evolut” THV series separately (Exhibit K-B 5). The effect of this change to the trial design is that the trial will no longer show a direct comparison between Meril’ products and Edwards’ products. This is a highly unusual change to make at such a late stage in a clinical trial (recruitment had finished in December 2023, four months before this change was announced). A further limitation of the LANDMARK Publication is that the data relating to Meril’ first- and second-generation products, which they themselves market as having “considerable changes” between them, is aggregated. Similarly, due to the change in the trial design, the data relating to Edwards’ THV of the “SAPIEN” series and to Medtronic’s THVs of the “Evolut” series is aggregated. As a result, it is scientifically impossible to draw any conclusions regarding a comparison between the infringing embodiment and Edwards’ “SAPIEN” THVs. Ìn the present circumstances, it must be inferred that Meril does not have data to support its allegation that the infringing embodiment is superior to Edwards’ products. In fact, Meril has not even been able to show, in its own study, that the infringing embodiment is non-inferior to Edwards` products.

- Notwithstanding the above-mentioned limitations of the LANDMARK Publication, some aspects of the study results are addressed in the following:

Meril alleges in subparagraph aa) on page 74 of the Statement of Defense that “the risk of annulus rupture can also be countered by precise and accurate sizing, which the [infringing embodiment] enables”. However, the LANDMARK Publication reports that there was one instance of annular rupture and two instances of cardiac tamponade in the “Myval” arm (see pg. 12, left-hand column), while none are reported for the “contemporary valves” arm. Furthermore, the rate of major vascular complications (which includes, among other complications, aortic rupture), was not statistically difference between the “Myval” arm and the “contemporary valves” arm (see Figure 2, pg. 7 of the LANDMARK Publication).

At subparagraph aa) on page 74 of the Statement of Defense, Meril alleges that the risk of coronary artery occlusion is “countered by the frame structure [of the infringing embodiment], which enables precise positioning and safe deployment, and the OctaAlign technique”. Again, this is not supported by the LANDMARK Publication. In particular, there was 1 incidence of “Coronary artery obstruction requiring intervention” reported in the “Myval” arm, but none reported in the “contemporary valves” arm (see Table 4, pg. 10 of the LANDMARK Publication).

Meril alleges in subparagraph bb) on page 75 of the Statement of Defense that “there is a lower incidence of conduction disturbances and consequently less need for pacemaker implantations” with the infringing embodiment, “due to the possibility of perfect sizing”. This is also not supported by the LANDMARK Publication. The rate of pacemaker implantation was 15% in the “Myval” arm and 17% in the “contemporary valves” arm, which is not a statistically significant difference (see Figure 2, pg. 7 of the LANDMARK Publication). Furthermore, the

rate in the “contemporary valves” arm is likely elevated by a higher incidence of pacemaker implantation from the ‘self-expanding’ portion of the “contemporary valves” arm (see pg. 2, left hand column of LANDMARK Publication).

Meril further alleges that the incidence of paravalvular leak (“PVL”) (also referred to as paravalvular insufficiency or prosthetic valve regurgitation) is reduced with the “Myval Octacor” (see pg. 89 of LANDMARK Publication). However, the LANDMARK Publication does not support this. In particular, there was no statistically significant difference between the rate of moderate and severe prosthetic valve regurgitation in the “Myval” arm and in the “contemporary valves” arm. The rate of moderate and severe prosthetic valve regurgitation in the “contemporary valves” arm is potentially also increased by the inclusion of the self-expanding valves which are known to have a higher rate of PVL (see pg. 2, left hand column of LANDMARK Publication).

