Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Local Division Munich
UPC_CFI_501/2023

Decision
of the Court of First Instance of the Unified Patent Court
Local Division Munich
concerning European Patent 3 669 828
issued on 4 April 2025

HEADNOTES

1. Art. 33(1)(b) UPCA allows multiple defendants to be sued at the domicile, principal place of business or, failing that, at the place of business of one of the defendants, provided that the defendants have a commercial relationship, and the action concerns the same alleged infringement. In the context of a European patent without unitary effect, the term "the same infringement" addresses situations where multiple defendants are accused of infringing the relevant national designations of the same European patent by the same product or process. Another interpretation would undermine the purpose of the Agreement on a Unified Patent Court to overcome the fragmented patent litigation landscape in Europe (preamble 2 of the UPCA).

2. For assessing whether an invention shall be considered obvious having regard to the state of the art, the problem-solution approach developed by the European Patent Office shall primarily be applied as a tool to the extent feasible to enhance legal certainty and further align the jurisprudence of the Unified Patent Court with the jurisprudence of the European Patent Office and the Boards of Appeal.

3. A cease-and-desist declaration without a penalty clause by one or two but not all defendants being members of a group of companies jointly infringing a patent cannot secure the patentee's interest in defending the exclusive nature of its right in the same way as a court order. The risk remains that the members of the group will re-organise their business around such isolated cease-and-desist declarations and thus continue to infringe the patent in the relevant territories without the risk of having to pay a penalty.

4. If a decision is immediately and directly enforceable from the date of service in each of the Contracting Member States pursuant to Rule 354.1 RoP no security must be lodged beforehand and there is no condition under Rule 118.2.a RoP. However, Rule 118.8 RoP must be complied with.

KEYWORDS

Jurisdiction; multiple defendants; commercial relationship; same infringement; cease and desist declaration without a penalty clause; danger of repetition; danger of first infringement; immediately enforceable; assessment of inventive step; problem solution approach.

CLAIMANT

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

represented by: Boris Kreye, Elsa Tzschoppe, Ioana Hategan
(Bird & Bird)

supported by: Bryce Matthewson, Siddharth Kusumakar, Daniel Down
(Powell Gilbert)
Bernhard Thum, Jonas Weickert
(Thum & Partner)

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 Gujarat - Vapi - IN

3) Meril Italy S.r.l.
Piazza Tre Torri 2 - 20145 - Mailand - IT

represented by: Andreas von Falck, Lukas Wollenschlaeger, Felipe Zilly
(Hogan Lovells)

PATENT AT ISSUE

European patent n° 3 669 828 B2

PANEL/DIVISION

Panel 1 of the Local Division Munich

DECIDING JUDGE/S

This decision was adopted by the Presiding Judge, Dr Matthias Zigann, acting as Judge-Rapporteur, the legally qualified Judge, Margot Kokke, LLM MSc, the legally qualified Judge, Tobias Pichlmaier, and the technically qualified Judge, Dr Stefan Wilhelm, LL.M.

LANGUAGE OF THE PROCEEDINGS

English

SUBJECT-MATTER OF THE PROCEEDINGS

Infringement action (ACT_597277/2023) with counterclaim for revocation (CC_23112/2024) and application to amend the patent (App_39429/2024). Preliminary objections (APP_8004/2024; APP_9990/2024).

DATE OF THE ORAL HEARING

11 February 2025

DATE OF THE ANNOUNCEMENT OF THE DECISION

4 April 2025

SUMMARY OF THE DISPUTE

The infringement action was filed by Edwards Lifesciences Corporation ("Edwards") against Meril Life Sciences PVT Ltd, Meril GmbH and Meril Italy S.r.l. (collectively "Meril") in the Local Division Munich on 27 December 2023 (ACT_597277/2023). Edwards alleges that Meril's “Myval” THV and its “Navigator” THV delivery device infringe independent claims 1 and 12 and dependent claims 2-11 and 13-14 of EP 3 669 828 ("the patent") titled "Prosthetic Heart Valve" and granted on 5 May 2021 (B1) and published in amended form (B2) on 26 June 2024.

Meril filed preliminary objections (APP_8004/2024; APP_9990/2024). The Judge-Rapporteur informed the parties pursuant to Rule 20.2 of the Rules of Procedure that the preliminary objections would be dealt with in the main proceedings.

Meril contests the alleged infringement and filed a counterclaim for revocation on 26 April 2024 (CC_23112/2024), invoking Arts. 76(1) and 123(2), 83, 54 and 56 EPC as grounds for revocation and argued that the patent was invalid in its entirety.

Edwards filed an application to amend the patent on 2 July 2024 (App_39429/2024), submitting AR 1-9, AR 3'-9' and AR 3''-9''.

An interim conference was held on 19 December 2024 at which various procedural motions of the parties were decided. Among other things, the ARs as filed by Edwards were admitted into the proceedings. Romania was also added to both the infringement action and the counterclaim (App_56822/2024).

The Court also invited the parties to submit physical objects or drawings to further illustrate the technical arguments, in particular with respect to the way in which parts of the leaflets are folded according to the patent, the contested embodiments and the relevant prior art cited in the counterclaim. The parties then produced various physical objects (App_4996/2025 - EDW-M-1-9 and App_4953/2025 - HL-CC-17-20).

The oral hearing before the Division took place on 11 February 2025 in Munich.

The patent at issue

The patent at issue (or patent in suit) is owned by Edwards. The patent is a first-generation divisional application of EP 2,624,785 (appl. No. 11831542.3). EP 2,624,785 is derived from PCT/US2011/054,973 filed on 5 October 2011 and published as WO2012/048,035A2 (referred to as "WO035") claiming priority from US 61/390,107 filed on 5 October 2010 ("P1") and US 61/508,513 filed on 15 July 2011 ("P2"). It should be noted that the specification of the divisional application underlying the patent (EP 19206328.7) is identical to the description of the original parent application (WO035) except that original claims 1-32 have been added at the end of the description of EP 19206328.7. Therefore, when the original disclosure is discussed below in relation to the disclosure of the earlier parent applications, reference is made only to the parent application (WO035).

The patent (in the B2 version as maintained by the Opposition Division of the EPO, see below) contains two independent claims, claim 1 and claim 12. Claim 1 is directed to an implantable prosthetic heart valve and claim 12 is directed to an assembly for implanting a prosthetic heart valve in a patient's body comprising a delivery device and an expandable prosthetic heart valve of any of claims 1-11.

An opposition to the patent was filed on 4 February 2002 by a third party, Abbott Cardiovascular Systems, Inc. of Santa Clara, USA. Oral proceedings were held before the Opposition Division (OD) on 28 September 2023. As a result, the patent was maintained in amended form with independent claims 1 and 12 as originally granted:

•Claim 1 of the claims maintained by the OD is the same claim as granted originally

•Dependent claim 9 as originally granted was deleted.

•The remaining claims were renumbered

•Claim 9 was amended to read as follows:

> *The prosthetic valve (10) of claim 1, wherein the prosthetic heart valve (10) further comprises an inner fabric skirt (1) positioned along an inner surface of the frame (12), wherein the inner skirt (16) is secured to the frame (12) via sutures (70).*

As no appeal was filed against the decision of the OD, this decision became final. A patent specification consistent with the OD decision was published on 6 June 2024 as EP 3 669 828 B2. Accordingly, the proceedings before the UPC must be based on the B2 specification.

The parties and the court refer to the separate features of claim 1 as follows:

Claim 1

Edwards Lifesciences Corpo
Meril Life Sciences Pvt Ltd.
Hogan Lovells Internatio

An implantable prosthetic heart valve (10), comprising:

1. *an annular frame (12) comprising a plurality of leaflet attachment portions (30); and*
2. *a leaflet structure (14) positioned within the frame (12) and secured to the leaflet attachment portions (30) of the frame (12),*
   - a) *the leaflet structure (14) comprising a plurality of leaflets (40),*
   - b) *each leaflet comprising*
     - (aa) *a body portion,*
     - (bb) *two opposing primary side tabs (116) extending from opposite sides of the body portion,*
     - (cc) *and two opposing secondary tabs (112) extending from the body portion adjacent to the primary side tabs (116), characterised in that*
3. a) *the secondary tabs (112) are folded about a radially extending crease*
   - b) *such that a first portion (142) of the secondary tabs (112) lies flat against the body portion of the respective leaflet (40),*
4. a) *and the secondary tabs (112) are folded about an axially extending crease*
   - b) *such that a second portion (144) of the secondary tabs (122) extends in a different plane than the first portion (142).*

The attacked embodiments

The action is directed against Meril`s implantable prosthetic heart valve “Myval” and the delivery apparatus “Navigator” as described in the Product and Process Description “PPD” (K25):

"Navigator" delivery apparatus

"Myval" prosthetic heart valve

The leaflet structure of the prosthetic heart valve is made up of three leaflets (p. 5 of the K25).

Fig. 4 below (reproduced from K25) shows one leaflet:

Figure 4

SUMMARY OF THE PARTIES' REQUESTS

Meril requests

to allow the preliminary objection to the extent requested and dismiss the action in part as inadmissible on the grounds of

– lack of jurisdiction of the Court (Rule 19.1(a) RoP) with regard to all requests insofar as the Claimant seeks a Decision with effect 'in the scope of the Agreement on a Unified Patent Court as of the date of the oral hearing, with the exception of Malta';

- the Court's lack of jurisdiction (R. 19.1(a) RoP), insofar as the requests, in particular the requests under points IV., V., VI., IX. and X., relate to periods prior to 1 June 2023;

- concerning the jurisdiction of the Local Division Munich (Rule 19.1 b) RoP) insofar as the Claimant brings an action against the third Defendant.

Edwards requests

to reject the preliminary objections in the main proceedings; and to

I. order Defendants to cease and desist with respect to

1) an implantable prosthetic heart valve, comprising: an annular frame comprising a plurality of leaflet attachment portions; and a leaflet structure positioned within the frame and secured to the leaflet attachment portions of the frame, the leaflet structure comprising a plurality of leaflets, each leaflet comprising a body portion, two opposing primary side tabs extending from opposite sides of the body portion, and two opposing secondary tabs extending from the body portion adjacent to the primary side tabs; characterized in that the secondary tabs are folded about a radially extending crease such that a first portion of the secondary tabs lies flat against the body portion of the respective leaflet, and the secondary tabs are folded about an axially extending crease such that a second portion of the secondary tabs extends in a different plane than the first portion,

(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 Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Romania, Slovenia or Sweden,

especially when

the second portion of each secondary tab is sutured to a respective primary tab,

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

and/or

the secondary tabs are positioned inside of the frame,

(dependent claim 3 of the Patent-in-Suit)

and/or

the first portion of each secondary tab pivots about the axially extending crease and lays flat against the second portion of the secondary tab when the prosthetic heart valve is collapsed to a radially collapsed configuration,

(dependent claim 4 of the Patent-in-Suit)

and/or

the first portion of each secondary tab comprises an inner edge spaced radially from an inner surface of the frame, and the body portion of the leaflet articulates about the inner edges of the two secondary tabs of the leaflet in response to blood 17.10.2024 Page 4 flowing through the prosthetic heart valve when the prosthetic heart valve is in operation within a patient's body,

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

and/or

the plurality of leaflet attachment portions comprises window frame portions each comprising an enclosed opening between first and second axially oriented side struts, and wherein the primary side tabs extend radially outwardly through respective commissure window frame portions to a location outside of the frame and are sutured to the secondary tabs to secure the leaflets around the side struts,

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

and/or

the prosthetic heart valve further comprises an annular outer skirt positioned around an outer surface of the frame, the outer skirt comprising an inflow edge secured to the frame at a first location, an outflow edge secured to the frame at a second location, and an intermediate portion between the inflow edge and the outflow edge; wherein when the prosthetic heart valve is in the expanded configuration, the intermediate portion of the outer skirt comprises slack in the axial direction between the inflow edge of the outer skirt

and the outflow edge of the outer skirt, and when the prosthetic heart valve is collapsed to the collapsed configuration, the axial distance between the inflow edge of the outer skirt and the outflow edge of the outer skirt increases, reducing the slack in the outer skirt in the axial direction,

(dependent claim 7 of the Patent-in-Suit)

and/or

the outflow edge of the outer skirt of the prosthetic valve of claim 7 comprises a plurality of alternating projections and notches, the projections being secured to the frame at the second location, the outer skirt being unsecured to the frame at the notches,

(dependent claim 8 of the Patent-in-Suit)

and/or the frame is made of a nickel-cobalt-chromium alloy, preferably a nickel-cobalt-chromium-molybdenum alloy,

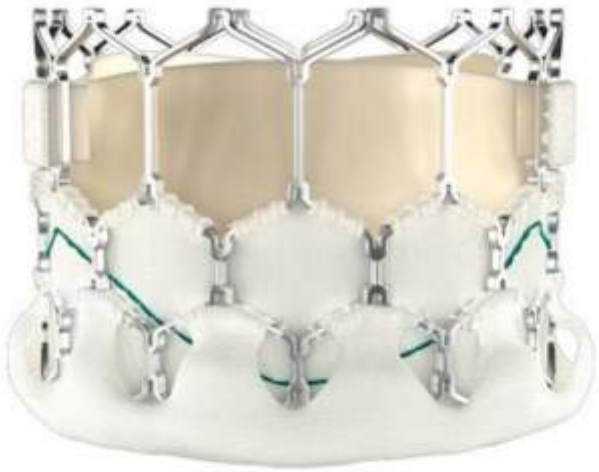
(dependent claim 11 of the Patent-in-Suit as granted / dependent claim 10 of the Patent-in-Suit as upheld)

and/or each of the plurality of leaflets further comprises: a free outflow edge portion extending between the primary side tabs adjacent to an outflow end of the frame; and an inflow edge portion extending between the primary side tabs adjacent to an inflow end of the frame, the inflow edge portion comprising opposing axial edge portions that extend from the primary side tabs toward the inflow end of the frame in a generally axial direction and an intermediate curved edge portion that extends between the axial edge portions, the intermediate edge portion comprising a curved apex portion adjacent to the inflow end of the frame and a pair of oblique portions that extend between the axial edge portions and the apex portion,

(dependent claim 12 of the Patent-in-Suit as granted / dependent claim 11 of the Patent-in-Suit as upheld)

especially when

the implantable prosthetic heart valve is a transcatheter prosthetic valve called "Myval" as shown below:



"Myval" prosthetic heart valve

2) an assembly for implanting a prosthetic heart valve in a patient's body, comprising: a delivery apparatus comprising an elongated shaft; and a radially expandable prosthetic heart valve of any one of claims 1 to 12 (as granted), respectively to 11 (as upheld), the prosthetic valve adapted to be mounted on the shaft in a radially collapsed configuration for delivery into the body,

(claim 13 of the Patent-in-Suit as granted / claim 12 of the Patent-in-Suit as upheld)

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 Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Romania, Slovenia or Sweden,

especially when the shaft has an inflatable balloon and the prosthetic heart valve is mounted over the balloon,

(dependent claim 14 of the Patent-in-Suit as granted / dependent claim 13 of the Patent-in-Suit as upheld)

especially when

the assembly comprises a delivery apparatus called "Navigator" and a prosthetic heart valve called "Myval" as shown below:

"Navigator" delivery apparatus

"Myval" prosthetic heart valve

II. order the Defendants to each pay penalty payments to the Court for each instance of non-compliance with the Order under Clause I. The penalty payments shall be set by the Court at an appropriate rate relative to the significance of the Order to be enforced, whereby an amount of EUR 20,000 is suggested for each instance of non-compliance and per defendant;

III. declare that the Defendants have infringed the Patent-in-suit with respect to the products identified in paragraph I above;

IV. the Court order 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 24 June 2020, specifying:

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

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

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

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) are to be submitted by Defendants as proof of the information, whereby confidential details outside the subject of the disclosure information may be redacted;

V. order the Defendants, under threat of a penalty payment of €1,000 for each day of delay, to take the following actions within one week of service of the Decision with regard to the products referred to in Section I. placed on the market since 5 May 2021, with reference to the legally established patent-infringing nature of the products, and with the binding commitment to take back the products and to bear any fees as well as necessary packaging and transport costs and customs and storage costs associated with the return, and to take back the products, with the proviso that these are then permanently removed from the distribution channels;

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

VII. order the Defendants to allow the Plaintiff to publish the Court's decision in whole or in part, including the publication of the decision in five public media and trade journals of its choice;

VIII. order the Defendants to publish the operative part of the Court's Decision on their websites;

IX. declare that the Defendants are obliged to compensate the Plaintiff for the damage (including interest) that the Plaintiff has suffered and will suffer as a result of the acts described in Section I above, committed since 5 May 2021;

X. order the Defendants to pay provisional damages to the Claimant, the amount being left to the discretion of the Court, but covering at least the foreseeable costs of the Claimant's claim for damages and compensation, and in any event an amount of at least EUR 663,000.00;

XI. order the Defendants to pay the costs of the action, including the costs of the measures sought under I. to VIII. above;

XII. include an Order of immediate enforcement in the Decision;

in the alternative, in the event that the plaintiff is ordered to provide security,

allow the plaintiff to provide this in the form of a bank or savings bank guarantee and to determine the amount of the security separately for each claim granted and for the basic decision on costs,

in the alternative,

allow the plaintiff to avert the enforcement of costs by providing security;

XIII. issue a default judgment in the event that the Defendants fail to act within the time limit provided for in these Rules of Procedure or set by the Court or fail to appear at an oral hearing after having been duly summoned.

Meril requests

that the patent in suit (EP 3 669 828 B2) be revoked in its entirety;

in the alternative:

that the patent in suit (EP 3 669 828 B2) be revoked in its entirety for all Contracting Member States in which EP 3 669 828 B2 has effect;

in the alternative:

that the patent in suit (EP 3 669 828 B2) be revoked with effect in the territories of the Contracting Member States for which the European Patent has effect at the time of the decision on the counterclaim for revocation, namely Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Romania, Slovenia and Sweden;

in the alternative:

that the patent in suit (EP 3 669 828 B2) be revoked with effect in the territories of the Contracting Member States for which the European Patent had effect at the time of the counterclaim for revocation, namely Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Slovenia and Sweden;

2. that Claimant and Counterclaim Defendant bear the costs of the proceedings.

3. the decision be put under the condition subsequent pursuant to Article 56(1) UPCA that the patent in suit is not held to be wholly or partially invalid by the final decision in respect of the counterclaim for revocation (in particular, if referred to the Central Division) (R. 118.2 lit. a) RoP);

4. in the event that Claimant fails to perform any action within the time limit provided for in the Rules of Procedure or set by the Local Division or fails to appear at an oral hearing after having been duly summoned, to issue a default judgment against Claimant.

5. the proceedings be stayed until the Court of Justice of the European Union has given a preliminary ruling pursuant to Article 267 para. 2 TFEU in accordance with Rules 295 lit. i), 266.5 sentence 1 RoP.

Edwards requests

I. the Counterclaim for revocation be dismissed;

in the alternative,

II. the patent in suit EP 3 669 828 B2 be maintained based on one of the proposed amendments (Auxiliary Requests 1 to 9, 3' to 9' and 3'' to 9'') within the scope of the territory of the Agreement on the Unified Patent Court at the time of the oral hearing - except in Malta - or, in the alternative, in Belgium, Bulgaria, Denmark, Germany, Estonia, Finland, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Portugal, Romania, Sweden and Slovenia, and the Counterclaim for revocation be dismissed insofar as the patent in suit is maintained as such; and in the further alternative,

III. the patent in suit EP 3 669 828 B2 be maintained within the scope of the territory of the Agreement on the Unified Patent Court at the time of the oral hearing - except in Malta - or, in the alternative, in Belgium, Bulgaria, Denmark, Germany, Estonia, Finland, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Portugal, Romania, Sweden and Slovenia, based on the independent validity of one or more of its dependent claims in combination with independent claim 1 or independent claim 12 of EP 3 669 828 B2 according to the dependencies of the claims of EP 3 669 828 B2 and the Counterclaim for revocation be dismissed insofar as the patent in suit is maintained as such;

IV. the Defendants be ordered to bear the costs of the proceedings;

V. in the event that the Defendants or any of them fail(s) to perform any action within the time limit provided for in the RoP or set by the Local Division or fail(s) to appear at an oral hearing after having been duly summoned, to issue a default judgment against such Defendant.

Meril requests

1. The patent be revoked in its entirety.

2. Auxiliary requests 1, 2, and 3 to 9, 3'-9', 3''-9'' be declared inadmissible.

3. Claimant to pay the costs of proceedings.

SUMMARY OF THE PARTIES' SUBMISSIONS

In its preliminary objections, Meril argues that the UPC lacks jurisdiction for actions directed to "the territory of the Agreement on a Unified Patent Court at the time of the oral hearing (except Malta)" and for actions relating to acts of infringement before 1 June 2023. Furthermore, the UPC does not have jurisdiction over Meril Italy.

Meril also argues that feature 2.b.aa (leaflet comprising a body portion) must be interpreted as requiring a V-shaped tip of the body portion. The "Myval" heart valve prosthesis does not infringe because the leaflets do not have a V-shaped but a rounded tip of the body portion.

Meril also argues that features 3a and 4a (radially and axially extending crease) are not restrictive. Thus, the prior art references are novelty destroying and render the subject matter of the patent claims at least obvious. Furthermore, the invention is not disclosed sufficiently clearly and completely for it to be carried out by a person skilled in the art.

In any event, corrective measures would not be proportionate because there is a public need for the Meril devices.

Edwards argues that the Unified Patent Court in general and the Local Division Munich in particular have jurisdiction over all claims and all defendants. The claim construction proposed by Meril is not convincing and must be rejected. Consequently, the patent is valid and infringed. Corrective measures would be proportionate, since sufficient alternative devices are available. Any remaining public need for XL devices continues to be adequately met by the existing medical request portal for the Myval valve prosthesis.

For further details reference is made to the grounds for the decision and to the parties' written pleadings.

GROUNDS FOR THE DECISION

In summary: the preliminary objections are widely rejected. The counterclaim is dismissed. The contested embodiment makes direct and literal use of the patent as upheld by the OD. Consequently, the relief sought is widely granted. The defence of proportionality is almost entirely rejected.

Preliminary objections

The preliminary objections are widely rejected.

1. Meril contended that the Court lacked jurisdiction (Rule 19.1(a) RoP) in respect of all the claims because the claimant sought a decision "within the area of application of the Unified Patent Court Agreement as of the date of the hearing, excluding Malta".

a. Meril understands the above cited wording in claimant's request as meaning that if, between the filing of the Statement of Claim on 1 June 2023 and the date of the hearing, additional member states in which the patent in question is validated ratify the UPCA, there will be an "automatic" extension of the action, which Meril considers inadmissible.

b. This question can remain unanswered because Edwards' request is improperly drafted and therefore invalid. It is the responsibility of the claimant to specify the exact territories for which relief is sought. This can be done either by including a list with the names of the Contracting Member States (CMS) for which relief is sought or by referring to the territory of those CMS for which the European patent has effect (UPC_CoA_523/2024 APL_51115/2024CoA - Sumi Agro/Syngenta, mn. 103-109). Although there are no transitional provisions in Art. 34 UPCA with the effect that upon ratification and accession by a UPC signatory state Art. 34 UPCA extends to that CMS from day one (UPC_CoA_523/2024 APL_51115/2024CoA - Sumi Agro/Syngenta, mn. 107), the relevant date for determining the relevant territories covered by the patentee's request is the date of filing of the statement of claim and not the date of the last oral hearing. Otherwise, the defendant would not have a clear picture of the territories for which he needs to prepare a defence and, in particular, file a counterclaim. Since Edward's main request relates to the date of the last oral hearing, it does not serve that purpose and is therefore inadmissible. However, the auxiliary request, which expressly mentions the territories in question (Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Romania, Slovenia or Sweden), is admissible.

2. Meril also contended that the Court lacked jurisdiction (R. 19.1(a) RoP) with respect to the claims, in particular those in Sections IV, V, VI, IX and X, relating to periods prior to 1 June 2023.

a. 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 prior to the entry into force of the Agreement on a Unified Patent Court on 1 June 2023.

b. This interpretation is incorrect. Reference is made to the decision of the Court of Appeal of 16 January 2025 (UPC_CoA_30/2024 APL_4000/2024).

3. Finally, Meril argued that the Local Division Munich does not have jurisdiction over Meril Italy.

a. Edwards argued that the Local Division Munich also had jurisdiction over Meril Italy under Art. 33(1)(b) UPCA. As already stated in the statement of claim (recital 301), the first and third defendants are wholly owned subsidiaries of the second defendant. As the "European headquarters", defendant 1 is responsible, inter alia, for the distribution of the infringing products in Europe, while defendant 3 is responsible for distribution in Italy, which is also part of the European market. In addition, defendant 2 supplies the infringing products to defendant 1 and, where appropriate, to defendant 3.

b. Art. 33(1)(b) UPCA allows multiple defendants to be sued at the domicile, principal place of business or, failing that, at the place of business of one of the defendants, provided that the defendants have a commercial relationship, and the action concerns the same alleged infringement. In the context of a European patent without unitary effect, the term "the same infringement" addresses situations where multiple defendants are accused of infringing the relevant national designations of the same European patent by the same product or process. Another interpretation would undermine the purpose of the Agreement on a Unified Patent Court to overcome the fragmented patent litigation landscape in Europe (preamble 2 of the UPCA).

c. In the present case, all three defendants are accused of infringing the respective national designations of the same European patent with the same attacked embodiments. Therefore, the requirement that the same infringement is concerned, is met. Furthermore, there is a sufficient commercial relationship between the three defendants. Defendant 2 is the parent company of Defendants 1 and 3 and the manufacturer of the attacked embodiments. Defendant 1 serves as the European headquarters of the group and is as such also responsible for Defendant 3, which is based in Italy.

The patent at issue and claim construction

1. Legal standard for claim construction

The principles of claim construction under Art. 69 EPC and the Protocol on its interpretation have already been explained by the Court of First Instance and the Court of Appeal in many decisions. However, with regard to the arguments presented in this case, it must be emphasised that a narrowing construction of a broader claim language (" Auslegung unterhalb des Wortlauts") on the basis of the description or drawings should only be allowed in exceptional cases (UPC_CFI_355/2023).

2. Background of the patent

The human heart can suffer from various valvular diseases. These valvular diseases can lead to significant dysfunction of the heart and ultimately require replacement of the native valve with an artificial valve. According to the patent specification, there are a number of known artificial valves and a number of known methods of implanting these artificial valves in humans ([0002] of the patent).

