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**Datasheet for the decision  
of 1 December 2025**

**Case Number:** T 1601/23 - 3.2.02

**Application Number:** 19189293.4

**Publication Number:** 3593762

**IPC:** A61F2/24, A61M29/02

**Language of the proceedings:** EN

**Title of invention:**

PROSTHETIC HEART VALVE AND DELIVERY DEVICE

**Patent Proprietor:**

Edwards Lifesciences Corporation

**Opponents:**

Meril GmbH  
Abbott Cardiovascular Systems, Inc.

**Relevant legal provisions:**

EPC Art. 54, 56, 76(1), 83, 84, 123(2), 123(3)  
RPBA 2020 Art. 12(4), 12(6)

**Keyword:**

New requests filed on appeal - admitted (yes)

New objection filed on appeal - admitted (no)

Added subject-matter

Clarity

Sufficiency of disclosure

Novelty

Inventive step

**Decisions cited:**

T 0294/89, T 2044/09, T 0885/20, T 1289/22



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Case Number: T 1601/23 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 1 December 2025**

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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
4 July 2023 concerning maintenance of the  
European Patent No. 3593762 in amended form.**

**Composition of the Board:**

**Chairman**            M. Alvazzi Delfrate  
**Members:**            S. Dennler  
                              N. Obrovski

## **Summary of Facts and Submissions**

I. The patent proprietor and opponent 1 both filed an appeal against the opposition division's interlocutory decision to maintain the contested patent as amended on the basis of the request then on file as auxiliary request 21.

II. The patent was granted from a divisional patent application ("the divisional application") derived from an earlier European patent application ("the parent application"), which was published as the following document:

D2 WO 2012/048035 A2

III. In its decision, the opposition division had found that the patent could not be maintained as granted because claims 1, 7, 8 and 15 as granted contained added subject-matter. On the other hand, auxiliary request 21, which had been filed during the oral proceedings to replace a previously filed auxiliary request 21 and which the opposition division admitted into the proceedings, was found allowable since it did not contain added subject-matter, complied with Article 123(3) EPC, was sufficiently disclosed, and the subject-matter of claim 1 of that request was novel in view of D7 and involved an inventive step starting from D7, D16 or D14, in combination with common general knowledge or D17.

D7, D14, D16 and D17 are the following documents:

D7 WO 2007/013999 A2

D14 US 2009/0157175 A1

D16 US 2006/0259137 A1

D17 WO 2009/042196 A2

- IV. The appellant-patent proprietor ("the patent proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, in amended form on the basis of one of auxiliary requests 1 to 15 filed with the patent proprietor's statement of grounds of appeal or one of auxiliary requests 16 to 72 filed with the patent proprietor's reply to the opponents' statement of grounds of appeal.
- V. The appellant-opponent 1 ("the opponent") requested that the decision under appeal be set aside and that the patent be revoked.
- VI. Opponent 2, party as of right to the appeal proceedings, did not take a position on the substance of the case and did not submit any requests during the appeal proceedings. It informed the Board by letter dated 11 November 2025 that it would not attend the oral proceedings to which the parties had been summoned.
- VII. Oral proceedings were held before the Board on 1 December 2025, in the absence of opponent 2 as announced. At the end of the oral proceedings, the present decision was announced.
- VIII. Claim 1 of the main request (claim 1 as granted) reads as follows (with feature numbering introduced by the Board):

- 1            *"An assembly for implanting a balloon-expandable prosthetic aortic valve (10) in a patient's body, the assembly comprising:*
- 1.1         *a delivery apparatus comprising an elongated shaft (180) having an inflatable balloon (182);*
- 1.2         *a radially expandable and collapsible prosthetic aortic valve (10) adapted to be mounted on the shaft (180) in a radially collapsed configuration for delivery into the body, the prosthetic aortic valve (10) comprising:*
- 1.2.1       *a balloon-expandable annular frame (12) comprising a plurality of angularly spaced commissure windows (30) each comprising an enclosed opening between first and second axially oriented side struts; and*
- 1.2.2       *a leaflet structure (14)*
- 1.2.2.1     *positioned within the frame (12) and secured to the commissure windows (30) of the frame (12),*
- 1.2.2.2     *the leaflet structure (14) comprising a plurality of leaflets (40)*
- 1.2.2.3     *each comprising*
- 1.2.2.3.1     *a body portion,*
- 1.2.2.3.2     *two opposing primary side tabs (116) extending from opposite sides of the body portion, and*
- 1.2.2.3.3     *two opposing secondary tabs (112) extending from the body portion adjacent to the primary side tabs (116);*
- 1.2.2.4.1   *wherein the secondary tabs (112) are folded about a radially extending crease*

1.2.2.4.2 *such that a first portion (142) of the secondary tabs (112) lies flat against the body portion of the respective leaflet (40),*  
1.2.2.5 *and the secondary tabs (112) are folded about an axially extending crease such that a second portion (144) of the secondary tabs (122) [sic] extends in a different plane than the first portion (142)."*