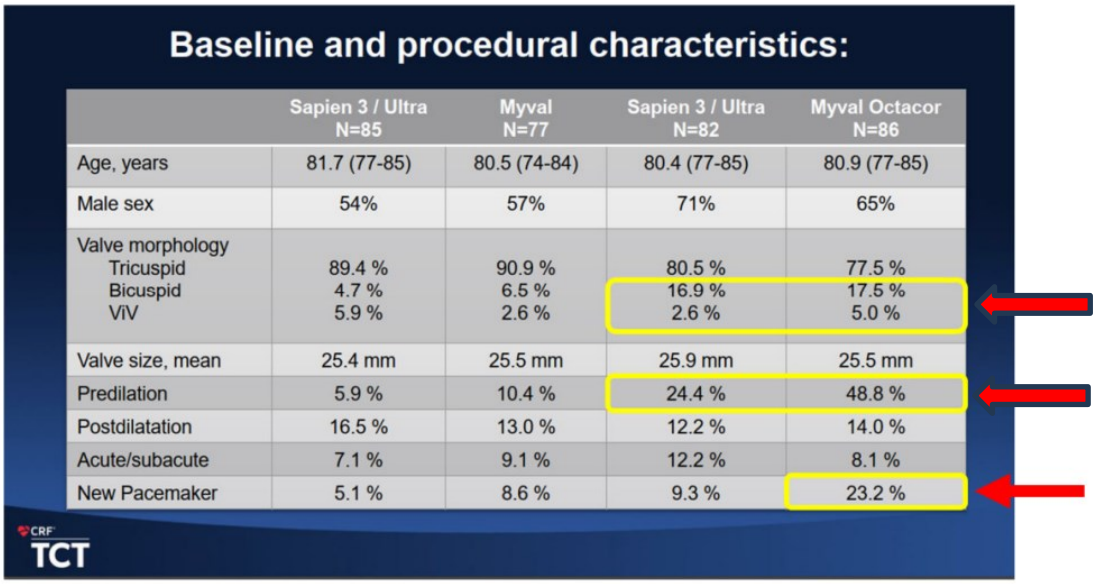
Meril further alleges that the risk of valve embolization is decreased with the infringing embodiment (subparagraph bb) on pages 83-84 of the Statement of Defense). While the LANDMARK Publication does not report specifically on the incidence of valve embolization, there was no statistically significant difference in incidence of “Valve malposition” (which includes valve migration and valve embolization) in the “Myval” and “contemporary valves” arms (see Table 3, pg. 9 and Table 4, pg. 10 of the LANDMARK Publication). Again, the incidence in the “contemporary valves” arm may be skewed by a known higher incidence of valve embolization in self -expanding valves (see subparagraph bb) on page 75 of the Statement of Defense).

Meril also alleges that there would be a decreased incidence of patient-prosthesis mismatch with the infringing embodiment (subparagraph bb) on pages 85 of the Statement of Defense). Again, this is unsupported by the LANDMARK Publication. The LANDMARK Publication reports that the incidence of “[s]evere patient–prosthesis mismatch was 4% in both the Myval and contemporary groups” (pg. 9, right hand column, LANDMARK Publication).

Meril alleges that the infringing embodiment is better suited for the treatment of patients with a bicuspid aortic valve (pgs. 94-95 of LANDMARK Publication). This is unsupported by the LANDMARK Publication in which clinicians used the ‘contemporary valves’ to treat bicuspid patients more often than the ‘Myval’ valves (8% vs 6%; see Table 1, pg. 6 of LANDMARK Publication).

- In summary, the LANDMARK-Trial, despite being Meril`s ‘flagship’ study to date, does not establish any advantages of the infringing embodiment over the available THVs such as “SAPIEN 3/Ultra”, but instead only concludes that “Myval” – which could be either the infringing embodiment “Octacor” or the original “Myval” – is not inferior to a pooled cohort of THVs from the “SAPIEN 3” and/or “Evolut” series.

- These findings are in line with the results of the TCT conference presentation, 23-26 October 2023 in San Francisco (Exhibit K94), that shows that the infringing embodiment performs worse than the "SAPIEN 3/Ultra" valve in many respects. These results thus also refute Meril's submission that the use of the infringing embodiment - and in particular its intermediate sizes - reduces the risk of valve leakage (contrary to p. 89 SD) and the risk of subsequent pacemaker implantation (contrary to p. 93 SD):



Baseline and procedural characteristics:

	Sapien 3 / Ultra N=85	Myval N=77	Sapien 3 / Ultra N=82	Myval Octacor N=86
Age, years	81.7 (77-85)	80.5 (74-84)	80.4 (77-85)	80.9 (77-85)
Male sex	54%	57%	71%	65%
Valve morphology				
Tricuspid	89.4 %	90.9 %	80.5 %	77.5 %
Bicuspid	4.7 %	6.5 %	16.9 %	17.5 %
ViV	5.9 %	2.6 %	2.6 %	5.0 %
Valve size, mean	25.4 mm	25.5 mm	25.9 mm	25.5 mm
Predilation	5.9 %	10.4 %	24.4 %	48.8 %
Postdilatation	16.5 %	13.0 %	12.2 %	14.0 %
Acute/subacute	7.1 %	9.1 %	12.2 %	8.1 %
New Pacemaker	5.1 %	8.6 %	9.3 %	23.2 %

[red marking added]

IV. No grace period

In the circumstances of this case, it is not appropriate to grant a grace period. In anticipation of the oral hearing at the CDP in June 2024, the oral hearing at the LDM had already been scheduled for a later date, namely September 2024. An additional postponement would imperil Edwards' interest as a patent proprietor in prompt enforcement.