3. Prior art

There are several surgical techniques that can be used to replace or repair a diseased or damaged native heart valve ([0003] of the patent). One option is to replace the defective native valve with a prosthetic valve. Another less drastic method of treating defective valves is repair or reconstruction, which is typically used for minimally calcified valves. If the native valve is replaced, surgical implantation of the prosthetic valve usually requires open-chest surgery, during which the heart is stopped, and the patient is placed on cardiopulmonary bypass (a so-called "heart-lung machine"). In a common surgical procedure, the diseased native valve leaflets are removed, and a prosthetic valve is sutured to the surrounding tissue at the valve annulus ([0004] of the patent).

Due to the disadvantages associated with conventional open-heart surgery, percutaneous and minimally invasive surgical approaches are receiving considerable attention. In one technique, a prosthetic valve is configured to be implanted via catheterisation in a much less invasive procedure. For example, US Patent Nos. 5,411,522 and 6,730,118 describe collapsible transcatheter heart valves that can be delivered percutaneously in a compressed state on a catheter and expanded to the desired position by balloon inflation or by using a self-expanding frame or stent. Further examples of percutaneously deployable heart valves can be found in US 2009/240320, WO 03/047468 and US 2006/259136 ([0005] of the patent).

4. Underlying problem

The problem with surgical therapy is the significant risk it poses to these chronically ill patients, with high morbidity and mortality rates associated with surgical repair ([0003] of the patent). Due to the trauma associated with the procedure and the associated duration of extracorporeal circulation, some patients do not survive the surgical procedure or die shortly thereafter. It is well known that the risk to the patient increases with the duration of extracorporeal circulation. Because of these risks, a significant number of patients with defective native valves are considered inoperable because they are too frail to survive the procedure. It is estimated that more than 50 percent of patients

over the age of 80 with valve stenosis are ineligible for valve replacement surgery ([0004] of the patent). Due to the disadvantages of conventional open-heart surgery, percutaneous and minimally invasive surgical approaches have been developed ([0005] of the patent).

An important design parameter of a transcatheter heart valve is the diameter of the folded or crimped profile. The diameter of the crimped profile is important because it directly affects the physician's ability to advance the transcatheter valve through the femoral artery or vein. In particular, a smaller profile allows a larger patient population to be treated with improved safety ([0006] of the patent).

Against this background, the invention aims to provide an implantable prosthetic heart valve with a smaller crimped diameter on the one hand and sufficient safety, product reliability, security and longevity on the other hand as explained in [0018] of the general disclosure and with view to an exemplary embodiment in paragraph [0056] of the patent-in-suit.

5. Skilled person

Both parties agree that the skilled person is a team. While Edwards suggests that the team consists of a medical device engineer and an interventional cardiologist, Meril wants to add a cardiac surgeon to the team. The Court considers that the addition of a cardiac surgeon to the team is unnecessary since an implantable prosthetic heart valve is usually delivered via a catheter and an interventional cardiologist is familiar with catheter-based cardiac procedures. However, it should be noted that this in no way affects the outcome of the decision.

6. Solution

As a solution, the patent and the underlying patent application WO035 disclose several inventions such as heart valves including the respective frame geometry, delivery systems and assemblies comprising both delivery systems and heart valves. Claim 1 of the patent-in-suit is directed to an implantable prosthetic heart valve having the following features

Claim 1

Edwards Lifesciences Corpo
Meril Life Sciences Pvt Ltd. e

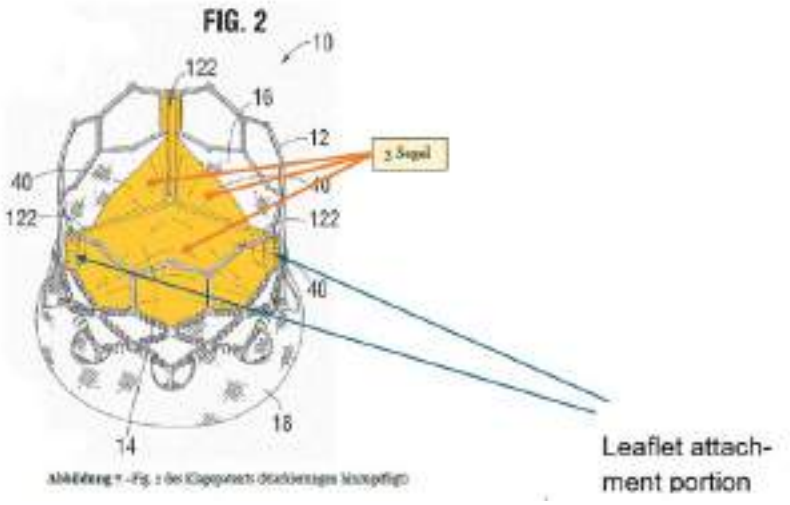
Hogan Lovells Internatio

An implantable prosthetic heart valve (10), comprising:

1. *an annular frame (12) comprising a plurality of leaflet attachment portions (30); and*
2. *a leaflet structure (14) positioned within the frame (12) and secured to the leaflet attachment portions (30) of the frame (12),*
   - a) *the leaflet structure (14) comprising a plurality of leaflets (40),*
   - b) *each leaflet comprising*
     - (aa) *a body portion,*
     - (bb) *two opposing primary side tabs (116) extending from opposite sides of the body portion,*
     - (cc) *and two opposing secondary tabs (112) extending from the body portion adjacent to the primary side tabs (116); characterised in that*
3. a) *the secondary tabs (112) are folded about a radially extending crease*
   - b) *such that a first portion (142) of the secondary tabs (112) lies flat against the body portion of the respective leaflet (40),*
4. a) *and the secondary tabs (112) are folded about an axially extending crease*
   - b) *such that a second portion (144) of the secondary tabs (122) extends in a different plane than the first portion (142).*

The invention as claimed in the patent-in-suit can best be understood with view to the exemplary embodiment disclosed in paragraphs [0049] - [0056] and Figs. 21 – 35.

The valve comprises a number of leaflets. A tricuspid configuration mimicking the construction of a natural heart valve is illustrated. The figure is reproduced from Edwards' statement of claim (German version), p. 29 SoC (with the term “leaflet attachment portion” and the corresponding arrows being added by the court).



“Fig. 2” indicates that it is a figure of the description of the patent. “Abbildung 7” refers to the numbering added by Edwards when displaying the figure in the SoC. Same applies to further figures.

An individual leaflet is shown below. It has a body portion (yellow), two opposing primary side tabs (116) (red) and two opposing secondary side tabs (112) (grey). The illustration is reproduced from Edwards' statement of claim, p.33 [German version].

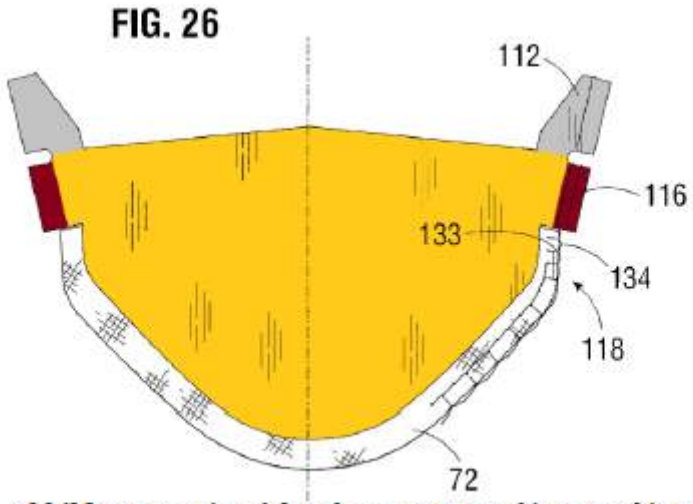


Abbildung 11 –Fig. 26 des Klagepatents (Markierungen hinzugefügt)

The leaflet structure 14 (= all three interconnected leaflets) is secured to the frame of the valve by the primary tabs 116 (red) and the secondary tabs 122 (grey) of the leaflets.

The operation of the primary tabs (red) in combination with the secondary tabs (grey) is described in the detailed description and the figures but is not part of the claims. The following passage relating thereto is reproduced from [0054], wherein the secondary tab is referred to as upper tab portion 112:

tor. As best shown in FIGS. 30 and 31, each upper tab portion 112 is creased lengthwise (vertically) to assume an L-shape having an inner portion 142 folded against the inner surface of the leaflet and an outer portion 144 folded against the connector 124. The outer portion 144 can then be sutured to the connector 124 along a suture line 146. Next, as shown in FIG. 31, the commissure tab assembly (comprised of a pair of lower tab portions 116 connected by connector 124) is inserted through the commissure window 20 of a corresponding window frame portion 30. FIG. 32 is a side view of the frame 12 showing the commissure tab assembly extending outwardly through the window frame portion 30.

The secondary tab 112 (grey) comprises a first (inner) portion 142 and a second (outer) portion 144. The first and second portions 142, 144 are subject to folding as required by features 3 and 4 of claim 1 (see below), mentioned after 'characterised in that' in the published version of the claims. The folding of the secondary tab thus constitutes the core of the invention.

Fig. 26 shown above provides for illustration purposes a vertically extending broken line running through secondary tab 112 depicted on the top right-hand side, illustrating the first (inner) and second (outer) portions (142, 144, respectively) of the secondary tab.

The folding of the secondary tab is carried out in two steps:

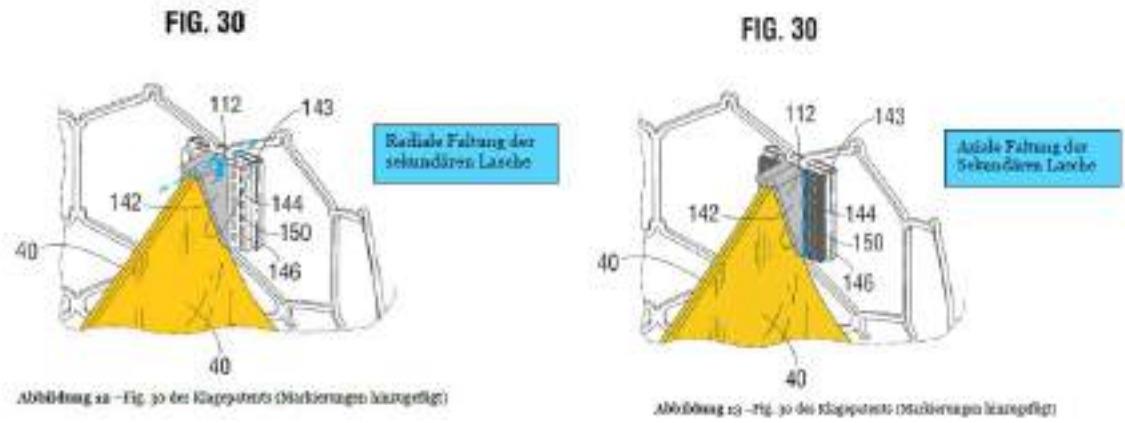
First, the secondary tab is creased longitudinally (vertically, in the direction of its length) so that it is folded about a radial axis.

Then, the second portion 144 is folded so as to obtain an L-shape of the secondary tab 112; this is obtained by folding the second portion 144 of the secondary tab 112 about an axial (vertical) axis.

This is shown in the following two versions of Figure 30, which are reproduced from Edwards' statement of claim, pages 34 and 35 (German version). Figure 30 depicted on the left shows the first folding step and the right Figure 30 shows the second folding step.

Both versions of Figures 30 illustrate the body portions of two leaflets (yellow) abutting each other. A perspective view of the body portion of only one of the two leaflets is shown.

The second leaflet is located behind the leaflet shown in the foreground. The second leaflet in the background also comprises primary and secondary tabs.

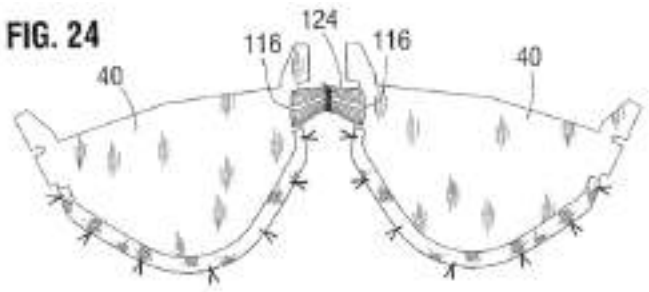


In the left-hand Figure 30, the first portion 142 of secondary tab 112 is folded longitudinally (vertically) in the first folding step about a radial axis shown in the left-hand Figure 30 as a dashed blue line. As a result of the first folding step, the first portion 142 of the secondary tab (light grey) lies flat on the body portion 40 of the leaflet (yellow).

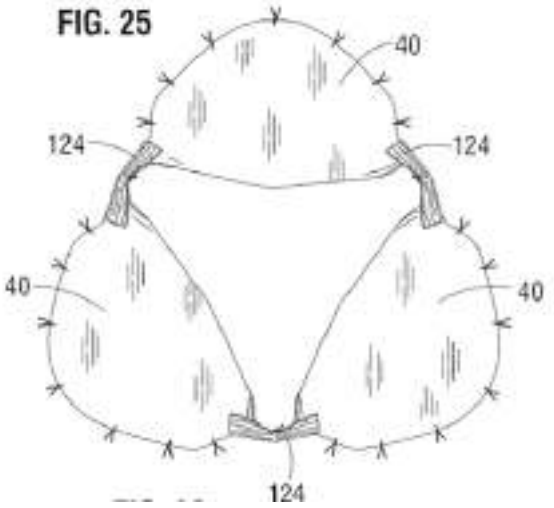
The second folding step of the secondary tab is shown at the right-hand Fig. 30 above. The second (outer) portion 144 of the secondary tab 112 is folded radially towards the first portion about an axially extending axis shown in the right-hand Figure 30 as a dashed blue line. As a result of the second folding step, the secondary tab has an L-shape comprising the second portion 144 of the secondary tab (dark grey) arranged perpendicularly to the first portion 142 of the secondary tab (light grey). The right-hand FIG. 30 thus shows two L-shaped secondary tabs belonging to the front and rear leaflets, respectively.

The manipulation of the primary tabs 116 is not part of claim 1 of the patent. The following is, however, mentioned for better understanding of the invention:

As shown in Figure 24 below, the primary tabs 116 of two adjacent leaflets are connected by a flexible connector 124. The resulting structure is also referred to as a commissure tab assembly (see [0054] cited above and Fig. 31):



When the third leaflet is fitted, the three leaflets of the valve are joined together as shown in Figure 25 below:



According to [0054] cited above, the commissure tab assemblies (primary tab 116 plus flexible connector 124) are inserted through the commissure windows 20 so that the leaflet structure of Fig. 25 is secured to the frame.

In practice, the leaflet structure of Fig. 25 is first secured to the commissure windows 20 of the frame via the primary tabs 116 and corresponding commissure tab assemblies before the secondary tabs are folded as described above and as claimed in claim 1.

The result of all the folding operations is shown below in a perspective view (Fig. 30) (left) and a corresponding cross-sectional view (Fig. 29) (right) (both figures taken from Edwards' claim):

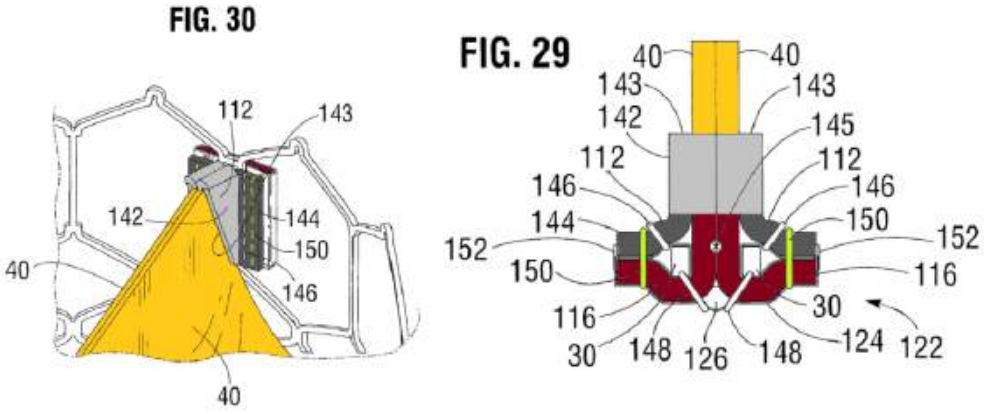


Abbildung 14 – Fig. 30 und 29 des Klagepatents (Markierungen hinzugefügt)

The primary tab 116 (red), inserted through the commissure window 30, sits opposite the second portions 144 of the secondary tabs (dark grey). The primary tab is positioned on the outside of the frame of the valve and is covered by the flexible connector 124.

The first portions 142 of the secondary tabs (light grey) are folded over and lie flat on the body portions of the leaflets (yellow). The second portion 144 of the secondary tab (dark grey) abuts the first portion 142 vertically. It should be noted that the second portion 144 of the secondary tab is located on the inside of the frame of the valve, opposite the primary tab that is located on the outside of the frame.

The advantages of this construction are summarised in [0018] and [0056]:

[0018] In some of these examples, the first portion of each the secondary tab pivots about the axially extending crease and lays flat against the second portion of the secondary tab when the valve is collapsed to a radially collapsed configuration. The first portion of each secondary tab comprises an inner edge spaced radially from an inner surface of the frame, and the body portion of the leaflet articulates about the inner edges of the two secondary tabs of the leaflet in response to blood flowing through the valve when the valve is in operation within a patient's body.

[0056] As shown in FIGS. 29 and 30, the folded down upper tab portions 112 form a double layer of leaflet material at the commissures. The inner portions 142 of the upper tab portions 112 are positioned flat abutting layers of the two leaflets 40 forming the commissures, such that each commissure comprises four layers of leaflet material just inside of the window frames 30. This four layered portion of the commissures can be more resistant to bending, or articulating, than the portion of the leaflets 40 just radially inward from the relatively more rigid four layered portion. This causes the leaflets 40 to articulate primarily at inner edges 143 of the folded-down inner portions 142 in response to blood flowing through the valve during operation within the body, as opposed to articulating about the axial struts of the window frames 30. Because the leaflets articulate at a location spaced radially inwardly from the window frames 30, the leaflets can avoid contact with and damage from the frame. However, under high forces, the four layered portion of the commissures can splay apart about a longitudinal axis 145 (FIG. 29) adjacent to the window frame 30, with each inner portion 142 folding out against the respective outer portion 144. For example, this can occur when the valve 10 is compressed and mounted onto a delivery shaft, allowing for a smaller crimped diameter. The four layered portion of the commissures can also splay apart about axis 145 when the balloon catheter is inflated during expansion of the valve, which can relieve some of the pressure on the commissures caused by the balloon and so the commissures are not damaged during expansion.

Thus, the above-mentioned problem, to provide an implantable prosthetic heart valve with a smaller crimped diameter on the one hand and sufficient safety, product reliability and longevity on the other hand is solved.

7. Some features require further explanation and construction.

a. Feature 2.b.aa "comprising a body portion"

aa. Meril's Interpretation

Meril submits in the context of the infringement test that the overall object of the patent is to provide a small(er) crimp profile and refers in that regard to paragraph [0006]:

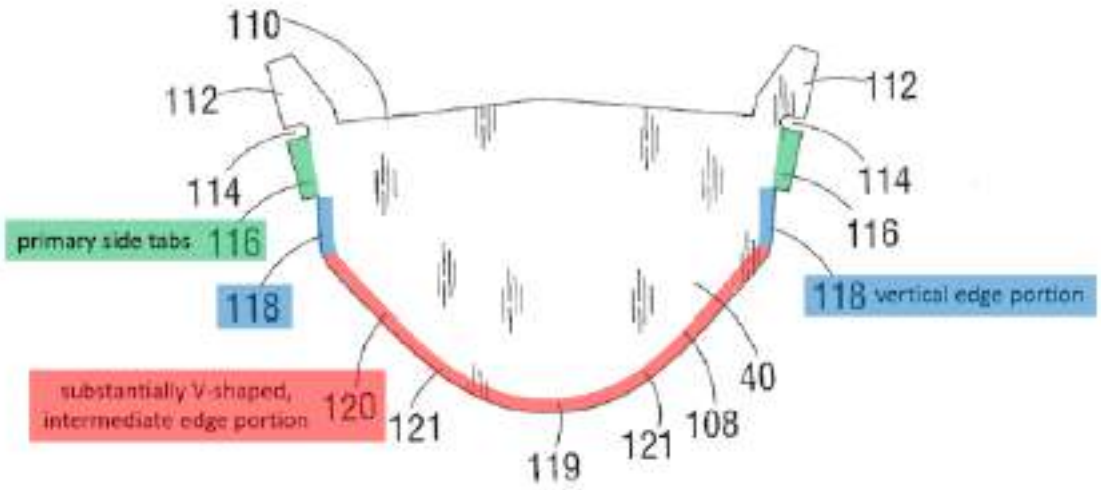
[0006] An important design parameter of a transcatheter heart valve is the diameter of the folded or crimped profile. The diameter of the crimped profile is important because it directly influences the physician's ability to advance the transcatheter heart valve through the femoral artery or vein. More particularly, a smaller profile allows for treatment of a wider population of patients, with enhanced safety.

This object is obtained by providing a tapered shape of the frame to make room for the attachment of an outer skirt according to paragraph [0008]:

[0008] An example of an assembly for implanting a prosthetic heart valve in a patient's body comprises a delivery apparatus comprising an elongated shaft and a radially expandable prosthetic heart valve mounted on the shaft in a radially collapsed configuration for delivery into the body. The prosthetic heart valve comprises an annular frame having an inflow end portion and an outflow end portion, and a leaflet structure positioned within the frame. The outer diameter of the inflow end portion of the frame is smaller than the outer diameter of the outflow end portion of the frame. The reduced diameter of the inflow end can be due to a reduce amount of materials positioned within the inflow end portion of the frame. The reduced diameter at the inflow end portion can make room for an outer skirt positioned around the inflow end portion.

In view of this, Meril argues that the objective problem of the patent requires leaflets having a "substantially V-shaped intermediate edge portion" 120 (red line) and a vertical edge portion (blue line):

FIG. 21



Meril submits that the shape is defined in paragraph [0049] in the sense of a legal definition using the patent as its own dictionary:

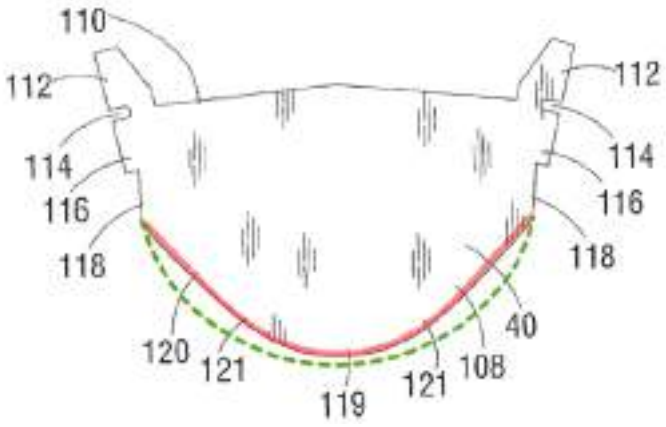
[0049] As noted above, the leaflet structure 14 can include three flexible leaflets 40 (although a greater or fewer number of leaflets can be used). As best shown in FIG. 21, each leaflet 40 in the illustrated configuration has an upper (outflow) free edge 110 extending between opposing upper tabs 112 on opposite sides of the leaflet. Below each upper tab 112 there is a notch 114 separating the upper tab from a corresponding lower tab 116. The lower (inflow) edge portion 108 of the leaflet extending between respective ends of the lower tabs 116 includes vertical, or axial, edge portions 118 on opposites of the leaflets extending downwardly from corresponding lower tabs 116 and a substantially V-shaped, intermediate edge portion 120 having a smooth, curved apex portion 119 at the lower end of the leaflet and a pair of oblique portions 121 that extend between the axial edge portions and the apex portion. The oblique portions can have a greater radius of curvature than the apex portion. Each leaflet 40 can have a reinforcing strip 72 secured (*e.g.*, sewn) to the inner surface of the lower edge portion 108, as shown in FIG. 22.

Meril further submits that this is also required on the basis of a functional claim construction because the V-shaped shape of the body portion ensures, according to paragraph [0060], that less leaflet material is present in the inflow portion of the valve, which supports a tapered shape of the valve ("can be at least partly due to"):

[0060] FIG. 56 shows the valve 10 of FIGS. 1-3 and 42-43 mounted on an elongated shaft 180 of a delivery apparatus, forming a delivery assembly for implanting the valve 10 in a patient's body. The valve 10 is mounted in a radially collapsed configuration for delivery into the body. The shaft 180 comprises an inflatable balloon 182 for expanding the balloon within the body, the crimped valve 10 being positioned over the deflated balloon. The frame 12 of the valve 10, when in the radially compressed, mounted configuration, comprises an inflow end portion 174 (see FIG. 54) that has an outer diameter D_2 that is smaller than the outer diameter D_4 of the outflow end portion of the frame. The tapering of the frame can be at least partially due to the V-shaped leaflets 40, as the V-shaped leaflets have less leaflet material within the inflow end portion of the frame 12 compared to a more rounded, U-shaped leaflet. Due to the tapered shape of the frame 12 in the mounted state, even with the additional thickness of the outer skirt 18 positioned around the inflow end portion 174 of the frame 12 the overall outer diameter of the inflow end portion of the valve 10 can be about equal to, or less than, the overall outer diameter of the outflow end portion of the valve.

This is illustrated in the below modified version of Fig. 21 of the patent taken from p. 22 of Meril's statement of defence where ".... a more rounded, U-shaped leaflet has been added for comparison purposes - see the green dashed line...." (sentence bridging from the bottom of p. 21 to top of p.22).

FIG. 21



The V-shape would be necessary to achieve the overall aim of the patent, i.e. a smaller crimping profile. Meril submits that, in view of this, feature 2 b) (aa) (=body portion) must be interpreted as "V-shaped body portion", i.e. limiting its literal meaning.

bb. Edwards' interpretation

Edwards argues that paragraph [0049] is in the example section of the patent and refers to the specific embodiment shown in Figure 21, which is referred to in paragraph [0049] as "the illustrated configuration" (see [0049] line 4 as reproduced above).