V. No compensation payment in lieu of an injunction

In the absence of a legal foundation, it is not possible to order a payment in lieu of an injunction. It could be deemed appropriate to consider this option when evaluating the interests of both parties, provided that the defendant has offered a sufficient financial settlement. However, this is not the case in the present circumstances. The proposed lump sum payment of €100,000 by Meril during the licensing negotiations is an inadequate and unreasonable offer. The value of the infringement action is estimated to be approximately €8 million. The market value of one single device is five digits.

VI. The relief sought is basically justified.

In light of the aforementioned findings, it can be concluded that Edwards is entitled to the following corrective measures:

1. Injunction

Under Art. 63 (1) UPCA, Meril is obliged to cease and desist from further infringements. Nevertheless, the principal request must be rejected on the grounds of its ambiguous territorial scope. It is possible to grant the auxiliary request without Romania, including dependent claims 2, 4 and 5.

It should be noted, however, that this order does not extend to XL devices that have already been scheduled for implantation in individualized patients by 15 November 2024. This is to ensure that no patient is harmed during the interim period required to disseminate information

regarding the applicability of the Medical Request Portal to XL-sized Myval Octacor devices. The XL device may be retained for an individual patient, and the practitioner may apply for an individual exemption on the patient's behalf. It is agreed that responses to these applications will be provided by Edwards without delay, provided that the practitioner furnishes all the requisite information.

2. Penalty payment

Under Art. 63 (2) UPCA and R 354.3 RoP non-compliance with the injunction shall be subject to a recurring penalty payment payable to the Court. In light of the five-digit market price of the product in question, it seems reasonable to impose a penalty of €20,000 for each case of non-compliance and per infringing product.

3. Declaration of infringement

Under Art. 64 (2) (a) UPCA the court can declare that the attacked embodiments are infringing the asserted patent claims.

4. Information and penalty payment

Edwards also has a claim against Meril for information pursuant to Art. 67 (1) UPCA in combination with R. 191 RoP. This claim is justified and proportionate. The claim for information serves inter alia to obtain information on the distribution channels of the infringing embodiment and the quantities and prices of the products delivered. Furthermore, the identity of third parties involved in the distribution of the infringing embodiment is of particular relevance to Edwards in order to effectively enforce its exclusive rights.

The late amendments must be rejected in accordance with the aforementioned rationale. Nevertheless, they may be deemed to be owed in any case on the basis of good faith considerations. To illustrate, under German law (§ 242 BGB), the debtor is obliged to perform the owed obligation in a manner that is consistent with the requirements of good faith and customary practice. As the parties have yet to elaborate on this point, it must be adjourned to the enforcement stage.

Under R 354.3 RoP the Court’s decisions and orders may provide for periodic penalty payments payable to the Court in the event that a party fails to comply with the terms of the order or an earlier order. The value of such payments shall be set by the Court having regard to the importance of the order in question. In the case at hand a periodic fine of EUR 1,000 for each day of delay seems to be reasonable.

5. Recall and penalty payment

Edwards is entitled to recall of infringing goods and their final removal from the distribution channels according to Art. 64 II (b) UPCA. Again, this order does not extend to XL devices that have already been scheduled for implantation in an individual patient by 15 November 2024.

In the case at hand a periodic fine of EUR 1,000 for each day of delay seems to be reasonable.

6. Destruction and penalty payment

Edwards can also demand from Meril under Art. 64 (2) (e) UPCA the destruction of the infringing goods they have in their possession in countries of the UPCA. Again, this order does not extend to XL devices that have already been scheduled for implantation in an individual patient by 15 November 2024.

In the case at hand a periodic fine of EUR 1,000 for each day of delay seems to be reasonable.

7. Publication by Edwards

Edwards has a legitimate interest in publication of the decision in five public media including industry journals of its choice under Art. 80 UPCA. In the event that the publication is to be made in its entirety, the judgment handed down today is to be published in its entirety. In the event of partial publication, the full text of the rubric and the complete operational part of the judgment are to be made available.

8. No publication by Meril

The request to mandate Meril to publish the operative part of the Court's decision on their websites is dismissed as disproportionate. Although such an order would essentially fall under Art. 80 UPCA, the panel has determined that, at this time, no further publication orders are necessary beyond the granting of rights to Edwards to publish the decision. Edwards did not provide a rationale for why this additional and humiliating method of publication is necessary.

9. Damages

Edwards is entitled to damages under Art. 68 UPCA in combination with R. 118.1 RoP (Rules of Procedure) because Meril acted culpably. Since Edwards is not yet able to quantify the damage incurred, it has a legitimate interest in having Meril`s liability for damages determined.

10. Preliminary damages

In addition, Edwards is entitled to payment of preliminary damages in accordance with Art. 68 UPCA in combination with R. 119 RoP. The final determination of the amount of damages should be the subject of separate proceedings. The proposed sum of € 663,000 had not been contested by Meril and thus should be ordered.

11. Costs of the proceedings

As the unsuccessful party Meril must pay the costs of the proceedings according to Art. 69 (1) UPCA.

12. Costs of compliance with above orders

According to Art. 64 (3) UPCA the Court shall order that those measures be carried out at the expense of the infringer, here Meril, unless particular reasons are invoked for not doing so. No particular reasons for not doing so have been invoked here.

13. Immediate enforceability

This decision is immediately and directly enforceable from the date of service in each Contracting Member State (R 354.1 RoP). In light of Meril's withdrawal of its request at the oral hearing (R 352.2 RoP), no security payment is ordered.

VII. No condition pursuant to Art. 56 (1) UPCA, R 118.2 (a) RoP.

No condition according to Art. 56 (1) UPCA, R 118.2 (a) RoP is warranted under the facts of this case.

1. Under R. 118.2 (a) RoP the Court may render its decision on the merits of the infringement claim, including its orders, under the condition pursuant to Article 56(1) of the Agreement that the patent is not held to be wholly or partially invalid by the final decision in the revocation proceedings, if, while there are infringement proceedings before a local or regional division, a revocation action is pending between the same parties before the central division.

2. This panel takes notice of the order by the standing judge of the CoA dated 6 September 2024 (App_45041/2024 UPC_CoA_457/2024) which stipulates at mn. 15 that the situation at hand (decision on infringement after the bifurcated counterclaim had been decided by the CDP) falls under R 118.2 (a) RoP although the bifurcated counterclaims for revocation have already been decided by the CDP and thus are no longer “pending between the same parties before the central division”.

3. The panel nevertheless asserts that, in light of the circumstances of this case, no condition in accordance with the aforementioned provisions is warranted. In exercising this discretion, the panel was acting in accordance with the provisions in question. The reasons are as follows:

a. Firstly, Meril made a false claim that the CDP had not addressed major nullity arguments in its decision. The aforementioned detailed explanations are referenced herewith.

b. Secondly and most importantly, the Meril Group attempted to outmaneuver the different divisions of the Unified Patent Court by creating a new entity, "Meril Italy", with the intention of filing a standalone nullity action with the CDP in order to disrupt and/or prolong the infringement proceedings. Despite the CDP's dismissal of Edwards' preliminary objection on the grounds of these circumstances, as evidenced by the JR´s order dated 13 November 2023 (App_572915/2023 UPC_CFI_255/2023), the Unified Patent Court should refrain from entertaining such strategic maneuvers. These actions should not result in the imposition of a condition in accordance with the aforementioned provisions, particularly given that the CDP has upheld the patent in question and that the infringement proceedings have already been delayed as a result of these strategic maneuvers. As previously stated, the date for the oral hearing had to be set later than warranted by the LDM's calendar in order to align with the date of the oral hearing at the CDP.

DECISION

For all these reasons and after having heard the parties Panel 1 of the Local Division Munich decides as follows:

I.1 Defendants are ordered to cease and desist with respect to a system comprising: a prosthetic heart valve comprising: a collapsible and expandable annular frame configured to be collapsed to a radially collapsed state for mounting on a delivery apparatus and expanded to a radially expanded state inside the body; wherein the frame is made of a nickel-cobalt-chromium-molybdenum alloy and comprises a plurality of rows of angled struts, the angled struts joined to each other so as to form a plurality of rows of hexagonal cells, wherein the frame is made up entirely of hexagonal cells, and wherein each of the hexagonal shaped cells is defined by six struts, including:

two opposing side struts extending parallel to a flow axis of the valve, a pair of lower angled struts, extending downwardly from respective lower ends of the side struts and converging toward each other, and a pair of upper angled struts extending upwardly from respective upper ends of the side struts and converging toward each other; and a delivery catheter comprising an inflatable balloon; wherein the prosthetic heart valve is crimped in its radially compressed state on the balloon of the delivery apparatus, and wherein the balloon is configured to be inflated to expand to radially expand the prosthetic heart valve at the desired deployment location, preferably within a native aortic valve, wherein the frame of the prosthetic heart valve does not include any struts that do not form part of one of the hexagonal cells, except for any struts that extend axially away from an inflow end or an outflow end of the frame for mounting the frame to the delivery catheter.