Claim 1, however, contains no such limitation. Edwards points out that it is settled case law in Germany that exemplary embodiments are generally not intended to limit or broaden the scope of an independent claim. A limitation is only possible in exceptional cases, e.g. if the technical teaching of the patent is only possible if the teaching of the narrower exemplary embodiment is applied. Insofar as Meril relies on the case law of the German Federal Court of Justice according to which a patent is to be regarded as "its own dictionary", such case law only applies if the claim uses a term which differs from its usual understanding in the CGK. This is not the case here, as the term "body portion" used corresponds to the terminology used by the person skilled in the art. Also, from a functional point of view, the patent does not require that the term "V-shaped leaflets" as used in paragraph [0060] reproduced above means that the leaflets have a strictly geometrical V-shape. This would be inconsistent with Figure 21 and paragraph [0049] and other passages of the specification summarised by Edwards as follows:

63. The Patent-in-Suit also clarifies in other parts of the description that the various exemplary embodiments do not have to have a geometrically exact "V" in order to be covered by the scope of claim 1. Indeed, para. [0049] refers only to a "substantially" V-shaped, intermediate edge portion (120). The examples in para. [0010] have a "generally" V-shaped leaflet. Para. [0024] describes Figs. 57 and 58 as having a "generally" V-shaped configuration. And para. [0067] only speaks of an "overall V-shape, similar to leaflets (40) described above". Therefore, the person skilled in the art learns from the different embodiments of the Patent-in-Suit that variations in shape may also be possible in order to achieve the described benefit of less leaflet material within the inflow end portion of the frame (12).

Edwards concludes that a precise V-shape of the body portion of a leaflet is not relevant to the function of the invention. The shape of the leaflets is referred to in dependent claim 11, which does not use the term "V-shape" but states that the intermediate portion of the edge portion of the leaflet has a curved apex portion (119) adjacent the inflow end of the frame (12) and a pair of oblique portions (121) that extend between the axial edge portions (118) and the apex portion (119): (based on [....] of the patent)

11. The prosthetic valve (10) of claim **1**, wherein each of the plurality of leaflets (40) further comprises:

a free outflow edge portion (110) extending between the primary side tabs (116) adjacent to an outflow end of the frame (12); and
an inflow edge portion (108) extending between the primary side tabs (116) adjacent to an inflow end of the frame (12), the inflow edge portion (108) comprising opposing axial edge portions (118) that extend from the primary side tabs (116) toward the inflow end of the frame (12) in a generally axial direction and an intermediate curved edge portion (120) that extends between the axial edge portions (118), the intermediate edge portion (120) comprising a curved apex portion (119) adjacent to the inflow end of the frame (12) and a pair of oblique portions (121) that extend between the axial edge portions (118) and the apex portion (119).

In view of this, a limitation of the term "body portion" of the leaflet, as suggested by Meril, cannot be inferred from the wording of the claims and/or the specification and the drawings.

cc. The Court's interpretation

The presence of V-shaped leaflets is optional and not mandatory. Claim 1 does not further specify the shape of the body portion of a leaflet, so that claim 1 broadly refers to valves with leaflets of any shape.

Paragraphs [0017] and [0018] of the general part and paragraphs [0049] - [0056] of the example part of the specification relate to the invention as claimed.

The term "V-shape" is only referred to in paragraph [0049] of this group of paragraphs:

[0049] As noted above, the leaflet structure 14 can include three flexible leaflets 40 (although a greater or fewer number of leaflets can be used). As best shown in FIG. 21, each leaflet 40 in the illustrated configuration has an upper (outflow) free edge 110 extending between opposing upper tabs 112 on opposite sides of the leaflet. Below each upper tab 112 there is a notch 114 separating the upper tab from a corresponding lower tab 116. The lower (inflow) edge portion 108 of the leaflet extending between respective ends of the lower tabs 116 includes vertical,

or axial, edge portions 118 on opposites of the leaflets extending downwardly from corresponding lower tabs 116 and a substantially V-shaped, intermediate edge portion 120 having a smooth, curved apex portion 119 at the lower end of the leaflet and a pair of oblique portions 121 that extend between the axial edge portions and the apex portion. The oblique portions can have a greater radius of curvature than the apex portion. Each leaflet 40 can have a reinforcing strip 72 secured (*e.g.*, sewn) to the inner surface of the lower edge portion 108, as shown in FIG. 22.

The substantially V-shaped shape of the body portion of the leaflet is referred to in [0049] as "in the illustrated configuration" and is therefore exemplary and not mandatory. It is true that a "generally V-shaped leaflet" is shown in Figs. 21-28 of the set of Figs. 21-31 relating to the claimed invention, but this is stated, for example, in [0024]:

FIGS. 21-28 show the assembly of an exemplary leaflet structure.

Such a subtantially V-shaped shape of the body portion of the leaflet is claimed in claim 11 that is dependent on claim 1, although the term “V-shaped” is not used in the claim language:

11. The prosthetic valve (10) of claim 1, wherein each of the plurality of leaflets (40) further comprises:

a free outflow edge portion (110) extending between the primary side tabs (116) adjacent to an outflow end of the frame (12); and
an inflow edge portion (108) extending between

the primary side tabs (116) adjacent to an inflow end of the frame (12), the inflow edge portion (108) comprising opposing axial edge portions (118) that extend from the primary side tabs (116) toward the inflow end of the frame (12) in a generally axial direction and an intermediate curved edge portion (120) that extends between the axial edge portions (118), the intermediate edge portion (120) comprising a curved apex portion (119) adjacent to the inflow end of the frame (12) and a pair of oblique portions (121) that extend between the axial edge portions (118) and the apex portion (119).

This underlines that a substantially V-shaped format of the leaflet is not a mandatory requirement for independent claim 1.

The technical considerations put forward by Meril do not justify a narrow interpretation of the term either.

Meril states on p. 21 of its defence to Edwards' claim in section 5:

5. The above understanding of the leaflet's body portion is further confirmed by a functional claim construction.

For the purpose of achieving a smaller crimped profile in the heart valve prosthesis, it is an indispensable feature that the leaflets are V-shaped. It is precisely this feature that ensures that less leaflet material is present within the inflow end portion of the frame (compared to a conventional rounded, U-shaped leaflet) and, consequently, allows the frame to assume a tapered shape. With such a tapered shape of the frame in the crimped state, the goal of an overall smaller crimped profile is achieved according to the patent in suit. The patent specification describes this effect in paragraph [0060] (emphasis added):

> [...] *The **tapering of the frame** can be at least partially **due to the V-shaped leaflets** 40, as the **V-shaped leaflets have less leaflet material within the inflow end portion of the frame 12 compared to a more rounded, U-shaped leaflet. Due to the tapered shape of the frame 12 in the mounted state**, even with the additional thickness of the outer skirt 18 positioned around the inflow end portion 174 of the frame 12 the **overall outer diameter of the inflow end portion of the valve 10 can be about equal to, or less than, the overall outer diameter of the outflow end portion** of the valve.*

It needs to be noted, however, that the above quoted passage of paragraph [0060] (yellow highlighting added by the Court) clearly states: "The tapering of the frame **can be at least partially due** to the V-shaped leaflets" (emphasis added).

The Patent discloses various ways of achieving a tapered configuration of the frame in the crimped state of the frame. An example is disclosed in paragraph [0012] of the general part of the specification as follows

> **[0012]** In some examples, the frame comprises an inflow row of openings at the inflow end portion of the frame, an outflow row of openings at the outflow end portion of the frame, and at least one intermediate row of openings between the inflow row of openings and outflow row of openings. The openings of the inflow row of openings are larger than the openings of the at least one intermediate row of openings.

The technical effect of this frame design is described in paragraph [0036] and illustrated in Figures 53 and 54:

[0036] Also, as can be seen in FIG. 5, the openings 36 of the lowermost row of openings in the frame are relatively larger than the openings 38 of the two intermediate rows of openings. As shown in FIG. 54, this allows the frame, when crimped, to assume an overall tapered shape that tapers from a maximum diameter D_1 at the outflow end of the valve to a minimum diameter D_2 at the inflow end of the valve. When crimped, the frame 12 has a reduced diameter region extending along a portion of the frame adjacent the inflow end of the frame, indicated by reference number 174, that generally corresponds to the region of the frame covered by the outer skirt 18. The diameter of region 174 is reduced compared to the diameter of the upper portion of the frame (which is not covered by the outer skirt) such that the outer skirt 18 does not increase the overall crimp profile of the valve. When the valve is deployed, the frame can expand to the cylindrical shape shown in FIG. 4. In one example, the frame of a 26-mm valve, when crimped, had a diameter D_1 of 14 French at the outflow end of the valve and a diameter D_2 of 12 French at the inflow end of the valve.

FIG. 5

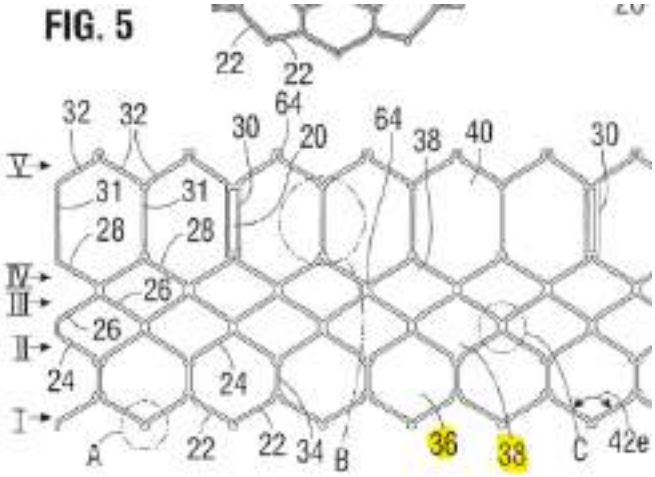


FIG. 53

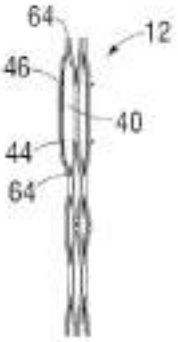
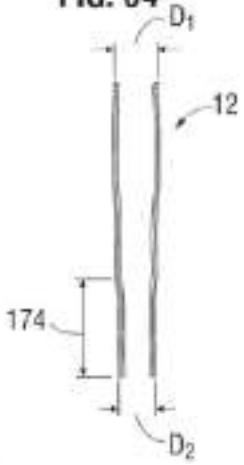


FIG. 54



In addition, the patent specification discloses another way of providing a tapered shape of the frame, e.g. in paragraph [0014] of the general part of the description as follows

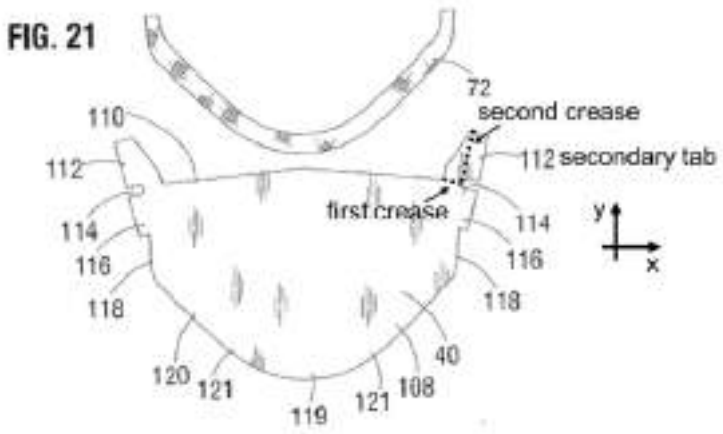
[0014] In some examples, the inflow end portion of the frame comprises a frame thickness that is less than a frame thickness of an intermediate portion of the frame between the inflow end portion and the outflow end portion.

Thus, the presence of V-shaped leaflets is only optional and not mandatory.

b. Features 3.a and 4.a "folded about a radially extending crease" and "folded about an axially extending crease"

aa. Meril`s interpretation

Meril argues in the context of the validity attack that the terms “radially extending” and “axially extending” are relative terms without a precise meaning at least in claim 1 as there is no indication in claim 1 that the leaflets are secured to the frame by the tabs. Also, in Figure 21, for example, both the radially and axially extending creases are inclined against the x- and y-directions respectively, i.e. not aligned with the flow axis of the valve and the radial axis which is perpendicular to the flow axis.



.

As a result, the terms "radially extending" and "axially extending" include orientations that are tilted relative to the x- and y-directions, so that these terms are not limiting and can be disregarded.

Meril further points out that the term "folding" describes a process step which, according to the case law of the EPO, only contributes to the patentability of a product claim if the process step results in a new constructional feature of the article. In the present case, the folding step would result in a double-layer structure of the secondary leaflet tabs, which could also be achieved by other means.

bb. Edwards` interpretation

Edwards argues that the terms "'radially" and "axially" are absolute and not relative. While relative terms such as thick/thin can have different meanings depending on the context, the terms "axially" and "radially" both refer to directions relative to the flow axis of the valve, which is an unambiguous reference axis. As a result, the terms "axially" and "radially" would describe concrete and specific spatial directions that are essentially perpendicular to each other.

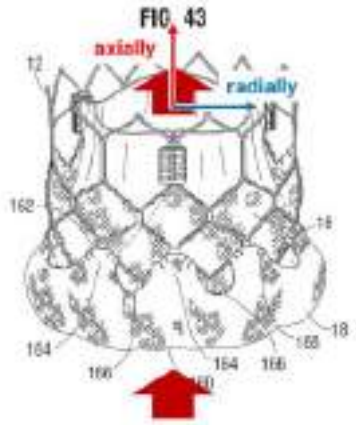


Figure 1: FIG. 43 of EP 828 (annotations added)

The terms "axially extending crease" and "radially extending crease" used in the patent claims do not have a strict geometric meaning as these terms are used in the technical context of a valve rather than in mathematics. Thus, for example, the term "radially extending crease" will be understood by those skilled in the art to mean that the crease extends substantially perpendicular to the axial direction of flow.

The radially extending fold, both in the assembled valve and in the flat-folded leaflet, can be seen from the following annotated figures provided by Edwards:

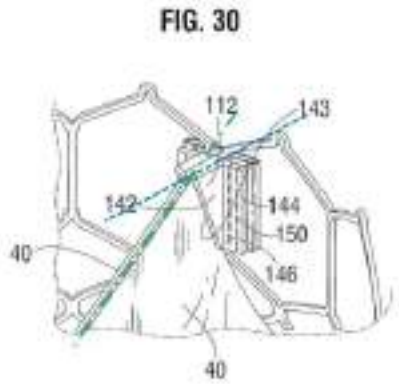


Figure 2: FIG. 30 of EP 828 (annotations added)

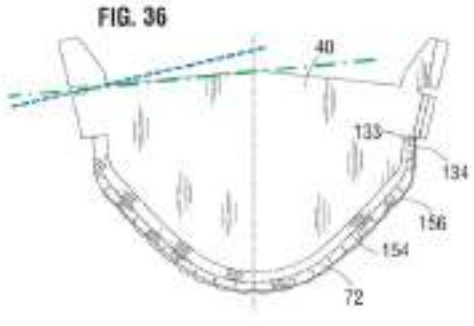


Figure 3: FIG.36 of EP 828 (annotations added)

Edwards argues that the orientation of the crease is represented by the dashed blue line, whereas the dashed green line would represent the direction of extension of the top edge of the leaflet. Therefore, the orientations of the crease and the top edge are not the same.

As to the issue of an alleged process feature in claim 1, Edwards argues that this issue is irrelevant because claim 1 includes the term "folded" rather than " folding". The terms "folded about radially or axially extending creases" provide clear structural limitations.

cc. The Court`s interpretation

The Court notes, first, that the terms 'axial direction' or 'axis' are used in the patent to mean the direction of the length of the frame or the direction of the flow of blood. This is clear, for example, from the following passages:

[0045] Thus, when the metal frame 12 is crimped (as shown in FIG. 18), the skirt 16 can elongate in the axial direction along with the frame and therefore provides a more uniform and predictable crimping profile. Each cell of the illustrated metal frame includes at least four angled struts that rotate towards the axial direction (*i.e.*, the angled struts become more aligned with the length of the frame). The angled struts of each cell function as a mechanism for rotating the fibers of the skirt in the same direction of the struts, allowing the skirt to elongate along the length of the struts. This allows for greater elongation of the skirt and avoids undesirable deformation of the struts when the valve is crimped.

[0015] Implantable prosthetic valves disclosed herein can be radially collapsible to a collapsed configuration and radially expandable to an expanded configuration. Such prosthetic valves can comprise an annular frame, a leaflet structure positioned within the frame, and an annular outer skirt positioned around an outer surface of the frame. The outer skirt can comprise an inflow edge secured to the frame at a first location, an outflow edge secured to the frame at a second location, and an intermediate portion between the inflow edge and the outflow edge. When the valve is in the expanded configuration, the intermediate portion of the outer skirt comprises slack in the axial direction between the inflow edge of the outer skirt and the outflow edge of the outer skirt, and when the valve is collapsed to the collapsed configuration, the axial distance between the inflow edge of the outer skirt and the outflow edge of the outer skirt increases, reducing the slack in the outer skirt in the axial direction.

The radial direction is the direction in which the valve expands or collapses and is perpendicular to the axial/blood flow direction; see, for example, the following passage:

[0016] In some of these examples, the outer skirt is not stretched in the axial direction when the valve is radially collapsed to the collapsed configuration and slack is removed from the intermediate portion of the outer skirt.

These definitions do not appear to be disputed by the parties and are also consistent with CGK in the field of transcatheter heart valves.

The Court agrees with Edwards that the terms “axial” and “radial” do not require a strict orientation along the y-axis in a mathematical sense but that a certain deviation from the x- and y-axis is possible. To the skilled person this is a clear teaching of the Patent-in-suit.

In claim 1 of the patent-in-suit the terms “radial” and axial” are disclosed when specifying that the secondary tab is folded about a radially and axially extending crease, respectively (features 3 and 4).

These features need to be considered in conjunction with features 1 and 2

An implantable prosthetic heart valve (10), comprising:

1. an annular frame (12) comprising a plurality of leaflet attachment portions (30); and

2. a leaflet structure (14) positioned within the frame (12) and secured to the leaflet attachment portions (30) of the frame (12),

   a) the leaflet structure (14) comprising a plurality of leaflets (40),

3. a) the secondary tabs (112) are folded about a radially extending crease

   b) such that a first portion (142) of the secondary tabs (112) lies flat against the body portion of the respective leaflet (40),

4. a) and the secondary tabs (112) are folded about an axially extending crease

   b) such that a second portion (144) of the secondary tabs (122) extends in a different plane than the first portion (142).

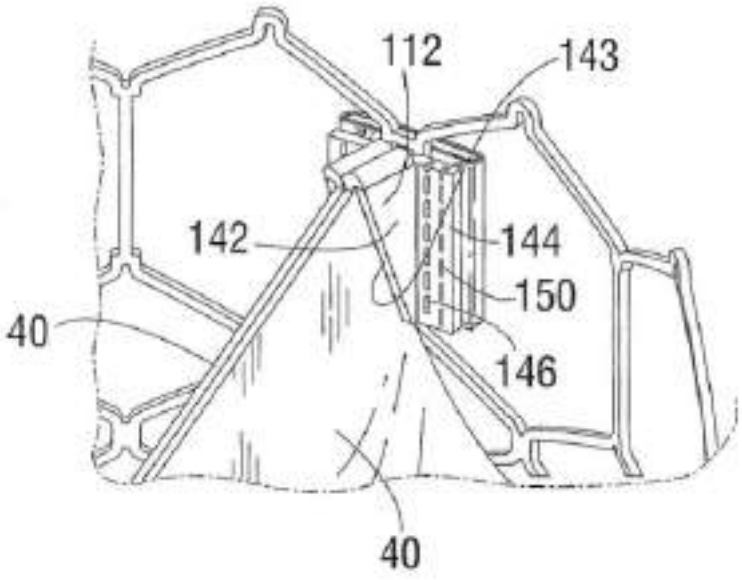
According to feature 1 the implantable prosthetic heart valves comprises an annular frame. The frame extends between an inflow and outflow end (e.g. [0010] and [0015] that extends along the axial (flow) direction and is thus (essentially) cylindrical in shape. The leaflet structure that comprises a plurality of leaflets (feature 2a) is positioned within the frame and secured to the leaflet attachment portion (commissure windows) of the frame (feature 2).

It follows from this that features 3a and 4a of claim 1 (folding about radially and axially extending creases, respectively) refer to the assembled leaflet structure as mounted into and secured to the frame.

According to [0054] of the Patent features 3a and 4a are illustrated in Fig. 30.

[0054] FIG. 29 is a cross-sectional view of a portion of the frame and leaflet structure showing the adjacent tab portions of two leaflets secured to a corresponding window frame portion 30. FIGS. 30-36 show one specific approach for securing the commissure portions 122 of the leaflet structure 14 to the commissure window frame portions 30 of the frame. First, as shown in FIG. 30, the flexible connector 124 securing two adjacent sides of two leaflets is folded widthwise and the upper tab portions 112 are folded downwardly against the flexible connector. As best shown in FIGS. 30 and 31, each upper tab portion 112 is creased lengthwise (vertically) to assume an L-shape having an inner portion 142 folded against the inner surface of the leaflet and an outer portion 144 folded against the connector 124. The outer portion 144 can then be sutured to the connector 124 along a suture line 146. Next, as shown in FIG. 31, the commissure tab assembly (comprised of a pair of lower tab portions 116 connected by connector 124) is inserted through the commissure window 20 of a corresponding window frame portion 30. FIG. 32 is a side view of the frame 12 showing the commissure tab assembly extending outwardly through the window frame portion 30.

FIG. 30



It can be seen that the second portion of the leaflet extends axially along the frame, and the same is true for the axially extending crease about such portion was folded. Due to

the L-shaped geometry of the folded secondary tab the radially extending crease is vertical relative to the axially extending crease.

As to Meril's argument that claim 1 lacks an explicit limitation that the leaflets are secured to the frame by the tabs, this is not correct in view of the clear language of features 1 and 2 of claim 1. The skilled person appreciates that the leaflet structure of claim 1 is part of an **implantable** prosthetic heart valve that is intended to function within a human heart. It is therefore clear to the person skilled in the art that the body portion of the leaflets must perform the function of controlling the flow of blood, while the tabs have the function to secure the leaflets to the frame. Consequently, the Court is satisfied that the features of "an axially extending crease" and "a vertically extending crease" are clearly and unambiguously disclosed and have a technical meaning because they characterise the position and the general direction of the extension of the creases of the assembled leaflet structure relative to the blood flow direction. They are not relative terms and cannot be disregarded.

Furthermore, the Court agrees with Edwards that the terms ''folding'' and ''folded'' are different. The term 'folded' does not describe a folding operation but is a structural feature describing the position of the creased tabs in relation to the body of the leaflet.

c. Leaflet to be composed of a single, unitary piece of material

aa. Meril's interpretation

Meril argues in the context of the validity attack that the patent does not require the leaflet to be made of a single, unitary piece of material; the body portion could be made of material being independent from the material of the tabs.

bb. Edwards' interpretation

Edwards refutes Meril's claim construction in this respect. The language of feature 2b) of claim 1 is clear and requires that the body portions of the leaflet and the side tabs are one piece.

cc. The Courts interpretation

The Court agrees with Edwards' claim construction.

Looking at the claim language as a whole, the skilled person will appreciate that each leaflet comprises a body **portion** and not a body **part**.

Furthermore, the primary and secondary side tabs **extend** from opposite sides of the body portion. In the case of leaflets with tabs composed of different parts, the skilled person would refer to the parts forming the side tabs as being attached to the body part. Not a single embodiment in the specification shows a multi-part leaflet. Consequently, there is no information as to how the different parts are attached to each other.

Finally, the secondary tabs are folded around a radially extending crease. In the case of a multi-part leaflet, there would be a place where the multiple parts are joined together. This location cannot be the crease. The skilled person would only refer to a crease in relation to a one-piece situation. If the leaflet could be composed of multiple parts, information would be needed to define the specific relationship between the place where the parts are joined and the crease. There is no such information in the specification.

Therefore, the patent is directed to a leaflet structure comprising only one-piece leaflets.

VALIDITY

Added matter

1. Legal Standard

Pursuant to Art. 65(2) UPCA and Art. 138(c) EPC, a European patent may be revoked with effect for a Contracting State on the ground that the subject-matter of the European patent extends beyond the contents of the application as filed or, if the patent was granted on a divisional application or on a new application under Article 61 EPC, beyond the contents of the earlier application as filed.

Thus, in order to determine whether there is added matter, the court must first determine what the person skilled in the art would deduce directly and unambiguously from the whole of the application as filed, using his common general knowledge and viewed objectively and in relation to the date of filing, whereby implicitly disclosed subject-matter, i.e. matter which is a clear and unambiguous consequence of what is expressly mentioned, is also considered to be part of the content of the application as filed. Where, as here, the patent is a divisional application, this requirement applies to each earlier application. The Court of Appeal notes that the assessment of added matter cannot be limited to those parts of the original application which the patentee has indicated as the basis for an amended claim during the examination proceedings before the EPO, since a proper understanding of those parts also requires an assessment of their content in the context of the disclosure of the application as a whole (UPC_CoA_382/2024 APL_39664/2024).

2. No added matter objection against claims 1-6

It is undisputed that claims 1-6, as granted and maintained by the OD, correspond to claims 16-21 of WO035, so there is no added matter issue with respect to these claims. Meril has not expressly conceded this but has not raised any added matter objections to these claims.

3. Dependent claims 7 and 8

a. Dependent claims 7 and 8 read as follows:

> **7.** The prosthetic valve (10) of claim 1, wherein the prosthetic heart valve (10) further comprises an annular outer skirt (18) positioned around an outer surface of the frame (12), the outer skirt (18) comprising an inflow edge secured to the frame (12) at a first location, an outflow edge secured to the frame (12) at a second location, and an intermediate portion between the inflow edge and the outflow edge; wherein when the prosthetic heart valve (10) is in the expanded configuration, the intermediate portion of the outer skirt (18) comprises slack in the axial direction between the inflow edge of the outer skirt (18) and the outflow edge of the outer skirt (18), and when the prosthetic heart valve (10) is collapsed to the collapsed configuration, the axial distance between the inflow edge of the outer skirt (18) and the outflow edge of the outer skirt (18) increases, reducing the slack in the outer skirt (18) in the axial direction.
>
> **8.** The prosthetic valve (10) of claim 7, wherein the outflow edge of the outer skirt (18) comprises a plurality of alternating projections and notches, the projections being secured to the frame (12) at the second location, the outer skirt (18) being unsecured to the frame (12) at the notches.

b. Meril`s argument

Meril submits that original claims 13 and 14 do not provide a basis for claims 7 and 8 of the patent because original claims 13 and 14 were not dependent on original claim 16 (corresponding to claim 1 of the patent B2) and because the disclosure of WO035 did not provide any indication that such a combination should be made.

Furthermore, claims 7 and 8 would be an intermediate generalisation with respect to original paragraphs [0007] and [0008] of WO035. [0008] discloses an assembly comprising a delivery device having an elongate shaft and a radially expandable prosthetic heart valve mounted on the shaft in a radially collapsed configuration. [0008] further discloses that the reduced diameter of the frame at the inflow end portion can make room for an outer skirt positioned around the inflow end portion. These features are absent from claim 7 as claimed.

c. Edwards` argument

Edwards points out that original claim 16 can be combined with original claims 13 and 14 in view of the overall teaching of WO035 and refers in this respect to Fig. 43 which shows the arrangement and folding of the primary and secondary side tabs as claimed in original claim 16, as further illustrated by reference to original Fig. 30.

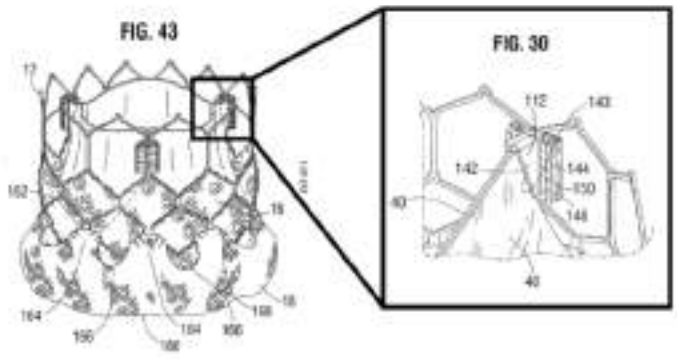


Fig. 43 is discussed in original paragraph [084], which discloses that the valve has an outer skirt which bulges outwardly as the frame shortens during radial expansion. It is also disclosed in [084] that "the slack between the lower and upper edges of the outer skirt 18 allows the frame 12 to expand axially during crimping without resistance from the outer skirt, and the outer skirt does not substantially affect the outer diameter of the prosthetic valve in the crimped position".

d. Meril's counterargument

Meril argues in its response to the defence that a combination of Figs 43 and 30 together with [084] does not disclose the subject matter of claims 7 and 8 as maintained by the OD because Fig 43 comprises several other features such as:

- The outer skirt shown in Fig. 43 has projections 164 and notches 166
- in Fig. 43, each projection 164 being sutured to the second row II of struts 24
- Claim 7 does not include the term "foreshortening" disclosed in [084].

e. The Court`s finding

The Court agrees with Meril that original claim 16 cannot be combined with original claims 13 and 14 because claims 13 and 14 are not dependent on claim 16.

However, the Court notes that original claim 16 can be combined with original paragraph [0015], which provides literal support for claim 7, as maintained by the OD. It is clear from the wording of [0015] that its disclosure can be applied to all valves of the invention, including the one shown in Figure 43 in combination with Figure 30 and paragraph [0084]:

[0015] Implantable prosthetic valves disclosed herein can be radially collapsible to a collapsed configuration and radially expandable to an expanded configuration. Such prosthetic valves can comprise an annular frame, a leaflet structure positioned within the frame, and an annular outer skirt positioned around an outer surface of the frame. The outer skirt can comprise an inflow edge secured to the frame at a first location, an outflow edge secured to the frame at a second location, and an intermediate portion between the inflow edge and the outflow edge. When the valve is in the expanded configuration, the intermediate portion of the outer skirt comprises slack in the axial direction between the inflow edge of the outer skirt and the outflow edge of the outer skirt, and when the valve is collapsed to the collapsed configuration, the axial distance between the inflow edge of the outer skirt and the outflow edge of the outer skirt increases, reducing the slack in the outer skirt in the axial direction.

[0015] does not specify that the outer skirt includes projections and notches, so these features are not mandatory. [0015] also does not specify the term " foreshortening", but discloses that when the valve is collapsed to the collapsed configuration, the axial distance between the inflow and outflow edges of the outer skirt increases (relative to such distance in the expanded configuration); this appears to be synonymous with the term "foreshortening" (cf. the definition of the term "foreshortening" as "shortening in length" in [084] of WO035). Hence this is covered by the term 'collapsable' of claim 1 which is part of claims 7 and 8 by reference. [015] also does not require the outer skirt to cooperate with an inner skirt, or that the outer skirt does not substantially affect the outer diameter of the prosthetic valve in the crimped condition. There is, consequently, no intermediate generalisation.

Since claim 7 was originally disclosed, support for claim 8 can be found in original claim 14.

Thus, claims 7 and 8 are originally disclosed.

4. Dependent claim 9

a. Claim 9 corresponds to claim 10 as granted with the addition of the feature highlighted in yellow:

> **9.** The prosthetic valve (10) of claim 1, wherein the prosthetic heart valve (10) further comprises an inner fabric skirt (16) positioned along an inner surface of the frame (12), wherein the inner fabric skirt (16) is secured to the frame (12) via sutures (70).

b. Merril's argument

Meril argues that original claim 22 cannot provide a basis for claim 9 of the patent-in-suit because claims 16 and 22 of WO035 are independent claims which cannot be combined unless a specific pointer could be identified in WO035. In addition, claim 22 would include features such as the valve being radially expandable and collapsible which are not included in claim 9. Also, claim 22 requires that the inner skirt comprises a weave of a first with a second set of strands, both of which are non-parallel to the axial direction of the valve. The same comments apply to paragraph [019] of WO035, which therefore also cannot provide a basis for claim 9 of WEO035.

c. Edwards` argument

Edwards points to the first sentence of paragraph [064] of WO035, reproduced below, and submits that this would provide literal support for claim 9:

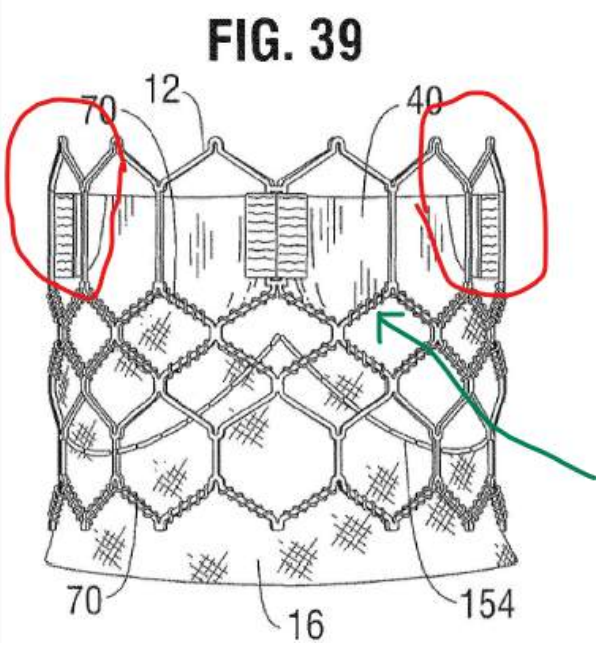
> [064] The skirt 16 can be secured to the inside of frame 12 via sutures 70, as shown in FIG. 39. Valvular structure 14 can be attached to the skirt via one or more thin PET reinforcing strips 72 (which collectively can form a sleeve), discussed below, which enables a secure suturing and protects the pericardial tissue of the leaflet structure from tears. Valvular structure 14 can be sandwiched between skirt 16 and the thin PET strips 72 as shown in FIG. 38. Sutures 154, which secure the PET strip and the leaflet structure 14 to skirt 16, can be any suitable suture, such as an Ethibond suture. Sutures 154 desirably track the curvature of the bottom edge of leaflet structure 14, as described in more detail below.

Edwards further argues that the literal disclosure for claim 9 in claim 22 and paragraph [019] of WO035 could be combined with the exemplary embodiment shown in Figures 43 and 30 of the patent specification.

d. The Court`s finding

The Court notes that the first paragraph of paragraph [064] of WO035 provides literal support for claim 9, whereas the other features disclosed in [064] are optional (see reproduction of [064] above).

Figure 39, referred to in [064], shows that the leaflets tabs are folded as required by claim 16 in combination with an inner skirt sutured to the frame with sutures 70 :



The OD had stated in its preliminary opinion on claim 10 as granted as follows

8.3 Claim 10 is preliminarily considered as having an intermediate generalisation.

The proprietor argues that the disclosure of the inner skirt throughout the description in many different embodiments means that it is not inextricably linked to specific features.

The opposition division are currently of the opinion that the wording "positioned along an inner surface of the frame" forms an intermediate generalisation as the inner skirt is qualified as being "secured" or "sutured" to the frame and not merely "positioned along" it.

The Court agrees with that statement and considers that the intermediate generalisation originally identified by the OD has been cured by the inclusion of the words "wherein the inner fabric skirt (16) is secured to the frame (12) via sutures (70)".

The Court also considers that the feature of a specific composition of the inner skirt comprising a weave of first and second sets of strands, both of which are not parallel to

the axial direction of the valve, is not intrinsically linked to the feature of the inner skirt being secured to the frame. It is true that both features are disclosed side by side in paragraph [019] of the general part of the specification of WO035 and in independent claim 22. It is also disclosed in [019] that the technical effect of this fabric construction is to allow the inner skirt "to elongate in the axial direction along with the frame". However, the Court notes that the specific construction of the fabric of the inner skirt is not inseparable from the securing of the inner skirt to the frame, since the inner skirt can alternatively be formed, for example, from woven elastic fibres (see [072]).

For these reasons, the Court concludes that claim 9 is originally disclosed.

5. Dependent claim 10

a. Claim 10 reads as follows:

> **10.** The prosthetic valve (10) of claim 1, wherein the frame (12) is made of a nickel-cobalt-chromium alloy, preferably a nickel-cobalt-chromium-molybdenum alloy.

b. Meril`s argument

Meril argues that a nickel-cobalt-chromium-molybdenum frame is only disclosed in [052] and [053] of WO035. [052] refers to Fig.4 and requires balloon expansion for frames made of plastically expandable materials. Similarly, the selection of nickel-cobalt-chromium-molybdenum represents a selection from several lists that was not originally disclosed.

c. Edwards` argument

Edwards refers to the OD's decision that paragraph [053] of WO035 discloses that the frame may be expanded by a balloon or equivalent expansion mechanism, i.e. a balloon is not mandatory. [053] discloses "suitable plastically expandable materials" so that any material selected from [053] is a plastically expandable material – therefore no selection is required. Also, the skilled person would understand that a nickel-cobalt-chromium-molybdenum material can be used for the frames disclosed in WO035 in general and is not intended to be used exclusively for the frame of Figure 4.

d. The Court`s finding

The Court agrees with the OD and Edwards for the reasons stated.

6. Dependent claim 11

a. Claim 11 reads as follows:

> **11.** The prosthetic valve (10) of claim 1, wherein each of the plurality of leaflets (40) further comprises:
>
> a free outflow edge portion (110) extending between the primary side tabs (116) adjacent to an outflow end of the frame (12); and
> an inflow edge portion (108) extending between the primary side tabs (116) adjacent to an inflow end of the frame (12), the inflow edge portion (108) comprising opposing axial edge portions (118) that extend from the primary side tabs (116) toward the inflow end of the frame (12) in a generally axial direction and an intermediate curved edge portion (120) that extends between the axial edge portions (118), the intermediate edge portion (120) comprising a curved apex portion (119) adjacent to the inflow end of the frame (12) and a pair of oblique portions (121) that extend between the axial edge portions (118) and the apex portion (119).

b. Meril`s argument

Meril argues that paragraph [010] of WO035 does not support claim 11 of EP828B2 because that paragraph does not specify opposing pairs of primary and secondary tabs. Paragraph [010] of WO035 is distinguished from paragraph [017] of WO035, which corresponds to claim 16 of WO035 and thus to claim 1 as maintained. Meril submits that paragraph [010] of WO035 refers to Figs 57 and 58 of WO035, which show leaflets comprising only one opposing pair of primary tabs.

c. Edwards` argument

Edwards refers to the decision of the OD that stated in mn. 18.4 of the decision:

> 18.4.2 The opposition division does not find these arguments convincing as the features of the claim relate to the leaflets in general and these leaflets are found not just in paragraph [010], but throughout the description and figures with the same configuration, so it is unambiguously understood that the general disclosure of paragraph [010] can be used with the other embodiments of the prosthetic heart valve.
>
> The opposition division finds that the wording "can" used in paragraph [010] renders the feature of the attachment location of the side tabs optional.

d. The Court`s finding

The Court agrees that the general disclosure of paragraph [010] can also be used with the leaflet structure of claim 16 of WO035. Paragraph [010] of WO035 provides literal support for claim 11:

[0010] In some examples, the leaflet structure can comprise a plurality of leaflets that each comprises opposing side tabs on opposite sides of the leaflet. The side tabs can be secured to the outflow end portion of the frame. Each leaflet can further comprise a free outflow edge portion extending between the side tabs adjacent to the outflow end of the frame and an inflow edge portion extending between the side tabs adjacent to the inflow end of the frame. The inflow edge portion can comprise opposing axial edge portions that extend from the side tabs toward the inflow end in a generally axial direction and an intermediate edge portion that extends between the axial edge portions. The intermediate edge portion can comprise a curved apex portion adjacent to the inflow end of the frame and a pair of oblique portions that extend between the axial edge portions and the apex portion. The oblique portions can have a greater radius of curvature than the apex portion, forming a generally V-shaped leaflet.

In addition, the leaflet exemplarily shown in Figure 21 of WO035 has all the features of claim 11, as shown in the annotated Figure 21 of WO035 provided by Edwards that is reproduced below:

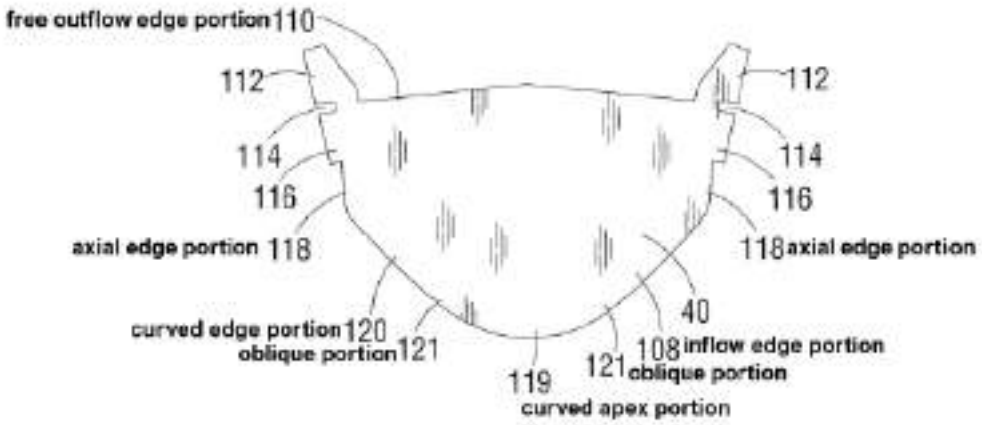


Figure 8: FIG. 21 of the Original Application (annotations added)

7. Independent claim 12 and dependent claims 13-14

a. These claims refer to an assembly for implanting a prosthetic heart valve and read as follows.

> **12.** An assembly for implanting a prosthetic heart valve (10) in a patient's body, comprising:
>
> a delivery apparatus comprising an elongated shaft (180); and
> a radially expandable prosthetic heart valve (10) of any one of claims 1 to 11, the prosthetic valve (10) adapted to be mounted on the shaft in a radially collapsed configuration for delivery into the body.
>
> **13.** The assembly of claim 12, wherein the shaft (180) has an inflatable balloon (182) and the prosthetic heart valve (10) is mounted over the balloon (182).
>
> **14.** The assembly of claim 12 or 13, wherein an outer diameter of an inflow end portion of the frame (12) is smaller than an outer diameter of an outflow end portion of the frame (12) when the prosthetic heart valve (10) is radially collapsed on the shaft.

b. Meril`s argument

Meril argues that claim 12 of EP828B2 is supported only by [0008] of WO035, whereas claims 1-9 of WO035 cannot provide a basis because the further features of those claims are not specified in claim 12. Paragraph [0008] requires the valve to be mounted on the shaft whereas claim 12 specifies that the valve is adapted to be mounted. Also, [0008] requires that "[t]he outer diameter of the inflow end portion of the frame is smaller than the outer diameter of the outflow end portion of the frame". This feature is absent from claim 12.

Meril argues in relation to claim 13 that only paragraph [0085] and Fig. 56 of WO035 cited therein refer to an elongate shaft bearing an inflatable balloon. Paragraph [0085] requires the frame of the valve to have a tapered shape, at least in part due to the presence of V-shaped leaflets. This feature is missing in claim 13, so there is an inadmissible intermediate generalisation.

> [085] FIG. 56 shows the valve 10 of FIGS. 1-3 and 42-43 mounted on an elongated shaft 180 of a delivery apparatus, forming a delivery assembly for implanting the valve 10 in a patient's body. The valve 10 is mounted in a radially collapsed configuration for delivery

into the body. The shaft 180 comprises an inflatable balloon 182 for expanding the balloon within the body, the crimped valve 10 being positioned over the deflated balloon. The frame 12 of the valve 10, when in the radially compressed, mounted configuration, comprises an inflow end portion 174 (see FIG. 54) that has an outer diameter D_2 that is smaller than the outer diameter D_1 of the outflow end portion of the frame. The tapering of the frame can be at least partially due to the V-shaped leaflets 40, as the V-shaped leaflets have less leaflet material within the inflow end portion of the frame 12 compared to a more rounded, U-shaped leaflet. Due to the tapered shape of the frame 12 in the mounted state, even with the additional thickness of the outer skirt 18 positioned around the inflow end portion 174 of the frame 12 the overall outer diameter of the inflow end portion of the valve 10 can be about equal to, or less than, the overall outer diameter of the outflow end portion of the valve.

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

c. Edwards` argument

Edwards rejects these attacks in a rather general way, as can be seen from its reply to the reply to the defence of the CC:

> 93. The unbiased person skilled in the art, when studying the original application in its entirety, will understand that the features of claims 12, 13, and 14 of EP 828 are general features applicable to several originally disclosed embodiments. They are not linked to specific features such as a relatively smaller outer diameter of an inflow end portion or the feature of V-shaped leaflets.

The OD addresses the original disclosure of claim 12 of EP828B" by referring to paragraph [0081] of WO031, which discloses an embodiment of claim 1 shown in Figures 29 and 30. The OD notes that this paragraph discloses a valve which is compressed and mounted on a delivery shaft. A tapered design of the frame having a larger diameter at the outflow end portion of the frame compared to the diameter of the inflow end portion is not disclosed in [0081], so that such a feature is optional. Therefore, claim 12 is originally disclosed.

The OD further argues in relation to claim 13 that paragraph [0008] is in the general part of WO035 and therefore broadly discloses the assemblies defined by claims 12 and 14. The OD notes that while paragraph [0008] discloses that the outer diameter of the inflow end of the valve is smaller than that of the outflow end to provide room for the outer skirt, that paragraph also states that this "may be due to a reduced amount of materials positioned within the inflow end portion of the frame".

[008] An exemplary embodiment of an assembly for implanting a prosthetic heart valve in a patient's body comprises a delivery apparatus comprising an elongated shaft and a radially expandable prosthetic heart valve mounted on the shaft in a radially collapsed configuration for delivery into the body. The prosthetic heart valve comprises an annular frame having an inflow end portion and an outflow end portion, and a leaflet structure positioned within the frame. The outer diameter of the inflow end portion of the frame is smaller than the outer diameter of the outflow end portion of the frame. The reduced diameter of the inflow end can be due to a reduce amount of materials positioned within the inflow end portion of the frame. The reduced diameter at the inflow end portion can make room for an outer skirt positioned around the inflow end portion.

Therefore, this feature and the effect it provides (making room for an outer skirt) are optional and need not be included in claim 13. Claim 13 is therefore originally disclosed.

With respect to claim 14, the OD concludes:

18.5.4 Furthermore, concerning the final argument with respect to claim 14, it is apparent that as the embodiments having a tapered diameter in paragraphs [061] and [085] are each linked to differing additional features then none of these features are inextricably linked to the feature of the frame being tapered.

Hence, claim 14 is also originally disclosed.

d. The Court`s finding

The Court agrees with the OD on these points.

Novelty

1. Legal Standard

Pursuant to Art. 65 (2) UPCA and Art. 138(a) EPC, a European patent may be revoked with effect in a Contracting State on the ground that the subject-matter of the European patent is not patentable under Articles 52 to 57 EPC.

For the purposes of Article 54 EPC, an invention is considered to be new if it does not belong to the state of the art. According to Article 54(2) EPC, the state of the art is to be taken to mean everything that has been made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application (or, where applicable, the priority date). The assessment of novelty under Art. 54 (1) EPC requires an examination of the entire content of the prior publication. It is decisive whether the subject-matter of the claim is directly and unambiguously disclosed with all its features in the prior art references (UPC_CFI_ 252/2023; UPC_CoA_182/2024).

2. Meril mentioned the following references in the counterclaim:

Reference no. CC	**Reference no. Opposition**	**Document no.**	**Main inventor "nick name" used in pleadings**
HL-CC 5	D11	US 2006/259,136 A1published 16 November 2006	Nguyen
HL-CC 6	D2	US 2009/0,157,175 A1 published 18 June 2009	Benichou
HL-CC 7	-	US 6,767,362 B2 published 24 July 2004	Schreck
HL-CC 8	D3	US 2004/0,186,563 A1 published 23 September 2004	Lobbi
HL-CC 9	D1	WO 2007/013,999 A2 published 1 February 2007	Jaramillo
HL-CC 10	D4	WO 2009/042,196 A2 published 2 April 2009	Braido
HL-CC 11	D9	US 2006/0,259,137 A1 published 16 November 2006	Artof
HL-CC 12	-	Chapters 2, 7, 8, 18, 21 and Appendices 3, 4 from	-

		Serruys, P. W., Piazza,N., Cribier, A., Webb, J. G., Laborde, J. C., & de Jaegere, P. (2009). Transcatheter Aortic Valve Implantation, informa healthcare	
HL-CC 13	-	Feldman, T., & Leon, M. B. (2007). Prospects for percu-taneous valve therapies. Circulation, 116(24), 2866-2877.	-
HL-CC 14	D5	US 2010/0036484 A1 (“Hariton”), published 11 February 2010	
HL-CC 15	-	US 6,730,118 B1	Spenser
HL-CC 16	-	Grube et al., JACC vol. 50, no. 1, 2007:69-76, 3 July 2007	Grube
HL-CC P1	P1	US 61/390,107 (first priority document)	
HL-CC P2	P2	US 61/508,513 (second priority document)	

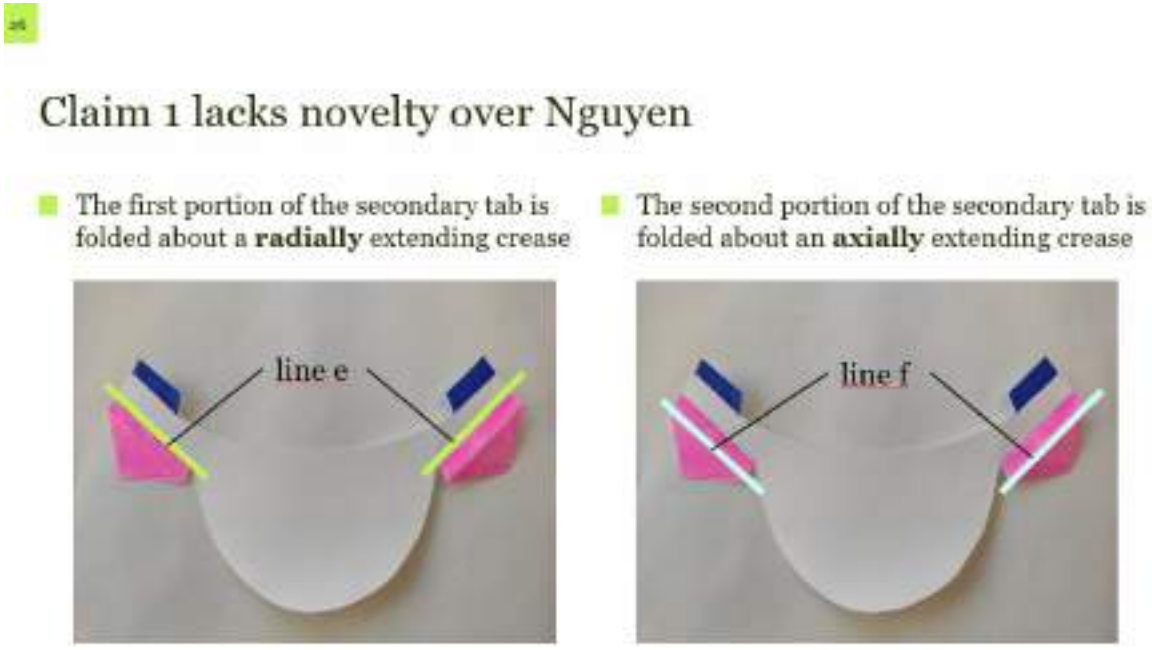
Prior art references HL-CC 15 and HL-CC 16 were filed late. Meril filed these references with the reply to the defence dated 2 September 2024, without giving any reason for the late filing. The Court therefore disregards the late filed prior art references and the arguments relating to them (Rule 9.2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

3. Nguyen

a. Meril`s argument

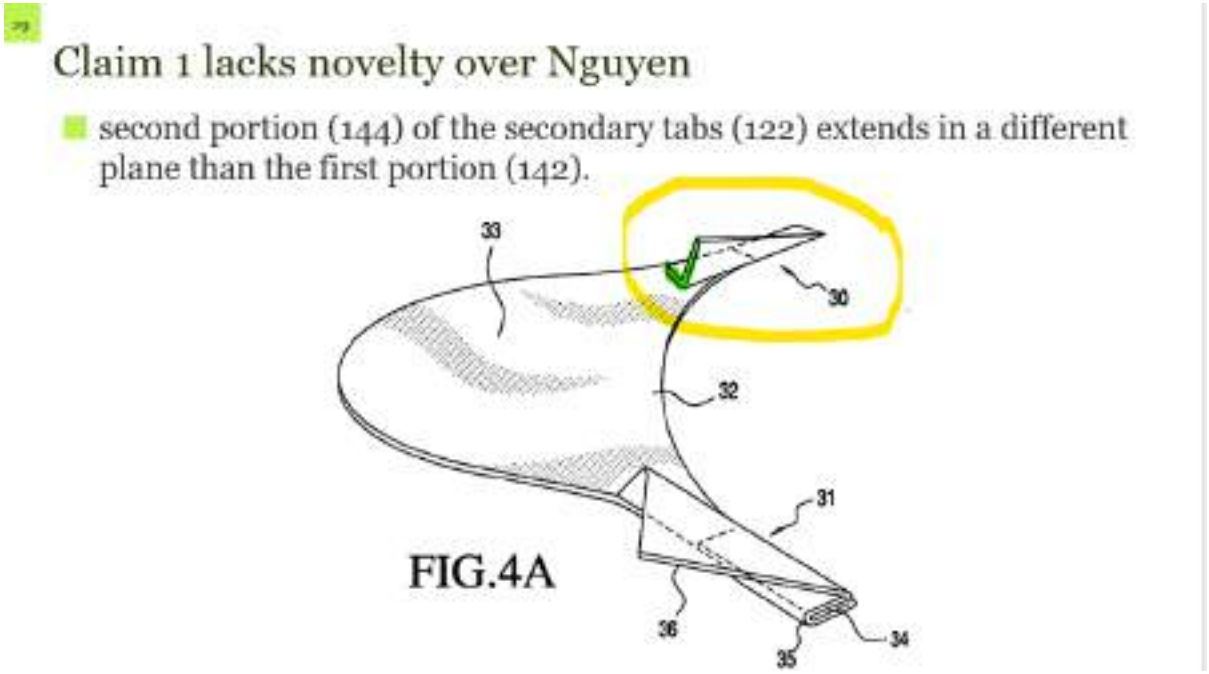
Meril argues, based on its claim construction discussed above, that the terms "axially and radially extending creases" are non-limiting relative terms that cannot establish novelty over Nguyen.