(independent claim 1 of the Patent-in-Suit as upheld),

from offering, placing on the market, using, or importing or storing it for the said purposes in Belgium, Bulgaria, Denmark, Germany, Estonia, Finland, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Portugal, Sweden and Slovenia

especially if

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

(dependent claim 2 of the Patent-in-Suit as upheld),

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 the Patent-in-Suit as upheld),

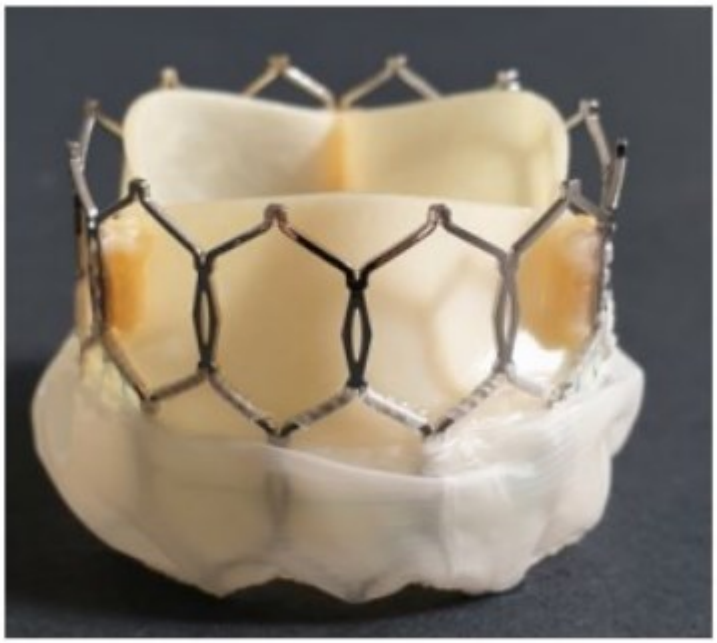
and/or

a system of any of claims 2 and/or 4 and/or 12, wherein the skirt is made of a fabric, the fabric preferably made of PET or UHMWPE;

(dependent claim 5 of the Patent-in-Suit as upheld),

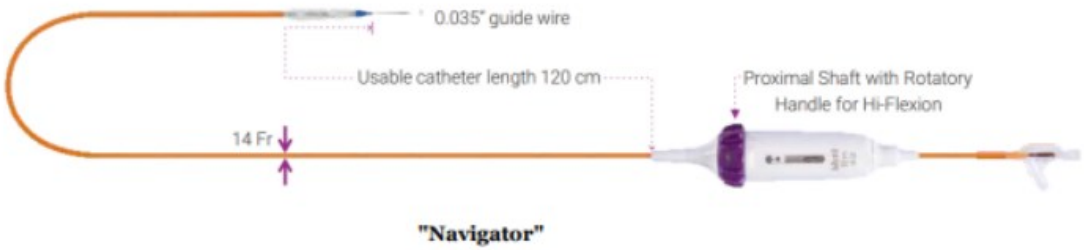
especially if the system contains

a) a transcatheter heart valve prosthesis with the designation "Myval Octacor" as shown below

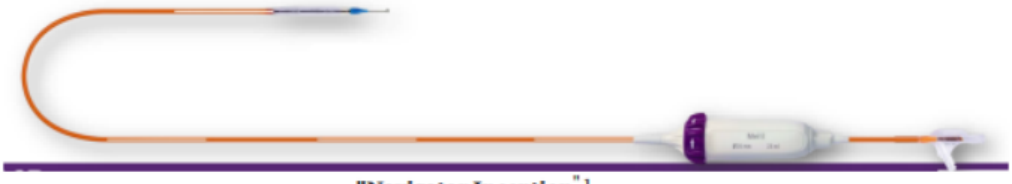


and/or

b) a delivery apparatus of the type "Navigator" and/or "Navigator Inception" as shown below



"Navigator"



"Navigator Inception"[1]

I.2 This order does not extend to XL devices that have already been scheduled for implantation in an individual patient by 15 November 2024.