During the oral hearing Meril has shown the slide reproduced below that show a leaflet of Nguyen in the non-assembled state.



Meril argues that fold line e is a radially extending crease whereas fold line f is an axially extending crease although both fold lines extend in parallel to each other. Since the fold lines would not extend in the axial direction, they would both have a radial and an axial component. According to Meril it depends on the result of folding what component of the fold line "prevails". By folding flap 35 along line e, it lies atop flap 34, forming seam 42 comprising a triple thickness of the tissue (Nguyen, p.4, right col., paragraph [0053]). This would be functionally equivalent to the folding of the first portion of the secondary tab 112 in claim 1 along a radially extending crease so that it lies flat against the body portion of the respective leaflet.

Contrary to that, flap 36 of Nguyen is folded along line f so that it extends in a different plane than flaps 34 and 35 (slide 29 of Meril presented during the oral hearing; highlighting added). Therefore, line f would qualify as an axially extending fold line



As a result, Nguyen discloses all features of claim 1 of the patent.

b. Edwards' argument

Edwards refers to its claim construction and argues that Meril's claim construction of feature groups 3 and 4 is incorrect. Edwards points out that Nguyen has three flaps on each side which are folded along fold lines d, e and f, all of which are parallel to each other and extend axially in the assembled valve. Therefore, there is no teaching in Nguyen that the tabs are folded along radially extending creases. Furthermore, the tabs in Nguyen are all folded so that they lie on top of each other and thus extend in the same plane of space.

Edwards also submits that the teaching provided by Nguyen is insufficient. Flaps 36 would extend outwardly in Fig. 4A but inwardly in Fig. 4B. This would be inconsistent, and it would be completely unclear how the arrangement of Fig. 4B can be obtained.

c. The Court`s finding

The Court notes that Nguyen (FL-CC5) was also on file as D11 in the opposition proceedings, but didn't play a major role there.

Nguyen discloses a heart valve with three leaflets 22 ([038] of Nguyen). A leaflet is shown in annotated Figure 3A below (taken from Meril's counterclaim for revocation, p. 41):

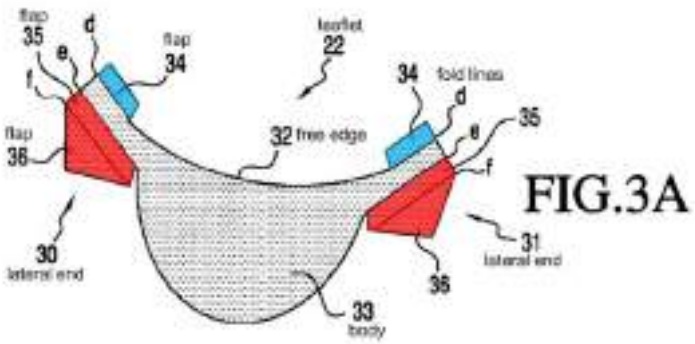


FIG.3A

A leaflet comprises three opposite pairs of tabs 34, 35, 36 on opposite sides of the body 33. The tabs are folded (Figs. 3A, 4A) about fold lines d, e and f and inserted into the skirt 21 of the valve to provide the assembly of valve body 14 (Fig. 4B).

[0053] Referring to **FIGS. 4A and 4B**, assembly of valve body **14** from skirt **21** and leaflets **22** is described. In **FIG. 4A**, flap **34** first is folded along line d. Flap **35** is folded along line e so that it lies atop flap **34**, forming seam **42** comprising a triple thickness of the tissue. Flap **36** then is folded along line f. Adjoining leaflets **22** then are fastened together along adjacent seams **42**, resulting in a leaflet assembly.

[0054] Reinforcing tabs **38** are folded along lines g, h and i to form seams **43** comprising a double thickness of tissue. Next, the leaflet assembly is attached to skirt **21** along the bottom edges of bodies **33** of the leaflets to form joints **44**. At this stage of the assembly, prior to attaching reinforcing tab **40** to **41** and the remaining seam **43** of leaflets **22**, the valve body appears as depicted in **FIG. 4B**. Reinforcing tabs **40** and **41** then are fastened together to form another seam **43** along skirt **21** and the remaining seam **43** between leaflets **22**. Valve body **14** then is ready to be affixed to frame **12**.

This is shown in the following annotated Figures 3A, 3B, 4A and 4B of Nguyen; the annotated figures are taken from Edwards' defence to the CC:

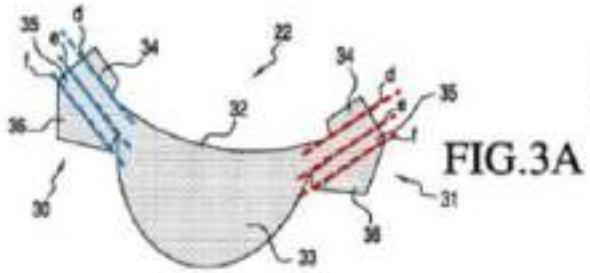


FIG.3A

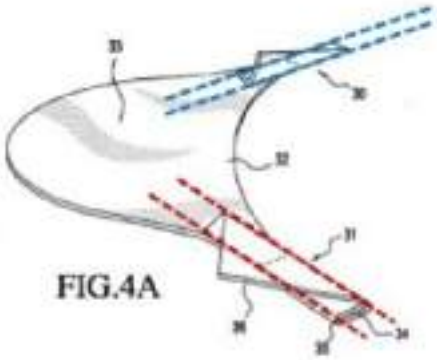


FIG.4A

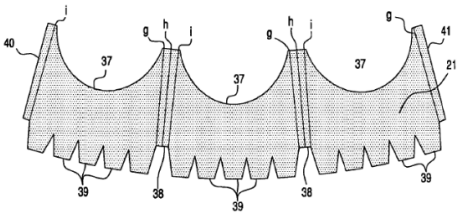


FIG.3B

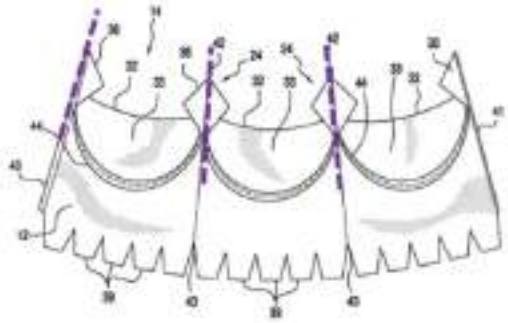


FIG.4B

Fig. 3A shows a leaflet 22 having a body portion 33 and lateral ends 30, 31 which each comprise tabs 34, 35 and 36. Three tabs 34, 35, 36 are folded about fold lines d, e and f that are parallel to each other. Flap 35 is folded along line e so that it lies atop flap 34 forming seam 42 comprising a triple thickness of the tissue ([0053]). Figure 4A shows the three tabs 34, 35 and 36 in a folded condition.

The seams 43 are formed by folding reinforcing tabs 38 about fold lines g, h and i, and by fastening together reinforcing end tabs 40 and 41 ([0054] and Fig. 3B).

Figure 3B shows the skirt 21 of the valve. Fig. 4B shows that adjacent leaflets 22 and the skirt 21 are joined) along seams 42 and 43 The leaflet assembly is attached to the skirt 21 along the lower edges of the leaflet bodies 33 forming the joint 44. The valve body 14 shown in Figure 4B is closed to form an annular body which is then attached to the frame 12 via the folded tab assemblies.

During the oral hearing, Meril showed a modified version of Fig. 4A that shows the leaflet in a position with that the leaflet is assembled into the skirt and the valve (modified Fig. 4A below on the right). This can be compared with original Fig. 4A of Nguyen that shows the leaflet in an arbitrary position (Fig. 4A on the left).

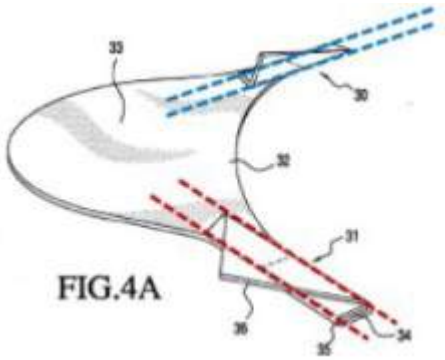


FIG.4A

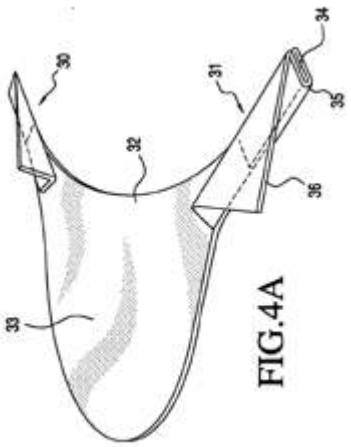


FIG.4A

The parallel folding lines d, e and f are arranged essentially <u>axially</u> when the leaflet is displayed in the assembled state. The slight deviation from the axial direction is removed when the valve body 14 shown in a flattened-out configuration in Fig. 4B is closed to a cylindrical configuration that is inserted into the frame (Fig.6).

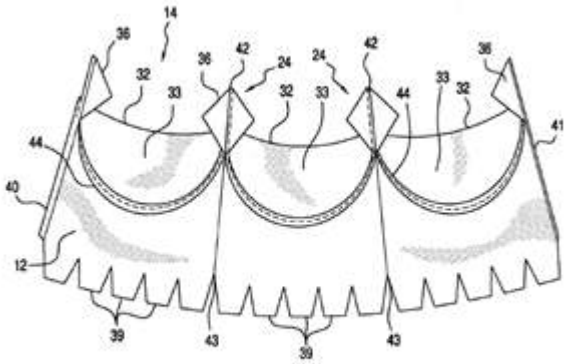


FIG.4B

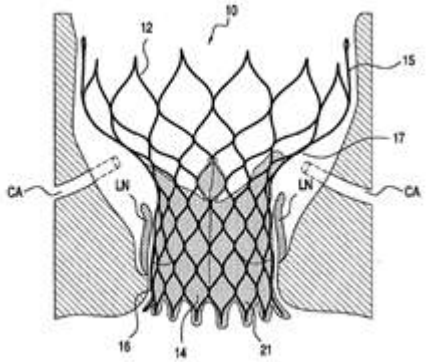


FIG.6

Therefore, all tabs of the leaflets of Nguyen are folded about parallel and axially (vertically) extending fold lines in the assembled valve body 14. There are no secondary tabs folded about a radially extending fold or fold line.

Thus, Nguyen does at least not disclose a radially extending fold line.

Furthermore, in the assembled state, all tabs 34-36 extend in the same plane (see [0055] and Figs. 4A and 6).

Therefore, Nguyen does at least not disclose features 3a, 3b and 4b and the patent-in-suit is novel over Nguyen.

4. Benichou

Meril has not referred to Benichou as a novelty-destroying reference in its reply to the defence to the CC for revocation and its presentation in the oral hearing anymore. In case this argument is nevertheless to be understood to be maintained, the following applies:

a. Meril`s argument

Meril's argument is based solely on the claim construction according to that the patent does not require that the leaflets be made of a single, unitary piece of material; they could also be made of a composite material.

b. Edwards` argument

Edwards again rejects Meril's claim construction. The language of feature 2b) of claim 1 is clear and requires that the body portions of the leaflet and the side tabs be made of the same material.

c. The Court`s finding

The Court notes that Benichou is on file in the CC proceedings as HL-CC 6 and corresponds to D2 in the opposition proceedings.

Benichou generally discloses a two-part foldable frame of a valve with an upper and a lower portion, each of the two portions being formed with rounded arcuate portions. The arc portions are separated by a gap 282 which sandwiches the leaflet attachment portions 314 (see Figs 5 and 6 of Benichou).

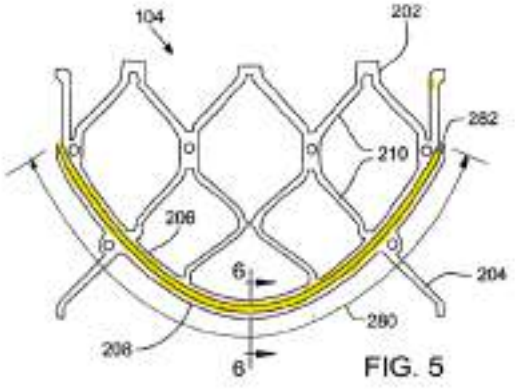


FIG. 5

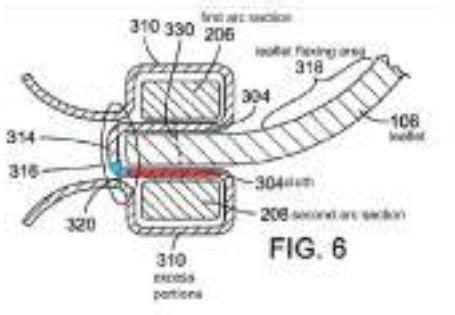


FIG. 6

Figure 6, taken from Meril's CC for revocation, p. 50, is taken along line 6-6 in Figure 5. Figure 6 shows that the leaflet is inserted into the gap between the upper and lower parts of the frame. The leaflet is attached to the first and second arch portions of the respective parts of the frame by fabric 304.

Figure 7 of Benichou shows a leaflet 106 (green) having a U-shaped bottom edge line. A plurality of fabric (or cloth) portions 310 are sutured to the leaflet via suture lines 330. The fabric portions are folded around the edge of the leaflet as shown in Figure 8 and then inserted into the gap between the upper and lower portions of the frame as shown in Figure 6. The upper and lower fabric portions are folded around the first and second arc portions as shown in Figure 6 above.

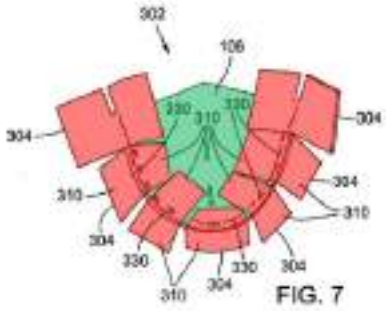


FIG. 7

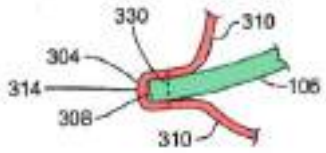


FIG. 8

This is described in [0053] of Benichou as follows:

[0053] To attach cloth **304** to the leaflet **106**, a cloth portion **304** can be folded over a lower edge portion **308** (FIG. **8**) of leaflet **106**, and cloth **304** and leaflet **106** can be sewn together along a leafletcloth suture line **330** (hereinafter "suture line **330**"). In this manner, leaflet edge **308** is captured between two layers of cloth **304** to form a leaflet attachment portion **314** (FIG. **6**). Excess portions **310** of cloth **304** extend along both sides of flexible leaflet **106** away from suture line **330** and away from edge **308**. As described in more detail below, excess cloth portions **310** can be used to secure the flexible leaflets **106** to the frame **104**. If desired, a plurality of separate cloth portions **304** (as shown in FIG. **7**) can be attached to the leaflet **106**. In this manner, when the leaflet is secured to the frame between the first and second arc sections **206**, **208**, the separate cloth portions **304** can extend between the struts that extend from the first arc section **206**.

It is clear from the highlighted passage that the leaflet 106 and the fabric portions 310 are separate elements, contrary to what is required by features 2 b), bb) and cc).

This is also recognised by the EPO's OD, which states in mn. 23.1.2: "D2 does not disclose leaflets with tabs but uses a separate cloth" (D2 corresponds to HL-CC 6 in the present proceedings).

Furthermore, the pieces of fabric do not have any creases or fold lines but are simply folded around the edge of the leaflet.

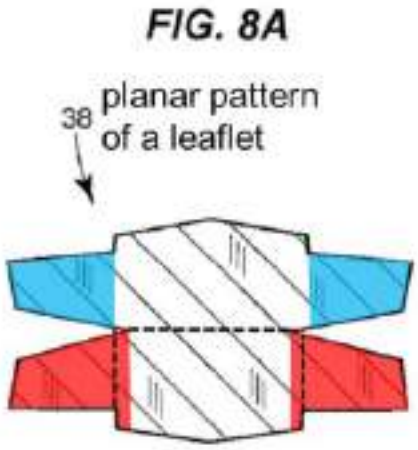
Accordingly, Benichou does not disclose any tab at all.

Consequently, D2 does not disclose features 2(b), 3 and 4. The patent is novel over Benichou.

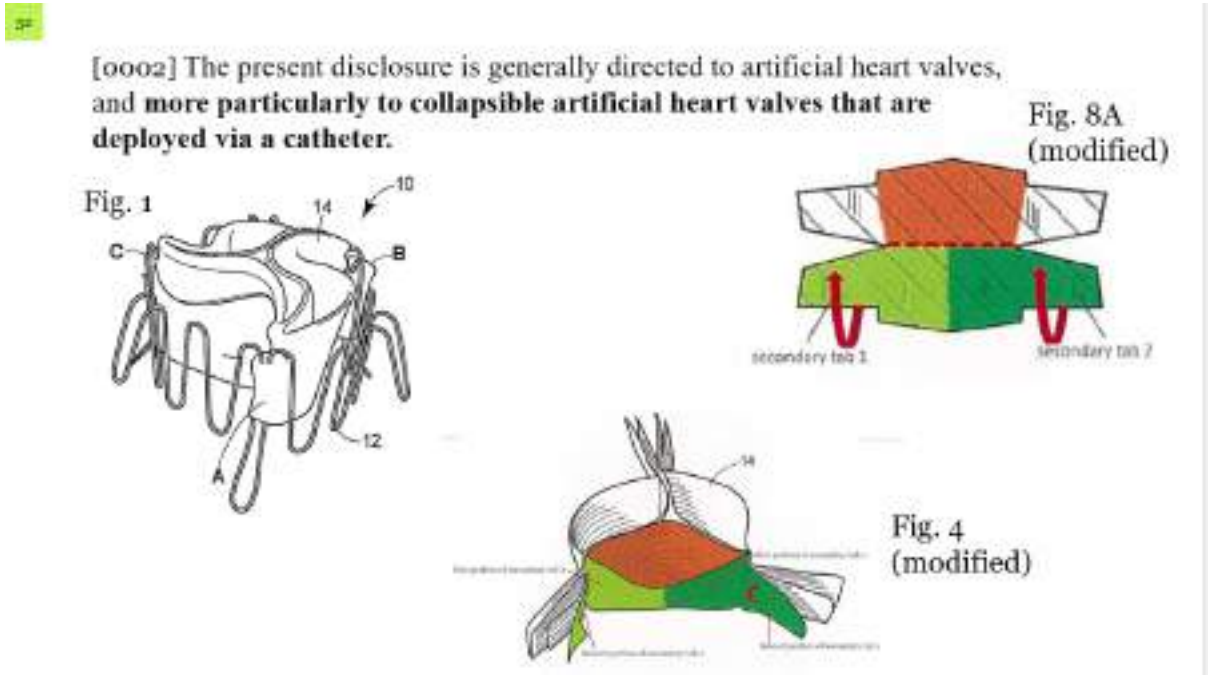
5. Jaramillo

a. Meril`s argument

Meril argued in its revocation counterclaim that the upper and lower opposing pairs of tabs (shown in red and blue in Jaramillo's Fig. 8 below that was taken from Meril's CC for revocation, p. 54) form primary and secondary tabs. The lower tabs, shown in red, are divided into two portions so that the small inner portions of the tab - together with the body portion of the leaflet - are folded along a radially extending crease. In this way, the small inner portions of the lower tabs are folded onto the body of the leaflet. The large outer portions of the lower tabs are folded along a vertical crease so that the large outer portions lie in a different plane to the body of the leaflet.



With its reply to the defence to counterclaim and at the oral hearing, Meril provided a different interpretation of Fig. 8A of Jaramillo as shown below (slide #32 provided by Meril):



Meril argues that in modified Fig. 8A of the revised interpretation (shown on the top right) only the orange portion represents the body portion of the leaflet that is connected to primary tabs that are white (not coloured). Only the red portion would coapt against other leaflets in the middle portion of the valve thereby allowing for blood flow in the open state and preventing blood flow in the closed state. The lower portion of the leaflet would be composed of two secondary tabs that would seal the valve against the frame. The secondary tabs have a first portion that is folded onto the white primary tabs and is then folded together with them about a vertically extending axis. The second portion of the secondary tab is folded along the radially extending crease and lies flat atop the body portion of the leaflet. The second portion of the secondary tab thus extends in a different plane than the first portion.

In view of this interpretation claim 1 of the Patent lacks novelty over Jaramillo.

b. Edwards` argument

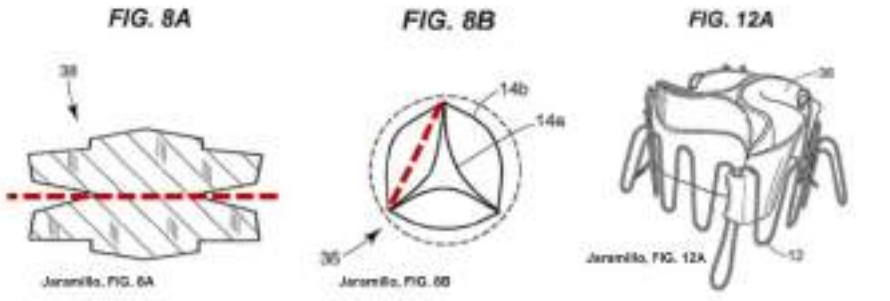
Edwards argues that the new construction provided by Meril is artificial because, e.g., the radially extending crease runs along the edge of the body of the leaflet and not within the tabs.

Edwards refers to paragraphs [070] and [076] of Jaramillo and submits that the person skilled in the art could only take from these paragraphs that the body portion of Jaramillo comprises both portions located on both sides of the central folding line.

Edwards further submitted the following slide in the oral hearing (slide # 28) that shows the folding line of a leaflet in an unfolded state (Fig. 8A) and in a top view of the valve (Fig.

8B). Edwards submits that the folding line is a secant that does not extend through the centre of the (dotted) circle. Therefore, the fold line would not represent a radially extending fold line:

Novelty – Jaramillo (WO 2007/013999 A2, HL-CC 9)

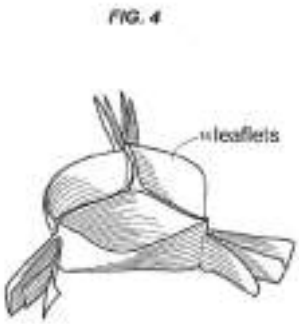


→ Leaflet fold line not radial

Since Jaramillo would not disclose a secondary tab at all and no radially extending fold line (feature groups 3 and 4 of claim 1) the patent-in-dispute is novel over Jaramillo.

c. The Court´s finding

First, the Court notes that Jaramillo discloses an unusual configuration of a heart valve



which is described in more detail in [0070] and [0076], and is schematically illustrated for a double coaptation leaflet in Figures 8A, 8B, 12A and 12B below (all taken from Edwards' defence to CC for revocation, pp. 39 and 40):

[0070] Each leaflet 14 is both peripherally and centrally coaptable. This feature allows the leaflet to have an adaptable geometry, especially peripherally and this adaptable geometry allows the leaflet 14 to be attached to the stent 12 with fewer sutures. The leaflet 14 provides a laminar flow across the leaflet when subjected to fluid flow having a viscosity similar to that of human blood. In other words, the Reynolds number of blood flowing across the leaflet 14 is less than approximately 2000. Additionally, the woven fabric material of the leaflet 14 is very durable, capable of performing more than approximately 600 million cycles before failure. Additionally, the leaflet 14 exhibits a backflow leakage of less than approximately 5%, and a backflow volume required to close of less than 2.5% of stroke volume when the leaflet 14 is used in a replacement heart valve.

[0075] FIGS. 8a-d show two leaflet 14 configurations. FIGS. 8a and 8b show a double coaptation leaflet 36 and the planar pattern 38 from which the double coaptation leaflet 36 is formed. FIGS. 8c and 8d show a central coaptation leaflet 40 and a planar pattern 42 from which the central coaptation leaflet 40 may be formed. Both central coaptation and double coaptation leaflets may be formed from planar geometries and similar manufacturing techniques. Each of the planar patterns 38, 42 of FIGS. 8a and 8c represents one leaflet. Three such leaflets may be used for each CBHV 10. The diagonal lines shown in the planar patterns 38, 42 represent an orthogonal orientation of the threads of the material. This orientation mimics the mechanical properties of natural leaflets. Natural leaflets have a higher elasticity along lines of coaptation and lower elasticity along the flow direction. This arrangement facilitates complete coaptation and strength against pressure gradients. The thread orientation shown in FIGS. 8a and 8c gives the leaflets 14 more elastic properties along the coaptation lines and stiffer properties in directions partially aligned with the flow.

[0076] As seen in FIGS. 8a and 8b, the double coaptation leaflet 36 is formed from a single sheet of material that is folded into two plies 14a and 14b. A first ply 14a coapts centrally with other leaflet 14 plies and a second ply 14b coapts peripherally with the stent 12 or vascular wall. The fold of the centrally coaptable leaflet 14 is oriented upstream from the free ends of the two plies 14a and 14b, in a direction of blood flow.

FIG. 8A

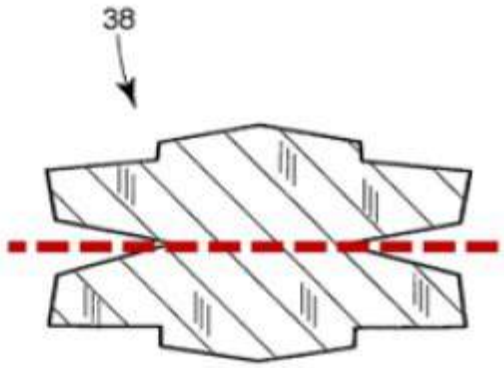


FIG. 8B

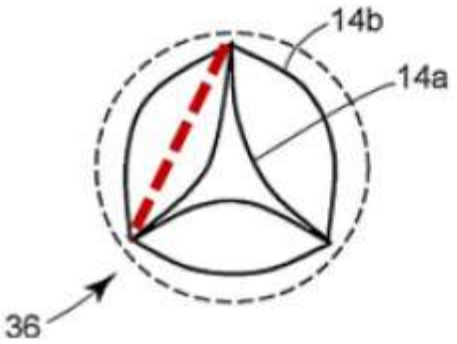


FIG. 12A

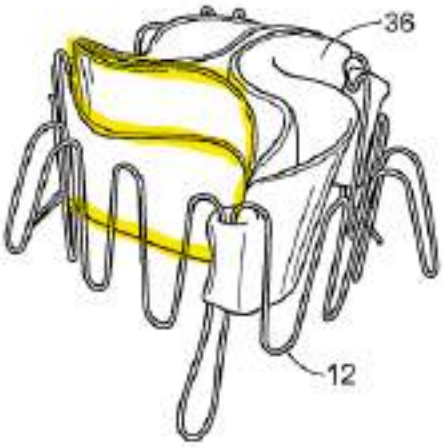
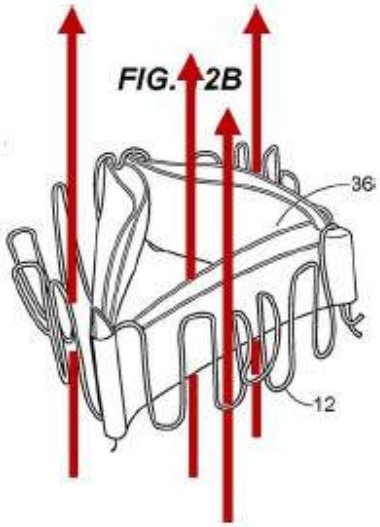


FIG. 12B

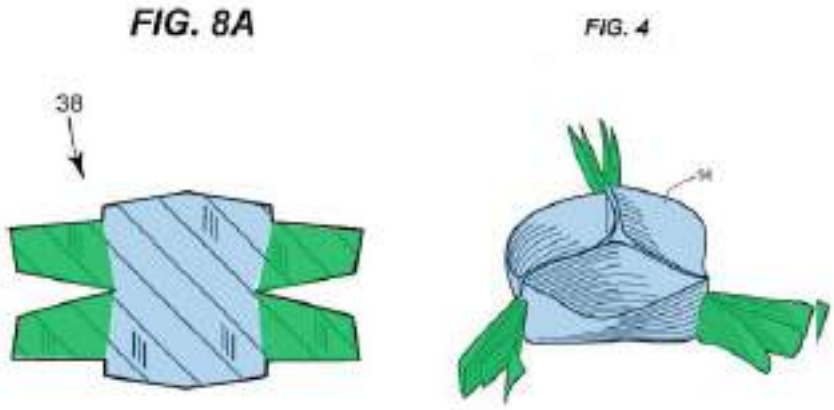


A leaflet for a double coaptation arrangement is shown in Figure 8A. The leaflet is folded about its horizontal axis (Fig. 8A) shown as a dashed red line (Figs. 8A and B) and forms a pocket-like structure in the assembled state (marked in yellow in the spherical view of Fig. 12A). The pockets are formed by plies 14a and 14b (top view of Fig. 8B). The red fold line of Figure 8A is also shown in the top view of Figure 8B (for another of the three pockets).

The valve is shown in the closed position in Figure 12A. It can be seen that the valve comprises three pockets which are centrally aligned with each other and peripherally aligned with a stent 12. The stent 12 is also of unusual construction.

Figure 12B shows the valve in the open position where it can be seen that the pockets are radially compressed to allow blood to flow both centrally and peripherally in the axial direction. In Figure 12B the number "1" is covered by one of the red arcs.

When Figures 8A and Fig. 4 are considered side by side (taken from Edwards' defence to CC for revocation, p. 40), it can be seen from Figure 8 that the leaflet 38 comprises a body portion (blue) and tabs (green) extending from the body portion.



The body portion (not a tab) is folded along the horizontal fold line (shown as red dashed lines in Figure 8A above on the previous page) to form the pocket-like structures shown in Figure 4.

This was also the position taken by the OD in its decision to maintain the patent in amended form:

22.3 The opposition division agrees that D1 discloses features 1.1 (figure 1, paragraph 64), 1.2 (paragraph 64), 1.2.1 (figure 8A), 1.2.2 (figure 8A)

The opposition division does not find the features 1.2.3 and 1.2.4 in D1 as it appears that the tabs of D1 are each folded about an axially extending crease, such that the entire tab lies against the body of the stent. The opposition division does not agree with the opponent that the fold which forms the double coaption leaflets of D1 is feature 1.2.3. It is seen in D1, figures 8A and 8C that this fold is formed by folding the leaflet body and not a leaflet tab. The structure formed by the fold is shown in figure 4 where the two parts on either side of this fold form leaflet body parts.

The OD refers to Jaramillo as D1. Features 1.2.3 and 1.2.4 correspond to features 3 and 4 of the feature analysis above. In particular, the OD states that the formation of the coaptation pockets is achieved by folding the body portion of the leaflet which cannot be considered as a tab (within the meaning) of the patent.

The tabs extending outwards from the pockets (Fig. 4) are used to attach the leaflets to the frame 12, as can be seen in Figs. 12A and 12B; in this respect they can be folded along a vertically extending edge line.

The interpretation of Fig. 8A shown by Meril is not convincing. It is explicitly stated in [0070], 1st sentence that "(E)ach leaflet is both peripherally and centrally coaptable". In terms of the double coaptation leaflet 36 of Figs. 8A and 8B it is stated in [0076]:

[0076] As seen in FIGS. 8a and 8b, the double coaptation leaflet 36 is formed from a single sheet of material that is folded into two plies 14a and 14b. A first ply 14a coapts centrally with other leaflet 14 plies and a second ply 14b coapts peripherally with the stent 12 or vascular wall. The fold of the centrally coaptable leaflet 14 is oriented upstream from the free ends of the two plies 14a and 14b, in a direction of blood flow.

Thus, Jaramillo explicitly states that the leaflets comprise two plies 14a and 14 b that seal centrally and peripherally. This is in clear contradiction to the interpretation of Meril suggesting that the outer ply 14 b is not part of the leaflet body but consists of two secondary tabs.

The interpretation proposed by Meril bends the disclosure of Jaramillo and attempts to artificially re-interpret it so that the outer ply 14b of the leaflet corresponds to secondary tabs in the sense of the patent-in-suit. There is absolutely no hint in this regard in Jaramillo, and the suggestion that this interpretation would correspond to the understanding of a leaflet and its function by the person skilled in the art is not convincing.

As was set out above, Jaramillo discloses a leaflet structure in which the body portions are folded along an axis of symmetry which constitutes a crease. The portions of the leaflet shown in green in modified Fig. 8A above can be considered as tabs because they are drawn through the frame 12 and folded around the axially extending edge portion of the leaflet and the corresponding portions of the frame for attachment. However, Jaramillo does not disclose secondary tabs having a first and a second portion, the first portion being folded along a radially extending crease to lie flat on the body of the leaflet portion, and a second portion being folded along an axially extending crease so that the second portion of the secondary tab lies in a different plane of space from the first portion. Thus, Jaramillo does not disclose a secondary tab at all.

Thus, features 2 b), (bb) and (cc) and features 3 and 4 are missing and the patent is novel over Jaramillo.

6. Independent Claim 12

Independent claim 12 (former claim 13 in EP828B1), claiming an assembly for implanting a heart valve according to claims 1-11, is novel over Nguyen, Benichou and Jamarillo at least for the reasons given above for claim 1.

Inventive Step

1. Legal Standard

a. Pursuant to Art. 65 (2) UPCA and Art. 138 (a) EPC a European patent may be revoked with effect for a Contracting State on the ground that the subject-matter of the European patent is not patentable under Articles 52 to 57 EPC. According to Article 56 EPC, an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

b. For assessing whether an invention shall be considered obvious having regard to the state of the art, the problem-solution approach (PSA) developed by the European Patent Office (EPO) shall primarily be applied as a tool to the extent feasible to enhance legal certainty and further align the jurisprudence of the Unified Patent Court with the jurisprudence of the EPO and the Boards of Appeal (BoA).

The Court of First Instance and the Court of Appeal of the Unified Patent Court have assessed inventive step in various decisions. Some decisions explicitly referred to the PSA, used by the the EPO, including the BoA, and several national courts; others applied a different approach, that is similar if not identical to the test of inventive step applied by the German Federal Court of Justice. Both tests, the 'German' test and the PSA, if correctly applied, should lead to the same results in the majority of the cases (see Deichfuss, GRUR Patent 2024, 94) and both tests require a “realistic starting point” and an “incentive” for the skilled person to do the “next step”, e.g. to amend the technical solution disclosed by the starting point to arrive at the patented solution. As none of the tests is enshrined in the European Patent Convention (EPC) and lead basically to the same results both can be applied as a tool to assess inventive step. However, this Panel takes the decision to apply the PSA as practiced by the EPO, including and the BoAs, to the extent feasible and to state this explicitly as there is a need for legal certainty for both the users of the system and the various divisions of the Unified Patent Court. Applying the PSA further aligns the jurisprudence of the Unified Patent Court with the jurisprudence of the EPO and the BoA.

In the present proceedings, the PSA is also the tool applied by the parties in their briefs.

2. Nguyen alone, with CGK or with Jaramillo

a. Meril`s argument

Meril submits that if the Court finds that Nguyen does not disclose features 3 a) and b), claim 1 would lack inventive step over Nguyen. Nguyen relates to an implantable prosthetic heart valve having a multitude of leaflets with flaps (tabs) extending therefrom. The tabs are folded “forming seam 42 comprising a triple thickness of the tissue” (para [0053] on p.4). The technical effect resulting from this stack of material is according to [0056] of Nguyen: “Moreover, the use of multiple thicknesses of material along seams 42 and 43 is expected to provide a highly durable valve body which will last for many years once implanted in a patient.”

Ngyuen thus is in the same field and disclosed a prosthetic heart valve comprising a frame and a leaflet structure attached to the frame. The primary objective underlying Nguyen is summarized in [0011] as follows:

> **[0011]** In view of the foregoing, it would be desirable to provide a valve that is capable of conforming to a patient's anatomy while providing a uniform degree of rigidity and protection for critical valve components. It therefore would be desirable to provide a valve prosthesis having portions that are capable of deforming circumferentially to adapt to the shape of the pre-existing valve annulus, but which is not susceptible to deformation or migration due to normal
>
> movement of the heart. Still further, it would be desirable to provide a valve prosthesis having a multi-level component that is anatomically shaped when deployed, thereby enhancing anchoring of the valve and reducing the risk of migration and perivalvular leaks.

Other objects addressed by Nguyen are given in [0012] to [0022]. It is further stated in [0056] that “the use of multiple thicknesses of material along 42 and 43 is expected to provide a highly durable valve body which will last for many years once implanted in a patient”.

Nguyen thus addresses the same object as the patent-in-suit in connection with the enlarged lateral end regions ([0038]), seams 42 provided by the folded tabs and seams 43 provided by folding reinforcing tabs 38 along fold lines g, h and i ([0051] and Fig. 3B of Nguyen). Nguyen therefore qualifies as closest prior art (CPA).

Meril claims that there is no technical effect associated with the missing features 3a and b so that the objective technical problem can be defined as providing an alternative configuration of the secondary tab. Starting from the Nguyen document and faced with

the objective technical problem defined above, the person skilled in the art would have been motivated to adapt the configuration of the secondary tabs so that a first portion is folded around a radially extending fold.

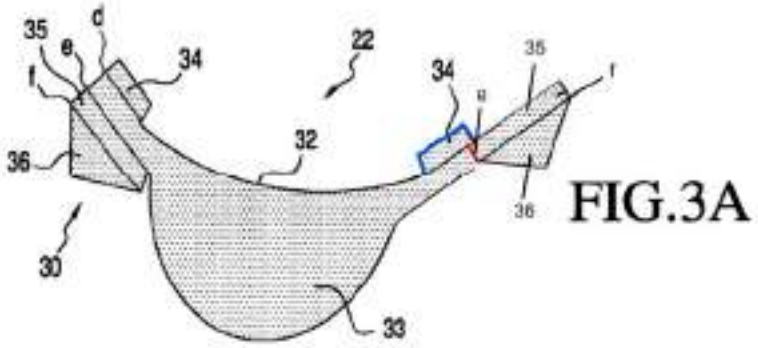


FIG.3A

Meril further submits that the CGK comprised leaflets with opposite pairs of tabs of different configurations, so that it was routine to consider different geometries and creases for a secondary tab. Meril refers, for example, to a combination of Nugyen and Jaramillo. For Meril it is obvious to change the position of tab 34 (marked in blue in the modified Fig. 3A above) and fold line e (marked in red) as shown above.

The claim limitations would be satisfied by this modified embodiment of Figure 3A.

b. Edwards` argument

Edwards submits that the patent-in-suit would distinguish by feature groups 3 and 4 over Nguyen. A technical effect relating to such distinguishing features is disclosed in paragraphs [0018] and [0056] of the patent-in-suit that is reproduced above.

Edwards concludes:

> 134. Therefore, Edwards submits that the objective technical problem to be solved is improving valve reliability, durability, and safety, including as a result of a smaller crimp profile.

Edwards generally argues that the references relied on by Meril in its inventive step attacks are patent references which are generally not part of the CGK. Meril also fails to provide any motivation as to why a person skilled in the art would have made the proposed modifications, which are quite substantial.

These comments also apply when relying on Nguyen. More specifically on Nguyen alone, Edwards submits that the proposed modification would not be considered by the person

skilled in the art because it is more complex and would require more material so that it would be more expensive than the original configuration. The proposed radially extending fold line would be very short and thus exposed to high forces of stress.

Also, the proposed modification would not result in the same configuration as in Fig. 4A because flaps 36 would extend inwardly rather than outwardly as in Fig. 4A.

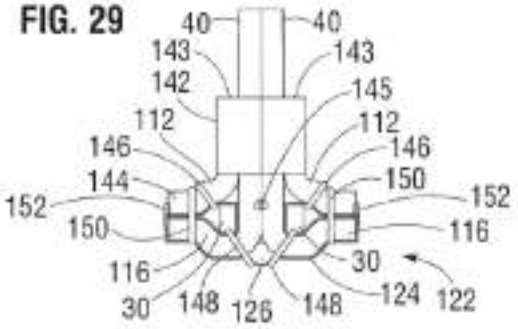
c. The Court`s finding

The Court agrees with the parties that Nguyen does not disclose features 3a) and 3b (folding about a radial crease). Nguyen does also not disclose feature 4b) requiring that the second portion of the secondary tab extends in a different plane than the first portion. The technical effect resulting from the missing features is disclosed in [0018] and [0056] and Figs. 29 and 30 of the patent-in-dispute.

[0018] In some of these examples, the first portion of each the secondary tab pivots about the axially extending crease and lays flat against the second portion of the secondary tab when the valve is collapsed to a radially collapsed configuration. The first portion of each secondary tab comprises an inner edge spaced radially from an inner surface of the frame, and the body portion of the leaflet articulates about the inner edges of the two secondary tabs of the leaflet in response to blood flowing through the valve when the valve is in operation within a patient's body.

[0056] As shown in FIGS. 29 and 30, the folded down upper tab portions 112 form a double layer of leaflet material at the commissures. The inner portions 142 of the upper tab portions 112 are positioned flat abutting layers of the two leaflets 40 forming the commissures, such that each commissure comprises four layers of leaflet material just inside of the window frames 30. This four layered portion of the commissures can be more resistant to bending, or articulating, than the portion of the leaflets 40 just radially inward from the relatively more rigid four layered portion. This causes the leaflets 40 to articulate primarily at inner edges 143 of the folded-down inner portions 142 in response to blood flowing through the valve during operation within the body, as opposed to articulating about the axial struts of the window frames 30. Because the leaflets articulate at a location spaced radially inwardly from the window frames 30, the leaflets can avoid contact with and damage from the frame. However, under high forces, the four layered portion of the commissures can splay apart about a longitudinal axis 145 (FIG. 29) adjacent to the window frame 30, with each inner portion 142 folding out against the respective outer portion 144. For example, this can occur when the valve 10 is compressed and mounted onto a delivery shaft, allowing for a smaller crimped diameter. The four layered portion of the commissures can also splay apart about axis 145 when the balloon catheter is inflated during expansion of the valve, which can relieve some of the pressure on the commissures caused by the balloon and so the commissures are not damaged during expansion.

FIG. 29



Radially folding the first portions of the secondary so that they lay flat on the body portions of the leaflets results in a 4-layer stack of leaflet materials 142. This causes the leaflets to articulate primarily at inner edges 143 of the folded-down inner portions 142 and thus spaced apart from the frame. As a result, the leaflets avoid contact with and damage from the frame. In the embodiment of the exemplary portion of the patent-in-suit the four-layer stack 142 can in addition to that splay apart about longitudinal axis 145 under high forces that occur when the valve is crimped. This allows for a smaller crimped diameter. High forces also apply during the subsequent balloon expansion. The stress is dissipated because of the splaying apart of the 4-layer stack thereby protecting the commissures.

The Court agrees with Edwards that the technical effect resulting from the missing features is to provide a reliable and durable valve.

The Court agrees with Meril that Nguyen qualifies as a realistic starting point. Nguyen discloses a prosthetic heart valve comprising a multitude of leaflets having tabs that are folded over to increase the durability of the commissures. Nguyen also addresses the technical problem to provide a reliable and durable valve.

However, the Court finds that the technical solution provided by Nguyen is structurally completely different from that disclosed in the patent. The tabs of the leaflets of Nguyen are folded along parallel and axially extending folding lines to create first seams 42 to increase the durability of the commissures (claim 11 of Nguyen). In the assembled state all tabs 34-36 are lying on top of each other and on the frame. Additional seams 43 extending axially along the lateral ends of the skirt are obtained when "reinforcing tabs 38 are folded along lines g, h, and i"([0054] of Nguyen). The combination of axially extending seams 42 and 43 provides a high durability of the valve body through even axial stress dissipation ([0056]). It is required that the leaflets are fastened together at enlarged lateral end regions ([0038]) so that the coaptation leaflets are at a distance below the commissures ([0057]).

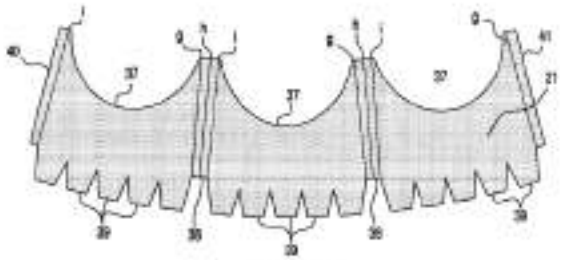


FIG.3B

[0056] When completely assembled to frame 12, valve body 14 is affixed to frame 12 along the edges of flaps 36 of the commissures, end tabs 39, leaflet seams 42, reinforcing tab seams 43 and joints 44. In this manner, forces imposed on leaflets 22, commissures 24 and joints 44 are efficiently and evenly distributed over the valve body and transferred to frame 12, thus reducing stress concentration and fatigue of the valve body components. Moreover, the use of multiple thicknesses of material along seams 42 and 43 is expected to provide a highly durable valve body which will last for many years once implanted in a patient.

Nguyen does not disclose any radial folding lines. Nguyen also does not disclose folding of portions of the tabs along a radially and longitudinally extending crease, respectively, so that they extend upon folding in the assembled state in different planes.

This, however, is the core of the technical teaching of the patent-in-suit. Folding of the first and second portions of the secondary tab about radially and longitudinally extending creases so that they extend in the assembled state in different planes puts the articulation point of the leaflets space apart from the frame so that the leaflets are not in contact with the frame are not damaged by it.

There was no incentive in Nguyen to have flaps 34, 35 and 36 extend in different planes upon folding in the assembled state. Tab 35 is folded so that it lies atop tab 34 because Nguyen requires a seam 42 comprising a triple thickness of the tissue. Then flap 36 is folded along line f and is arranged in the assembled state on top of tabs 34 and 35 to attach the leaflet structure to the frame and form commissures 24. This means in other words that the tissues both in seams 42 and 43 form stacks and lay flat on top of each other and are secured in that configuration to the frame.

Thus, Nguyen teaches away from using differently oriented folding creases.

The Court agrees with Edwards that there is absolutely no motivation for Nguyen to modify the tab design as suggested by Meril. The modified construction in changed Figure 3A could have made by the person skilled in the art but no motivation is provided ("would") so that this Fig. represents wishful thinking using the wisdom of hindsight.

In addition to that, the Court agrees with Edwards that the changed construction of Fig.3A had disadvantages (more material required in comparison to the construction of unmodified Fig.3 because of even further enlarged lateral end regions, high stress at short folding line) so that the person skilled in the art would have been withheld from using these constructions.

The same applies when combing Nguyen with the CGK or Jaramillo. Meril claims that the patent references cited against the patent-in-suit would form CGK so that the tab geometries disclosed therein could be arbitrarily combined. A motivation would not be required because no technical effect would be associated with the missing features.

The Court does not find this line of argument convincing. Patent references are generally not considered as CGK in the first place. Also, the features missing in Nguyen with respect to the patent-in-suit display a technical effect as was outlined above.

The person skilled in the art starting from Nguyen would not have considered Jaramillo that discloses a completely different leaflet design and valve construction. Even if such combination would have been made the person skilled in the art would not have arrived at the teaching of the patent-in-suit because Jaramillo does neither disclose secondary tabs nor radially extending folding lines of tabs.

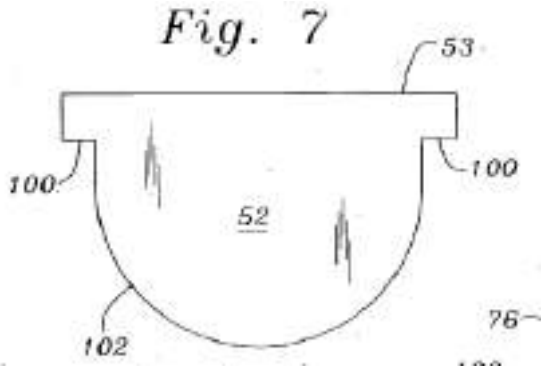
3. Lobbi in combination with Nguyen

a. Merril's argument

Meril argues that the person skilled in the art, starting from Lobbi, would take Ngyuen into account. Both documents relate to the durability of the heart valve. Meril submits that the skilled person would be motivated to combine Lobbi with Nguyen because Nguyen teaches that the durability of the valve can be improved by using the folded tab configuration of Figure 4A of Nguyen:

[0038] In a preferred embodiment the valve body comprises three leaflets that are fastened together at enlarged lateral end regions to form commissural joints, with the unattached edges forming the coaptation edges of the valve. The leaflets are fastened to a skirt, which is in turn affixed to the frame. The enlarged lateral end regions of the leaflets permit the material to be folded over to enhance durability of the valve and reduce stress concentration points that could lead to fatigue or tearing of the leaflets. The commissural joints are mounted above the plane of the coaptation edges of the valve body to minimize the contracted delivery profile of the valve prosthesis, while the configuration of the edges permits uniform stress distribution along the coaptation edges.

Referring to Figure 7 of Lobbi



and confronted with the objective technical problem of providing an alternative leaflet configuration, the skilled person would, having considered the teaching of Ngyuen in Fig. 3A

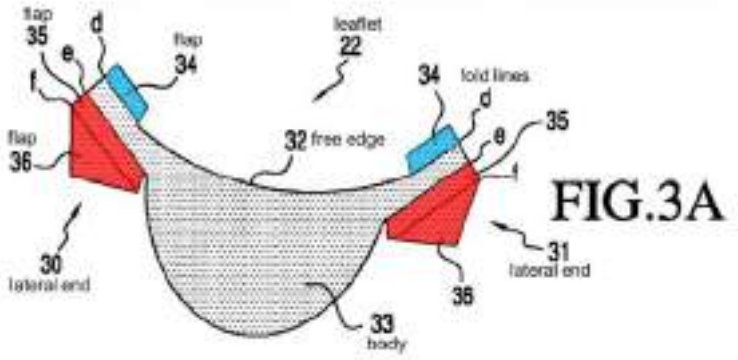
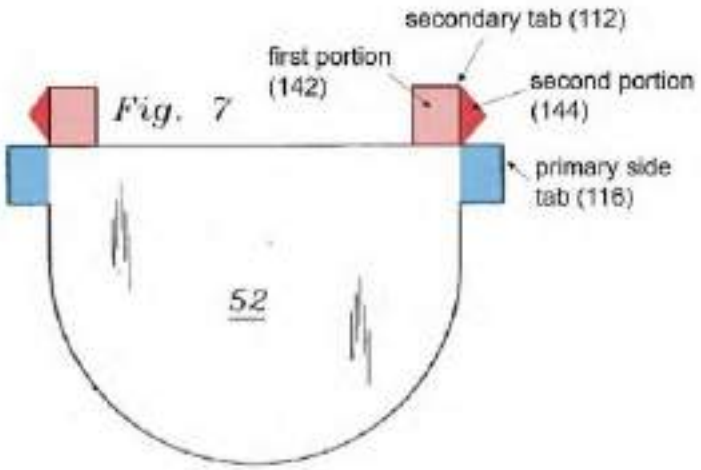


FIG.3A

have arrived at the leaflet configuration shown below:



According to Meril, this modified version of the Lobbi leaflet fulfils features 2b) (cc), 3 and 4.

b. Edwards` argument

Edwards submits that the modified Figure 7 has no basis in Nguyen at all because Nguyen discloses only folding about fold lines d, e and f, all of which extend in parallel and have an axial orientation in the assembled valve. Thus, a combination of Lobbi with Nguyen, if made at all, would not provide the features of the patent as claimed.

Edwards also refers to the decision of the OD of the EPO that states in para 24:

24 Arguments for lack of inventive step also use D3 as closest prior art.

24.1 The opponent has argued that D3 could be considered as the closest prior art, that it discloses equivalent features to D2 and that the same arguments could be used for lack of inventive step over the combinations of D3 with itself, with D4 and with D1. The opponent did not further substantiate these arguments.