II. In case of violation of the order according to Item I. defendants must pay a penalty payment of up to EUR 20,000 for each case of non-compliance and per infringing product to the Court.

III. The Patent-in-Suit was infringed by Defendants in respect to the products described above under Item I.

IV. Defendants are ordered, under penalty of a periodic fine of EUR 1,000 for each day of delay, within a period of three weeks from the date of service of the decision, to provide Claimant with information on the extent to which Defendants have committed the acts referred to in Item I. since 17 March 2021, specifying:

1) the origin and distribution channels of the infringing products,

2) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products, and

3) the identity of any third person involved in the production or distribution of infringing products.

V.1 Defendants are ordered, under penalty of a periodic fine of EUR 1,000 for each day of delay, within a period of one week from the date of service of the decision, to recall from the commercial customers the products described above under Item. I. that have been placed on the market since 17 March 2021, with reference to the infringement of the products determined by the Court and with the binding promise to pay any fees and necessary packaging and transport costs, as well as customs and storage costs associated with the return, and to take back the products to have them finally removed from the distribution channels.

V.2 This order does not extend to XL devices that have already been scheduled for implantation in an individual patient by 15 November 2024.

VI.1 Defendants are ordered, under penalty of a periodic fine 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 referred to above in Item I. and/or materials in their direct and/or indirect possession and/or ownership (including any products and/or materials that come into their direct and/or indirect possession and/or ownership pursuant to Item V above or otherwise) or, at its option, to hand them over to a bailiff to be appointed or commissioned by Claimant for the purpose of destruction.

VI.2 This order does not extend to XL devices that have already been scheduled for implantation in an individual patient by 15 November 2024.

VII. Claimant is allowed to publish the Court's decision in whole or in part, including the announcement of the decision, in five public media including industry journals of its choice. In the event that the publication is to be made in its entirety, the judgment handed down today is to be published in its entirety. In the event of partial publication, the full text of the rubric and the complete operational part of the judgment are to be made available.

VIII. Defendants are obligated to reimburse Claimant for any damages (including interest) incurred by Claimant since 17 March 2021 due to the actions described above under Item I. as well as those yet to be incurred.

IX. Defendants are ordered to pay preliminary damages of € 663,000 to Claimant within three weeks from the date of service of the decision.

X. Defendants are ordered to pay the costs of the proceedings, including those relating to the measures ordered above.

XI. All other applications and requests by the parties are rejected and dismissed.

XII. This decision is immediately and directly enforceable from the date of service in each Contracting Member State. No security payment is ordered.

INFORMATION ABOUT APPEAL

An appeal against the present Decision may be lodged at the Court of Appeal, by any party which has been unsuccessful, in whole or in part, in its submissions, within two months of the date of its notification (Art. 73(1) UPCA, R. 220.1(a), 224.1(a) RoP).

INFORMATION ABOUT ENFORCEMENT (ART. 82 UPCA, ART. ART. 37(2) UPCS, R. 118.8, 158.2, 354, 355.4 ROP)

An authentic copy of the enforceable decision or order will be issued by the Deputy-Registrar upon request of the enforcing party, R. 69 RegR

DETAILS OF THE DECISION

Order no. ORD_598479/2023 in ACTION NUMBER: ACT_459987/2023
UPC number: UPC_CFI_15/2023
Action type: Infringement Action

Done and delivered in Munich on 15 November 2024

Dr. Zigann Presiding Judge and Judge-rapporteur	Matthias ZIGANN Digital unterschrieben von Matthias ZIGANN Datum: 2024.11.11 14:46:26 +01'00'
Kokke Legally Qualified Judge	Margot Elsa KOKKE Digitally signed by Margot Elsa KOKKE Date: 2024.11.11 17:21:58 +01'00'
Pichlmaier Legally Qualified Judge	Tobias Günther Pichlmaier Digital unterschrieben von Tobias Günther Pichlmaier Datum: 2024.11.11 16:20:09 +01'00'
Dr. Wilhelm Technically Qualified Judge	Stefan Maria Wilhelm Digitally signed by Stefan Maria Wilhelm Date: 2024.11.11 16:55:55 +01'00'
for the Deputy Registrar	Anja Mittermeier Digital unterschrieben von Anja Mittermeier Datum: 2024.11.12 11:17:38 +01'00'