D3 does not disclose primary and secondary tabs but has single tabs, one on each side of the leaflet and uses separate cloth portions for attachment to the stent frame.

24.1.1 As the technical problem is considered the same as when starting the inventive step arguments from D2, i.e. simplification of the construction of the leaflets, the opposition division considers claim 1 inventive over D3 with itself, over D3 with D4 and over D3 with D1 respectively for the smae reasons as in poonts 23.2.1 and 23.3.1.

T

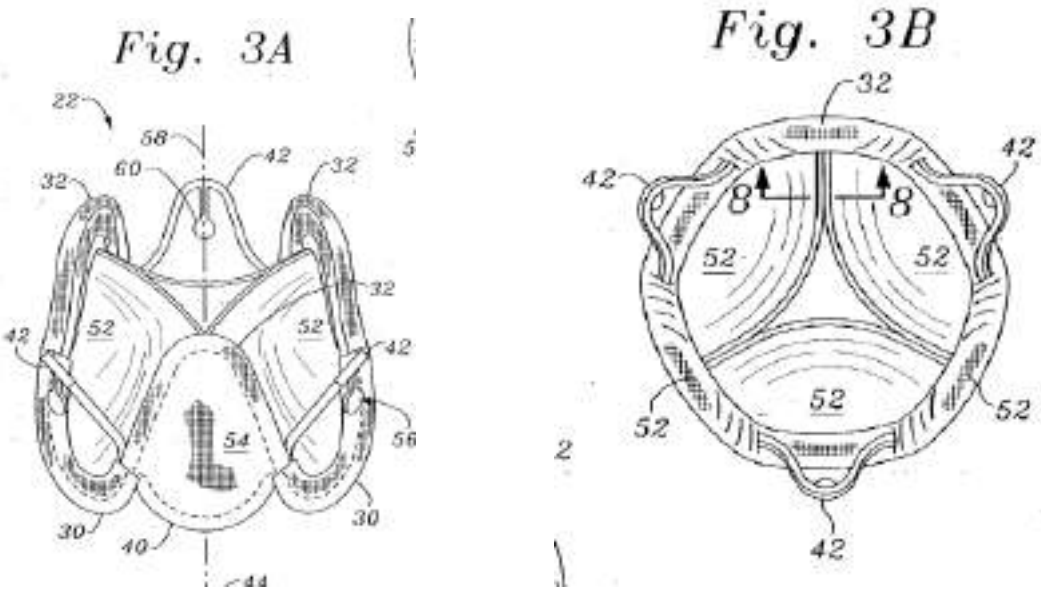
Reference D3 used as a starting point is Lobbi (HL-CC 8), and the secondary references referred to by the OD are Benichou (D2 = HL-CC 6), Jaramillo (D1 = HL-CC 9) and Braido (D4 = HL-CC 10).

c. The Court`s finding

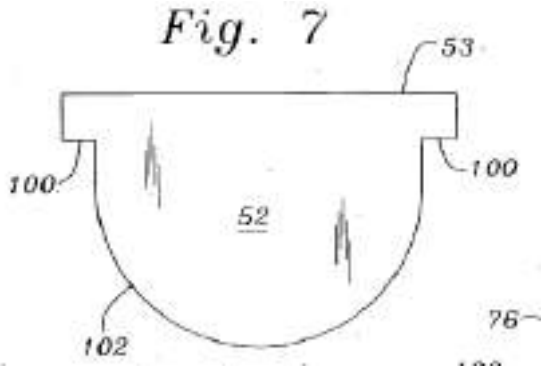
The Court sides with Edwards and the OD on this issue. Lobbi provides no motivation to consider Nguyen (could-would test) and even if such a combination had been made, the missing features of the patent would not have been obtained.

The Court finds that Lobbi generally discloses a valve leaflet frame having three cusp regions alternating and interposed with three commissure regions (see claim 1 of Lobbi).

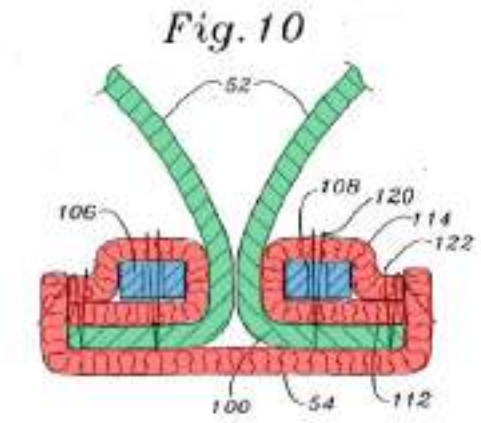
Figure 3A shows a perspective view of the valve construction and Figure 3B is a plan view of the valve:



A leaflet like disclosed by Lobbi is shown below (Figure 7):



The leaflet comprises only primary tabs 100 (shown in green in annotated Figure 10 below) which are inserted through the commissure windows 106,108 (blue) in the assembled valve as shown in Figure 10 below:



Annotated Fig. 10 as provided by Edwards in its defence to the CC

It is disclosed in paragraph [0084] of Lobbi that the folded leaflet tabs 100 are secured to the commissures provided by attachment flanges 106 and assembly holes 108 (see Fig. 5 of Lobbi) via cloth layers including fabric cover 114, cloth flange 114 and cloth covers 54 (marked in red in Fig. 10 above):

[0084] **FIG. 10** shows the attachment structure at the commissure tip **104**, and specifically illustrates sutures **120** passing through the fabric cover **114**, through the assembly holes **108**, and through the folded leaflet tabs **100**. A second suture **122** passes through the cloth flange **112**, the leaflet tab **100**, and cloth covers **54** (also shown in **FIG. 6B**). Because each of the leaflets **52** includes the tab **100** that extends to the

outside of the leaflet frame **72**, high forces that are seen with closing of the valve are less likely to pull the sutures **120** through the tabs. That is, the construction shown in **FIG. 10** causes tensile forces imparted by the leaflets **52** to be transferred as much as possible from the sutures **120**, **122** to the frame **72**, thus helping to prevent tearing of the flexible leaflets and rendering the valve **22** more durable.

Thus, Lobbi does not disclose secondary tabs. The pair of opposing single tabs 100 is attached to the frame via various clothes that are folded around and sutured to the commissure strut. The single tabs are folded around an axially extending fold line.

Thus, Lobbi fails to disclose features 2. b) (cc), 3 and 4.

This is supported by the OD in its decision to maintain the patent where D3 is Lobbi:

> D3 does not disclose primary and secondary tabs but has single tabs, one on each side of the leaflet and uses separate cloth portions for attachment to the stent frame.

In view of that, the Court does not consider Lobbi as a promising springboard for an inventive step attack.

Meril has argued that the folding of the first and second portion of the secondary tab would not have any technical effect so that the objective problem underlying the patent-in-suit would be to provide an alternative configuration. Based on a similar argument by the opponent Abott in the EPO opposition proceedings the OD has considered that the person skilled in the art may be motivated to simplify the construction of the leaflets in Lobbi and use a folded extension of the leaflet rather than a separate cloth.

Nguyen does not use a separate cloth but three leaflets that are fastened together at enlarged lateral end regions to form commissural joints ([0038] of Nguyen). Lobbi does not comprise extended lateral end regions of the leaflets so that the design of the leaflets and the overall design of the valve of Lobbi would have had to be changed considerably when combining Lobbi with Nguyen. Even if the person skilled in the art would have made that change and omit the cloth portions there is no disclosure in Nguyen of folding the two portions of a secondary tab about a radial and an axial crease line. In other words, even if the combination would have been made, the person skilled in the art would not have arrived at the invention as claimed. Nguyen discloses that the three leaflets are folded along parallel folding lines that all extend axially in the assembled configuration.

The Court does not agree, however, with the assumption that there is no technical effect associated with the features of folding the two portions of the secondary tab about a radially and an axially extending crease line, respectively. The technical effect associated with this is disclosed both in [0018] of the general portion and in [0056] of the exemplary portion of the patent-in-suit:

> **[0018]** In some of these examples, the first portion of each the secondary tab pivots about the axially extending crease and lays flat against the second portion of the secondary tab when the valve is collapsed to a radially collapsed configuration. The first portion of each secondary tab comprises an inner edge spaced radially from an inner surface of the frame, and the body portion of the leaflet articulates about the inner edges of the two secondary tabs of the leaflet in response to blood flowing through the valve when the valve is in operation within a patient's body.

Starting from Lobbi the person skilled in the art would not have considered Nguyen that does not address the object of spacing apart the articulation point of the leaflets from the frame. Nguyen does not even disclose folding two portions of a secondary tab about a radially and an axially extending fold line.

Meril has not provided any motivation for the skilled person to combine Lobbi with Nguyen. Even if the skilled person would have combined the two references the resulting valve would not show all features of claim 1. As Nguyen only discloses folding around folding lines d, e and f that all extend in parallel an axial orientation of creases in the assembled valve as claimed in the Patent will not be obtained.

Enablement

1. Pursuant to Art. 65(2) UPCA and Art. 138(b) EPC, a European patent may be revoked with effect for a Contracting State on the ground that the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

The subject-matter of a patent must be sufficiently disclosed on the basis of the patent as a whole, including the examples, and taking into account the common general knowledge of the person skilled in the art. It is up to the patentee to demonstrate the practicability of the claimed subject-matter. However, as the patent is directed to the person skilled in the art, the CGK of the skilled person must also be taken into account when considering the question of sufficiency. Evidence of such knowledge may include, for example, scientific textbooks. Sufficiency of disclosure means that the patent enables the skilled person to obtain substantially all embodiments falling within the scope of the claims. The disclosure in the patent must enable the claimed invention to be carried out in the whole range claimed ("whole range sufficiency"). To define the whole range claimed, all technically reasonable claim constructions must be considered. Specifying one way of carrying out the claimed invention may be sufficient to satisfy the description requirement of R. 42.1(e) EPC, but it is not necessarily sufficient to satisfy the sufficiency requirements of Art. 83 or Art. 138(1)(b) EPC. Rather, the person skilled in the art within the meaning of these articles must be enabled by the patent and his common knowledge to use the claimed invention to its full extent without having to embark on a research programme (i.e. without unreasonable effort). The requirement that the disclosure must enable the implementation of the claimed invention to its full extent is consistent with the concern that the right of exclusion conferred by a patent with respect to its scope of protection should in principle be commensurate with the actual contribution of the patent to the state of the art. Thus, the disclosure of only one way of carrying out an invention is sufficient only if it enables the invention to be carried out in

the entire scope claimed and not only in some embodiments of the claimed subject matter (UPC_CFI_355/2023).

2. Meril`s argument

Meril argues that it is essential that the folded tab regions are attached to the frame. This is particularly true for the second portion of the secondary tab, which might otherwise be moved by blood flow to lie flat on the leaflet body and the first portion of the secondary tab. The attachment of the folded tab regions to the frame is shown, for example, in Figure 30. As such feature is not mentioned in claim 1, the invention is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

This objection would apply to all claims because the feature is missing from claim 1 and all other claims are dependent on claim 1.

Meril further submits that dependent claim 4 lacks crucial features such as the material of the leaflets and the exact construction of the tabs to allow folding around the axially extending crease. Applying the teaching of claim 4 without including these features places an undue burden on the person skilled in the art and/or constitutes an invitation to a research programme.

A similar objection is raised by Meril in respect of dependent claim 5.

3. Edwards‘ argument

Edwards points out that

(i) the absence of an allegedly missing mandatory feature in claims 1-12 is a matter of clarity which is not a ground for opposition (Art. 100 EPC), and

(ii) "the detailed description and the figures, in particular paragraphs [0054] to [0057] together with Figs. 29 and 30, provide sufficient information on the design of the leaflets and their attachment to the frame to undoubtedly enable the skilled person to provide a valve with the features specified in claim 1" (p. 55, para. 190 of Edwards' defence to the CC).

4. The Court`s finding

Edwards' position is in line with the OD's decision (paras 25-26.4). The Court sides with the OD and Edwards on this issue. Applying the correct claim construction as set out above, the skilled person will understand that the leaflets are secured to the frame by the

tabs. This is implicitly disclosed in claim 1; another reading does not make technical sense. With respect to claim 4, the skilled person can rely on the specification and the CGK to select the correct material for the leaflets and to construe the leaflets to permit folding about the axially extending crease.

Infringement

1. Legal test

The scope of protection is determined by Art. 69(1) EPC that is directly applicable under the UPCA (see Art. 24(1) c UPCA). Art. 69(1) EPC stipulates that "[T]he extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims." This provision is further clarified in the Protocol on the Interpretation of Article 69 EPC requiring that courts should interpret the claims adopting an approach that combines a fair protection for the patentee with a reasonable degree of certainty for third parties. Reference is made to the claim construction above.

2. Literal infringement of feature 2.a.aa "body portion" of claim 1

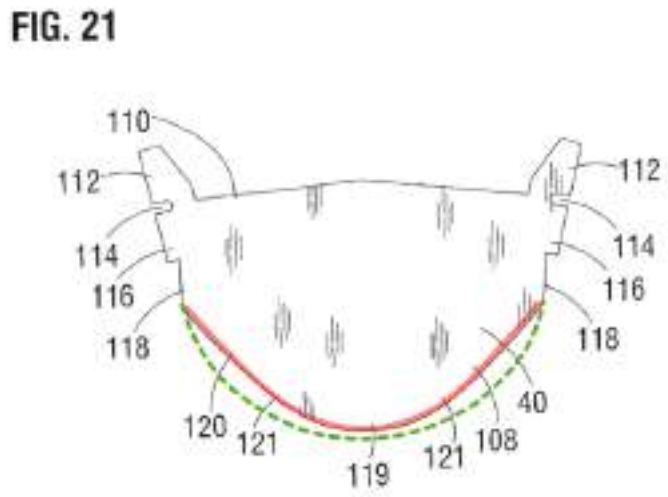
a. Meril`s argument

Meril only has one non-infringement argument. It argues on the basis of its claim construction that the leaflets used in its Myval prosthetic heart valve are U-shaped and not V-shaped.

A leaflet of the attacked embodiment is shown below (bottom of p.5 of K25):

Figure 4

Meril illustrates this argument by referring to an annotated Figure 21 of the patent. The V-shaped edge line of the inflow section of the body portion of the leaflet is highlighted in red. A U-shaped edge line is also shown as a dashed line in green for comparison:



Meril concludes that its Myval heart valve therefore does not infringe claim 1 or any other claim.

b. Edwards` argument

Edwards argues, based on its claim construction, that the attacked embodiment includes leaflets with a body portion and thus infringes the patent.

c. The Court`s finding

The Court refers to the claim construction set out above. As stated above, the patent broadly claims an implantable prosthetic heart valve comprising a leaflet structure having a plurality of leaflets comprising a body portion and side tabs. The shape of the body portions of the leaflets is not specified. The valves may consist of leaflets of any shape. For the claimed invention of the patent, it is not essential that the leaflets have a body portion which is generally V-shaped. Meril's Myval comprises leaflets with a body portion and thus literally infringes feature 2.b) (.aa) of claim 1.

3. Literal infringement of the other features of claim 1

Meril does not dispute the infringement of the other features of claim 1. The Court considers that Meril is right:

From the image of the leaflet shown above, it can be concluded that the leaflet has

- a body portion;

- two opposing primary side tabs (= the lower side tabs) extending from opposite sides of the body portion; and

- two opposing secondary side tabs (= upper side tabs) extending from the portion adjacent to the primary side tabs

- wherein the first portion of the secondary side tab is folded around a radially extending crease so that it lies flat atop the body portion of the leaflet, and

- the second portion of the secondary tab is folded around an axially extending crease so that the second portion extends in a different plane than the first portion. A leaflet is connected to an adjacent leaflet by attaching pieces of fabric (connectors 124) to the lower tabs (=primary tabs). This is illustrated in the PPD (K25) created by Meril and filed by Edwards. The PPD uses an enlarged cardboard model to visualise the construction of Meril's Myval THV using primary and secondary tabs to attach the leaflets to each other and to the valve frame.

The sequence of figures reproduced below from K25 shows the attachment of the fabric pieces (=connectors 124, green) to the lower tabs (=primary tabs).

The assembly is carried out in a sequence of 4 steps.

1st Step

A leaflet as shown at the bottom of p.5 of K25 is provided.

Figure 4

The leaflet has

- a body portion;
- two opposing primary side tabs (=the lower side tabs) extending from opposite sides of the body portion; and
- two opposing secondary side tabs (=upper side tabs) extending from the portion adjacent to the primary side tabs

(feature 2 b))

2nd Step

In a second step (Fig. 10), a piece of supporting fabric (green) is attached to part of the lower (primary) tab of a leaflet (step not disclosed in EP828B2). Then, in Figures 11 and 13, a piece of fabric (=connector 124, green) is sutured to the fabric support. The step is repeated with another leaflet so that two leaflets are connected (Figs 14 and 15). By attaching the remaining leaflet, all three leaflets are connected in a leaflet attachment element (leaflet structure 14) (right, unlabelled figure above).

(**feature 2a**))

Figure 10

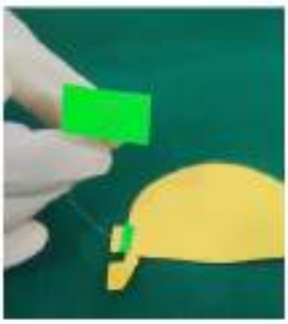


Figure 11

Figure 13

Figure 14

Figure 15

3rd Step

The next step is to assemble the leaflet structure to the frame. The frame comprises commissure windows 20, which are represented in the cardboard model exercise by clear polymer pieces (bottom left). A perspective view of the frame (Figure 8, right) shows that the frame has commissure windows.

Figure 8

The lower (primary) tabs are inserted through the commissure windows as shown in Figures 23-25 below:

Figure 25

Figure 24

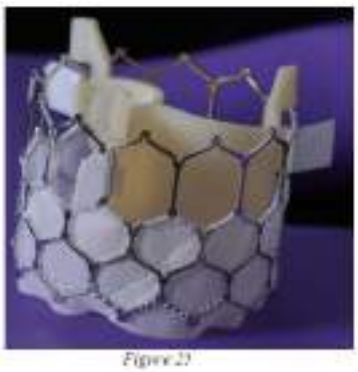


Figure 23

(**features 1. and 2.**)

4th Step

The upper (secondary) tab is then first folded (i) along a radial crease and then (ii) the outer (second) portion connected to the inner (first) portion of the upper (secondary) tab by a broken line is folded along such a broken axial line to provide an L-shaped form of the outer (secondary) tab.

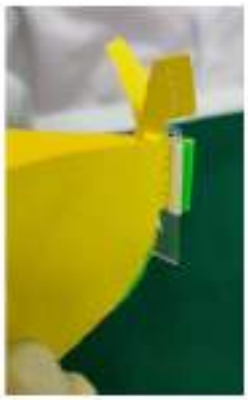


Figure 26

Figure 27

Figure 28

A spherical and a cross-sectional view of the joint are shown below. Both are taken from the PPD (K25).

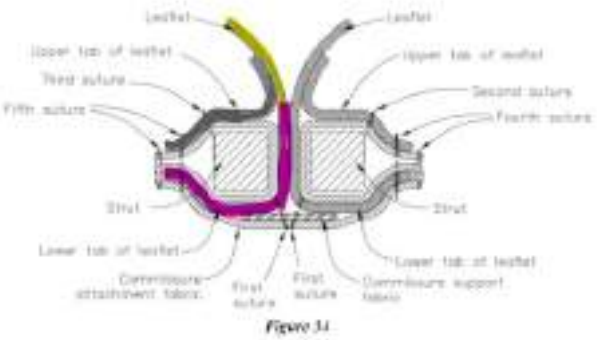


Figure 34

The leaflet is highlighted in yellow in the sectional view. The lower (primary) tab is marked in red. The upper (secondary) tab is marked in grey, with the first portion in lighter grey and the second portion in darker grey.

(**features 3 and 4**)

As a result, Meril's Myval THV literally infringes claim 1.

4. Literal infringement of claim 12

Meril does not contest the infringement of the other features of claim 12. The Court considers that Meril is right:

It is generally stated in mn.3 of K25's PPD:

3. The Myval THV is a balloon expandable prosthetic aortic heart valve, suitable for transcatheter implantation via the femoral artery. The Myval THV is crimped down to a low profile on the balloon of the Navigator delivery system, and is radially expanded from its crimped profile to deploy the prosthetic valve in the position of the native aortic valve by the inflation of the Navigator's balloon.

The Navigator THV delivery system is shown in Fig. 38 of the PPD:

Figure 38

The Navigator comprises an elongate shaft referred to as the "outer shaft" in Figure 38.

Meril's Myval THV is a radially expandable prosthetic heart valve (10) according to any one of claims 1-11, as shown in detail above for claim 1. It is described in mn. 32 of the PPD of K25:

32. The Myval THV is crimped onto the Navigator device using a piece of specialist equipment supplied by Meril. The Myval THV is crimped onto the balloon between stoppers on the Navigator device. A close-up image of this assembly is shown at Figure 39 below.

Figure 39

Therefore, claim 12 is also literally infringed by an assembly comprising the Navigator THV delivery system and the Myval THV.

5. Literal infringement of the other claims

Meril rightly does not contest the literal infringement of the other claims with other arguments as already dealt with.

Infringing Acts and Liability of the three Meril defendants

All three Meril defendants have committed infringing acts within the scope of the UPCA. And all Meril defendants are cumulatively liable because they acted in a close and interdependent commercial relationship based on their structure as members of a group of companies (see: ACT_18551/2024 UCP_CFI_166/2024):

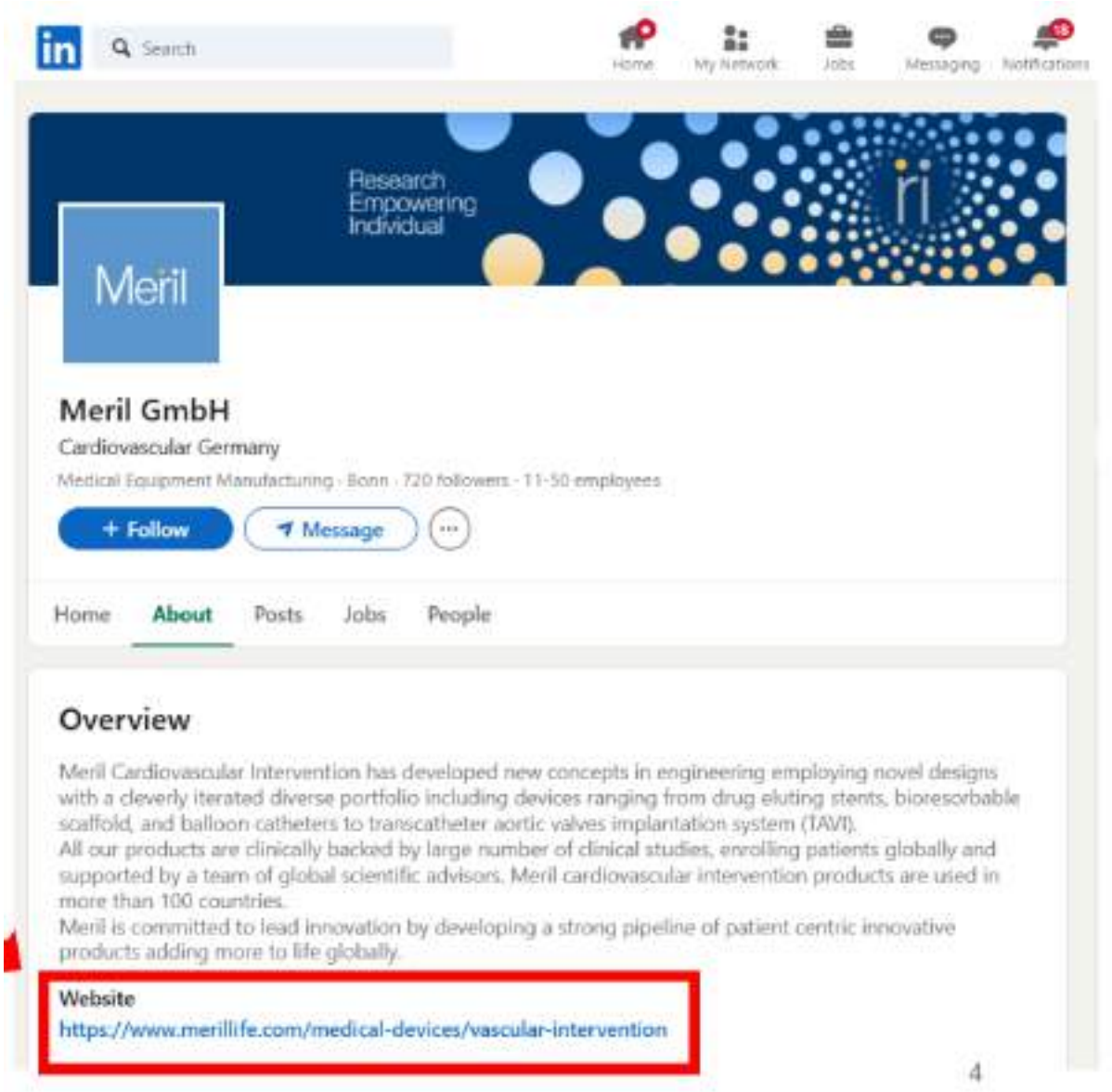
1. Defendant 2 (Meril India)

Meril India is the manufacturer of the attacked embodiments and the parent company of defendants 1 and 3. As its passive legitimacy is not contested, no further explanation is necessary.

2. Defendant 1 (Meril Germany)

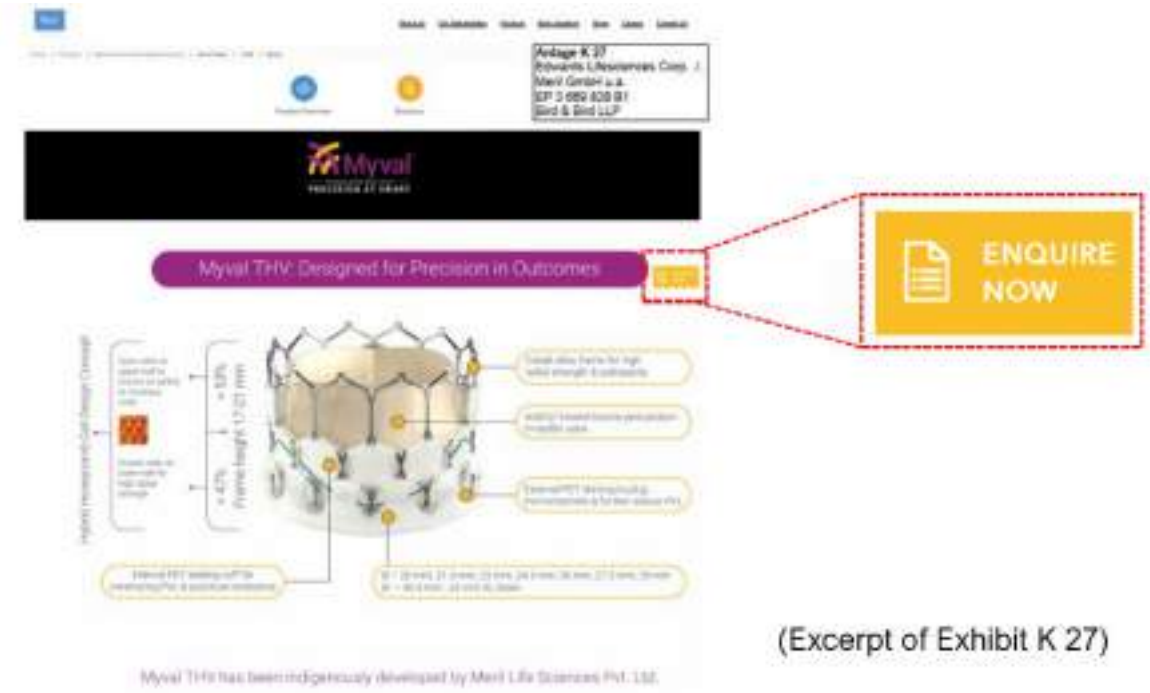
a. Website

Meril Germany does not have its own website but uses he Meril India`s website to offer the attacked embodiments. The user is automatically directed to Meril India`s website when searching for "Meril GmbH". Meril Germany has its own LinkedIn page, which also refers to the Meril India`s website:

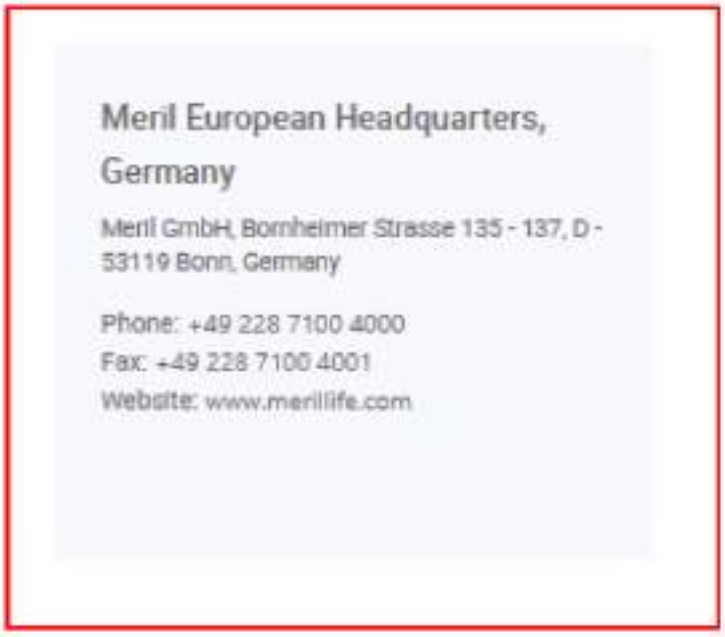


Meril India's website takes visitors directly to "vascular intervention" products, including "Myval":

The "Myval product section" contains images of the infringing embodiments and an "Enquire Now" button:



The "Enquire Now" button takes the user to the "Contact Us" page to enable the purchase of attacked embodiments. The "Contact Us" page lists Meril Germany as the "European Headquarters" (Appendix K 36):



The user will understand that Meril Germany supplies the infringing embodiments in Europe. In connection with the disclaimer:

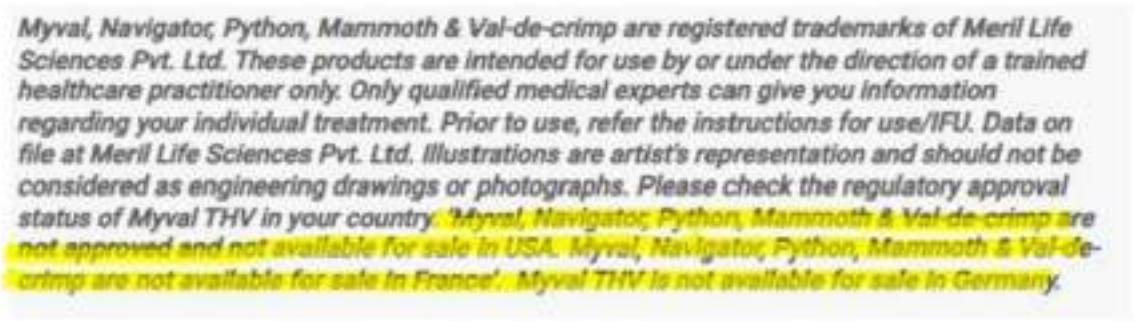


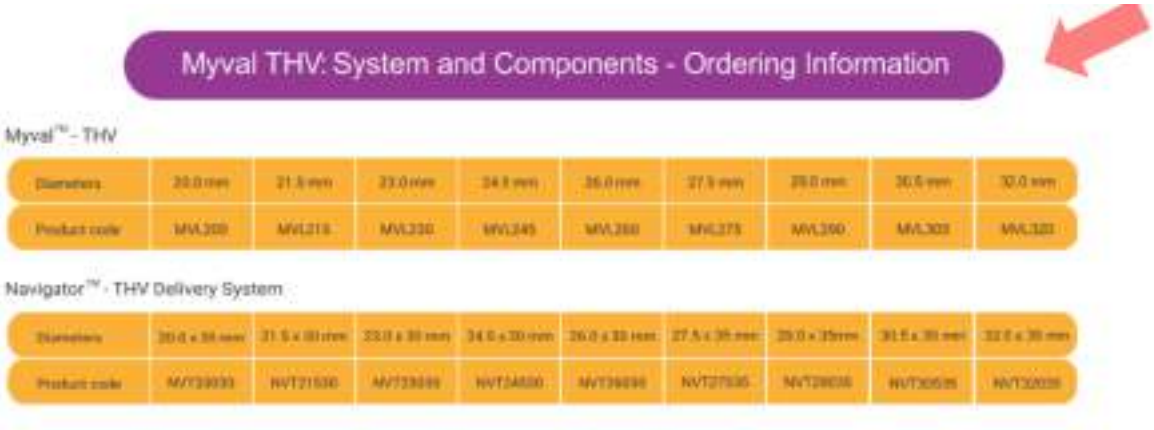
Abbildung 31 – Screenshot der Meril-Webseite (Hinweis)

The user will understand from the above that the attacked embodiments are offered for sale and available in all other Contracting Member States not listed in the disclaimer. Art. 34 UPCA provides that injunctive relief and other corrective measures may be ordered in respect of all Contracting Member States in which the European patent has effect and for which a decision of the Court has been requested as long as an act of infringement or the risk of a first infringement has been proven for at least one Contracting Member State (UPC_CoA_523/2024 APL_51115/2024 mn. 34).

b. Brochure with order information

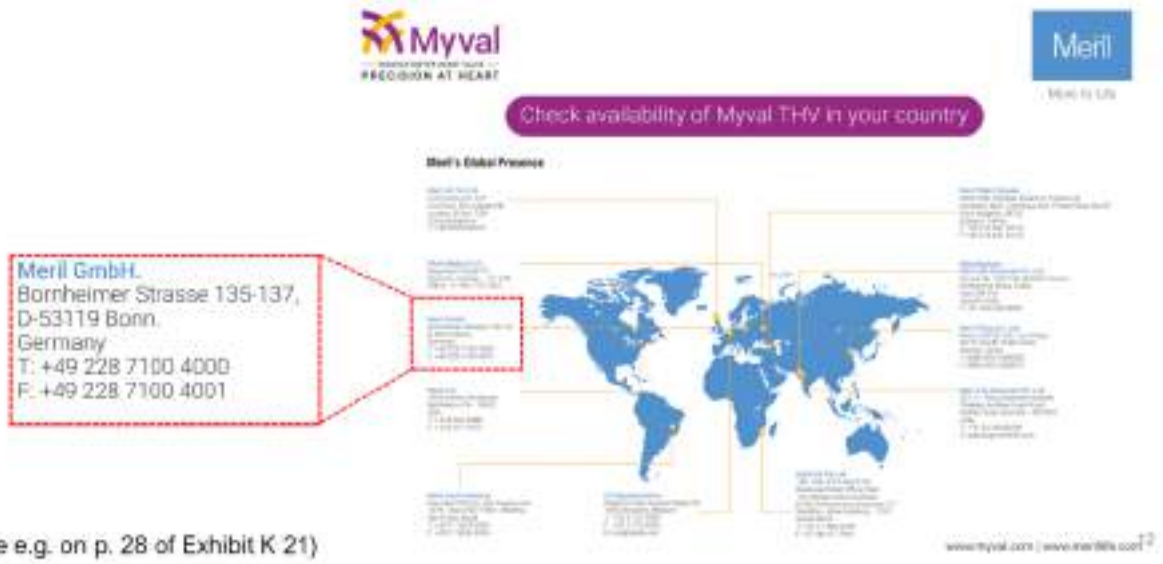
The following brochure (Exhibits K21 and K29) is available on the Meril India ´s website:

contains information on the attacked embodiments and ordering information



(p. 27 of Exhibit K 21)

including a reference to Meril GmbH as the only Meril entity in a UPCA Member State:



(see e.g. on p. 28 of Exhibit K 21)

Again, the disclaimer in the brochure:


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 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, Navigator, Python, Mammoth & Val-de-crimp are not available for sale in France, UK, Poland, Germany, Italy, Sweden & Denmark.
Myval, Navigator and Val-de Crimp, Val-de-crimp Neo are not available for sale in Germany.
Myval is CE certified by notified body,Polish Center for Testing and Certification (PCBC), Poland (NB 1434)

does not list all UPCA contracting member states. Furthermore, the territories mentioned differ from those mentioned on the website. On the other hand, there is information about a CE classification, which is required for Europe-wide sales. The reader is thus confused and uses the contact channels to obtain accurate information on the availability of the advertised products in the relevant territory. A customer contacting the salesperson is the first step in selling a product. Therefore, these activities fall within the infringing activity of "offering" in all Contracting Member States. The disclaimer has no effect.

c. Placing on the market

Meril GmbH sold the infringing embodiments in Germany after the grant of the patent (5 May 2021). Meril GmbH sold four Myval kits to Asklepios Klinik Hamburg on 19 May, 28 June and 5 July 2021 (Exhibit K 68) by entering into purchase agreements with Asklepios Klink Hamburg and instructing Herzzentrum Lahr to transfer the Myval devices previously delivered to it to Asklepios Klink Hamburg. The following slide illustrates the transactions:

Since Meril did not raise an exhaustion defence, these transactions constitute an act of putting the attacked embodiments on the market. The detour via the Herzzentrum Lahr for the physical delivery is of no significance.

This finding is consistent with a finding of the Munich Regional Court I in contempt proceedings regarding the same transaction. Reference is made to the court order of 14 February 2022 of that court (Exhibit K 66).

d. Conclusion

Infringement can be established as acts of offering and putting on the market by Meril Germany have been proved.

3. Defendant 3 (Meril Italy)

a. Shipping from India to Italy

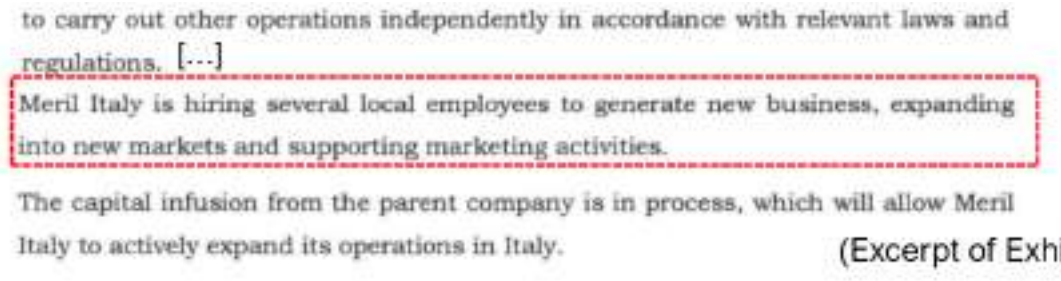
Meril India has in the past supplied several products to Meril Italy (Exhibit K-B 2). These included the Navigator, which is a delivery device included in the assembly of claim 12:

Trade date	Product	Supplier	Buyer	Buyer country	Supply country	qty
03.11.2023	MEDICAL DEVICE-MAMMOTH / BALLOON DILATATION CATHETER (AS PER INV VARIOUS SIZE)	meril life sciences pvt ltd.	meril italy s.r.l	Italy	India	6
03.11.2023	MEDICAL DEVICE-MYVAL OCTACOR (AS PER INV VARIOUS SIZE)	meril life sciences pvt ltd.	meril italy s.r.l	Italy	India	6
03.11.2023	MEDICAL DEVICE-PYTHON INTRODUCER SET - 14F	meril life sciences pvt ltd.	meril italy s.r.l	Italy	India	6
03.11.2023	MEDICAL DEVICE-NAVIGATOR INCEPTION / TRANSCATHETER HEART VALVE DELIVERY SYSTEM (AS PER INV VAERIOUS SIZE)	meril life sciences pvt ltd.	meril italy s.r.l	Italy	India	5

(Excerpt of Exhibit K-B 2)

However, there is no allegation that the Navigator was supplied with or for use with the Myval.

But together with Meril Italy's statement in the revocation actions against EP 825:


to carry out other operations independently in accordance with relevant laws and regulations. [...]

Meril Italy is hiring several local employees to generate new business, expanding into new markets and supporting marketing activities.

The capital infusion from the parent company is in process, which will allow Meril Italy to actively expand its operations in Italy.

(Excerpt of Exhibit K 5)

this gives rise to a risk of first infringement that the "Myval" and/or the "Navigator" for use with the "Myval" will be shipped to Italy in the future.

b. Use of Meril.Life.com

A customer searching for "Meril Italy" on Google is directed to Meril.Life.com. Via Meril.Life.com, the customer is redirected to Meril Germany, the European headquarters, as explained above. Meril did not contest this at the oral hearing. Therefore, Meril Italy uses and benefits from the offer activities on that website. The disclaimer on this website does not mention Italy. Thus, at least in Italy, offering has been established as an act of infringement.

4. Meril's statements during the oral hearing have not eliminated the risk of repetition.

a. UPC Representative for Meril Italy, Dr. Andras von Falk, said at the oral hearing [05:49:31.140 --> 05:49:50.790]: “Meril Italy has never and will never offer for sale or place on the market the [Myval] product. Meril Italy is only concerned with selling or was concerned with selling the Octacor product and is now engaging in other activities after the injunction by this panel.” Some time later [06:02:46.380 --> 06:03:02.580] he explained: “We believe that we're not infringing, we don't want to give an undertaking now and then have to carry the cost of the proceedings. We believe that this action is mature for dismissal.” Finally, he declared [: “Yes, I just want to declare on behalf of my clients Meril Germany sorry Meril GMBH and Meril Italy that neither of these two companies will engage in any business activities in relation to the Myval THV and in combination with the navigator product, and have not done so in the past.”

UPC representative for Edwards, Boris Kreye, said in reaction [06:25:11.660 --> 06:25:31.660]: “Even if it was directed to the patent owner we would not accept it without a penalty clause.”

b. Apart from the fact that this statement was not filed but made at the hearing, it is not appropriate, in the circumstances of the case, to allow the risk of repetition and/or the risk of a first infringement to be eliminated without a penalty clause. The three defendants are all members of the Meril Group. Meril India is the parent company and Meril Germany is the European headquarters. Meril Italy relies on the website provided by Meril India as explained above. The website refers customers to Meril Germany as the European headquarters. The present declaration is not made on behalf of all Meril defendants. In these circumstances, a declaration to cease and desist without a penalty clause cannot secure the patentee's interest in defending the exclusive nature of its right in the same way as a court order. The risk remains that the members of the group will re-organise their business around such isolated cease-and-desist declarations and thus continue to infringe the patent in the relevant territories without the risk of having to pay a penalty.

Public Interest defence and proportionality defence

The public interest defence and the proportionality defence are mainly rejected. As both parties agree that the same facts should be taken into account as in the decision of 15 November 2024 in EP 3 646 825 (ACT_459987/2023 UPC_CFI_15/2023), reference is made to the reasons given there. The Court found that there was a clear and urgent public need for Meril's XL prosthetic heart valve. This public need continues to be adequately met by the existing Medical Request Portal for the Myval valve prosthesis. At the oral hearing, Edwards conceded and confirmed that the Medical Request Portal for the XL Myval valve prosthesis will remain operational. The Medical Request Portal allows physicians to request a single-use licence to treat a specific patient. As the Medical Request Portal for the Myval valve prosthesis is functioning effectively, it is clear that no further conditions or restrictions are necessary with regard to the injunction, apart from the above-mentioned restrictions in the operational part of this decision.

Contrary to the decision of 15 November 2024, it is not necessary to limit/adapt the orders for recall and destruction. The information regarding the applicability of the Medical Request Portal to XL-sized Myval devices was already known in the market prior to the decision of 15 November 2024.

A referral to the Court of Justice of the European Union is therefore not justified.

No grace period

In the circumstances of this case, it is not appropriate to grant a grace period. The statement of claim was served on the defendants on 5 January 2024 and 7 February 2024. A primary date for the oral hearing in person was set for 17 December 2024 and an alternative date for 11 February 2025. UPC's representatives for the defendants argued that the entire team of defendants would not be available on these two dates for various reasons. The Judge-Rapporteur asked the defendants to choose between the two dates. The Defendants chose 11 February 2025 (ORD_598411/2023 of 29 July 2024). The announcement date is 4 April 2024. Thus, the Defendants have already been granted a grace period of more than three months compared to a decision following an Oral Hearing on 17 December 2024. The Defendants have not provided any arguments as to why a longer period would be necessary.

No compensation payment in lieu of an injunction

As regards compensation in lieu of an injunction, the Court finds that this is not justified by the circumstances of the case. Reference is made to the parallel decision in EP 3 646 825 of 15 November 2024 (ACT_459987/2023 UPC_CFI_15/2023).

The relief sought is widely justified

In the light of the foregoing, it can be concluded that Edwards is entitled to the following relief:

1. Injunctive relief

Pursuant to Art. 63(1) UPCA, Meril shall be obliged to cease and desist from further infringements. The auxiliary request can be granted with regard to the independent and dependent claims. The wording of the order is taken from UPC_CoA_382/2024 APL_39664/2024. As the act of "making" is not included in the requests it must not be included in the grated relief (Art. 76(1) UPCA).

As mentioned above, this order does not apply to XL devices where a physician has successfully applied for an individual exemption on behalf of a patient. It is agreed that Edwards will respond promptly to such requests, provided that the practitioner provides all necessary information.

2. Declaration of infringement

According to Art. 64(2)(a) UPCA, the court may declare that the attacked embodiments infringe the asserted patent claims.

3. Information

Edwards also has a claim against Meril for information pursuant to Art. 67(1) UPCA in conjunction with R. 191 RoP. This request is mostly justified and proportionate. Among other things, the request for information is intended to obtain information on the distribution channels of the infringing embodiment and the quantities and prices of the products supplied. In addition, the identity of third parties involved in the distribution of the infringing embodiment is of particular importance to Edwards to effectively enforce its exclusive rights. The information shall be provided at least in electronic form. This is required by considerations of good faith. To illustrate these considerations, reference can be made, for example, to German law (§ 242 BGB), under which the debtor is obliged to perform the obligation owed in a manner consistent with the requirements of good faith and customary practice, which the court also considers applying to orders of the UPC. It goes without saying that it is now common practice to collect and provide information in electronic form. However, it has not been established that it is customary to provide the information in both paper **and** electronic form. The remainder of the request must therefore be rejected.

Further the information is only due from the date after the grant of the patent (5 May 2021). Edwards requested information from 24 June 2020, the date of the application's publication. This is possible per se, as Rule 118.1 RoP and Art. 32(1) UPCA provide for compensation derived from the provisional protection of a European patent application. However, Edwards failed to provide any pleading that and why Meril also used the subject matter of the claims of the application. Therefore, the remaining request must be rejected.

4. Recall

Edwards is entitled to recall the infringing goods and their final removal from the distribution channels pursuant to Art. 64 II (b) UPCA. Again, this order does not apply to XL devices if a physician has successfully applied for an individual exemption on behalf of the patient.

5. Destruction

Edwards may also require Meril to destroy the infringing goods in its possession in countries where the UPCA applies pursuant to Art. 64 (2) (e) UPCA. Again, this order does not apply to XL devices if a doctor has successfully applied for an individual exemption on behalf of the patient.

6. Publication by Edwards

Edwards has a legitimate interest in the publication of the decision in five public media, including trade journals of its choice, pursuant to Art. 80 UPCA. In the event of full publication, the judgment delivered today shall be published in its entirety. In the event of partial publication, the full text of the rubric and the full operative part of the judgment shall be made available.

7. No publication by Meril

The request that Meril be ordered to publish the operative part of the Court's decision on its website is rejected as disproportionate. Although such an order would essentially fall under Art. 80 UPCA, the Court finds that no further publication order is necessary at this stage other than granting Edwards the right to publish the decision. Edwards has not provided any justification as to why this additional and humiliating method of publication is necessary.

8. Damages

Edwards is entitled to damages under Art. 68 UPCA in conjunction with R. 118.1 RoP because Meril acted culpably. Since Edwards is not yet able to quantify the damages it has suffered, it has a legitimate interest in having Meril's liability for damages determined.

9.Provisional damages

In addition, Edwards is entitled to payment of provisional damages pursuant to Art. 68 UPCA in conjunction with R. 119 RoP. The final determination of the amount of damages can be the subject of separate proceedings. The proposed amount of €663,000 has not been contested by Meril and shall therefore be awarded.

10. Costs of the proceedings

As the losing party, Meril must pay the costs and other expenses incurred by Edwards pursuant to Art. 69 (1) UPCA. The partial dismissals to the detriment of Edwards have no weight.

11. Penalty payment and costs of compliance with above orders

Pursuant to R 354.3 RoP, the decisions and orders of the Court may provide for periodic penalty payments to be made to the Court in the event that a party fails to comply with the terms of the order or any previous order. The amount of such payments shall be fixed by the Court having regard to the importance of the order in question. In the present case, a penalty payment of EUR 1,000 per day of **delay** seems appropriate.

Pursuant to Art. 63 (2) UPCA and R 354.3 RoP, non-compliance with the **injunction** is subject to a recurring penalty payment payable to the court. In view of the five-figure market price of the product in question, it seems appropriate to impose a penalty of €20,000 per case of non-compliance with the injunction and per infringing product.

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

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

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

1. Under R 118.2 (a) RoP the court may give its decision on the merits of the infringement action, including its orders, subject to the condition under Article 56(1) UPCA that the final decision in the revocation proceedings does not invalidate the patent in whole or in part, if an infringement action is pending before a local or regional division while a revocation action between the same parties is pending before the central division.

2. The sub-conditions of this provision are not met because the court has ruled on the counterclaim for revocation and decided to dismiss it.

Security for enforcement

As no request is made, it is not required to pay a deposit. The court also sees no reason to do so ex officio.

Immediately enforceable v. R 118.8, 352, 354 RoP

This decision is immediately and directly enforceable from the date of service in each of the Contracting Member States (R 354.1 RoP). This means that no security must be lodged beforehand and there is no condition under Rule 118.2.a RoP. However, Rule 118.8 RoP must be complied with.

DECISION

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

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

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

"Navigator" delivery apparatus

"Myval" prosthetic heart valve

within the territory of the Agreement on a Unified Patent Court where the patent has effect (except in Malta), (jointly: the Territory);

III. orders the three Meril defendants to comply with the order under item II. above, subject to a recurring penalty payment of up to EUR 20,000.00 for each violation of, or non-compliance with, the order. The placing on the market of each individual Infringing Product will be considered as a separate violation;

IV. declares that the three Meril-defendants have infringed the Patent-in-suit with respect to the products identified in item II. above in the Territory;

V. orders the three Meril defendants individually and jointly, under threat of a recurring penalty payment of up to EUR 1,000 for each day of delay, within a period of three weeks from the date of service of the decision, to provide Edwards with information on the extent to which the three Meril-defendants have committed the acts referred to in item II. since 5 May 2021 in the Territory, specifying:

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

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

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

whereby the list with the data has to be at least 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) are to be submitted by Defendants as proof of the information, whereby confidential details outside the subject of the information to be disclosed may be redacted;

VI. orders the three Meril defendants individually and jointly, under threat of a recurring penalty payment of up to EUR 1,000 for each day of delay, to take the following actions within one week of service of the Decision with regard to the Infringing Products placed on the market in the Territory since 5 May 2021:

a. to recall the Infringing Products not yet implanted with reference to the legally established patent-infringing nature of the products, and with the

binding commitment to take back the products and to bear any fees as well as necessary packaging and transport costs and customs and storage costs associated with the return, and

b. to take back the Infringing Products, with the proviso that these are then permanently removed from the distribution channels;

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

VIII. orders the three Meril defendants to allow Edwards to publish the Court's decision in whole or in part, including the publication of the decision in five public media and trade journals of its choice;

IX. declares that the three Meril defendants are jointly and severally obliged to compensate Edwards for the damage (including interest) that Edwards has suffered and will suffer as a result of the acts described in item II. above, committed since 5 May 2021;

X. orders the three Meril defendants to jointly and severally pay EUR 663,000 as provisional damages to Edwards within two weeks after service of the Decision;

XI. orders the three Meril defendants to jointly and severally bear the reasonable and proportionate legal costs and other expenses incurred by Edwards in the proceedings;

XII. orders that the measures mentioned above are to be carried out at the joint expense of the three Meril defendants;

XIII. declares that the above orders do not apply to XL devices where a physician has successfully applied for an individual exemption on behalf of a patient;

XIV. declares that this decision is immediately and directly enforceable from the date of service in each Contracting Member State;

XV. dismisses all other requests.

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 will be issued by the Deputy-Registrar upon request of the enforcing party, R. 69 RegR.

DETAILS OF THE DECISION

Order no. ORD_598588/2023 in ACTION NUMBER: ACT_597277/2023
UPC number: UPC_CFI_501/2023
Action type: Infringement Action

Order no. ORD_69128/2024 in ACTION NUMBER: CC_23112/2024
C number: UPC_CFI_501/2023
Action type: Counterclaim for revocation

Read in open court in Munich on 4 April 2025

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