Claim 2 to 15 of the main request (claims 2 to 15 as granted) are dependent claims. Claim 15 reads as follows:

*"The assembly of claim 1, wherein the frame (12) comprises a material selected from a group comprising stainless steel and a cobalt-chromium alloy."*

IX. Auxiliary requests 1 to 7 differ from the main request by the inclusion of one or more of the following amendments A-I, A-II and A-III, as indicated in the following table:

Auxiliary request	Amendment		
	A-I	A-II	A-III
1	x		
2		x	
3	x	x	
4			x
5	x		x
6		x	x
7	x	x	x

The amendments A-I, A-II and A-III are defined as follows (with the amendments to the wording of the granted claims highlighted by the Board):

(a) Amendment A-I

Feature 1.2 of claim 1 is amended as follows:

1.2           *"a radially expandable and collapsible prosthetic aortic valve (10) adapted to be mounted on the balloon (182) of the shaft (180) in a radially collapsed configuration for delivery into the body, the prosthetic aortic valve (10) comprising:"*

(b) Amendment A-II

Claim 6 as granted is deleted (claims 7 to 15 being renumbered as claims 6 to 14) and its features are added at the end of claim 1 as follows:

*"[...] a different plane than the first portion (142); and*

1.2.2.6.1 *wherein the primary side tabs (116) extend radially outwardly through respective commissure windows (30) to a location outside of the frame and*

1.2.2.6.2 *are sutured to the secondary tabs (112) to secure the leaflets (40) around the side struts."*

(c) Amendment A-III

Claim 15 (or claim 14 where claim 6 has been deleted) is amended to specify that the alloy is "a nickel-based cobalt-chromium alloy".

X. The present decision also refers to the following documents:

D8 US 2006/0259136 A1  
D12 J. Rodés-Cabau, "Transcatheter aortic valve implantation: current and future approaches", Nature Reviews, Cardiology, 9:15-29 (2012)  
D20 WO 2009/149462 A2  
D29 WO 2008/079962 A1

XI. The patent proprietor's arguments, where relevant to the present decision, can be summarised as follows.

*Main request and auxiliary request 1 to 6 - added subject-matter*

Claim 1 of the main request and claim 1 of auxiliary requests 1 to 6 did not contain added subject-matter.

Claim 1 as granted was essentially based on the combination of claims 16 and 21 of the parent application as filed. The parent application as filed provided ample support for an assembly comprising the valve as defined in these claims and a delivery apparatus.

The reference in feature 1.2 to the valve being generally mounted "on the shaft" of the delivery apparatus was supported by the original disclosure, which consistently used this wording in the context of valves mounted on balloon catheters for delivery, as illustrated e.g. in paragraph [085] and Figure 56. Moreover, the invention was not limited to configurations in which the valve was mounted directly on the balloon.

Original claim 16 specified that the leaflet structure was secured to the leaflet attachment portions of the frame, without defining the specific manner in which the primary and secondary tabs were involved in the attachment. This provided a basis for omitting the second part of claim 21 from claim 1 as granted.

A cobalt-chromium alloy as generally defined in claim 15 as granted was explicitly disclosed in paragraph [053] of the parent application as filed as an alternative to a nickel-cobalt-chromium alloy.

*Auxiliary request 7*

*Admittance*

Auxiliary request 7 should be admitted in the appeal proceedings.

Auxiliary request 7 corresponded to the auxiliary request 21 originally filed in the opposition proceedings. The amended auxiliary request 21 deleting claims 7 and 8 had been filed in the oral proceedings before the opposition division to overcome the objections to these claims which the opposition division had found convincing, consistent with the patent proprietor's earlier statement, made already when filing the original auxiliary request 21, that it would be prepared to delete dependent claims if necessary and that it abstained from filing further auxiliary requests with reduced sets of claims only for reasons of procedural economy. This did not mean that the patent proprietor had abandoned the subject-matter of these claims, which had been maintained in the main request underlying the decision under appeal, now pursued on appeal. Moreover, by reintroducing them

auxiliary request 7 did not introduce any issue going beyond those discussed in the decision under appeal. Furthermore, auxiliary request 7 had been filed at the very beginning of the appeal proceedings.

*Added subject-matter*

None of the claims of auxiliary request 7 contained added subject-matter.

Amendments A-I to A-III overcame all objections to the granted claims that the Board had found convincing.

In the context of the contested patent, the terms "commissure windows" and "window frame portions" were equivalent. Moreover, the commissure windows were angularly spaced in all embodiments of the original disclosure. Amending the wording of original claim 16 to refer to "angularly spaced commissure windows" in feature 1.2.1 therefore did not add subject-matter.

Paragraph [085] disclosed an assembly comprising a balloon-inflatable valve and an associated balloon delivery apparatus. The person skilled in the art would understand from the original disclosure that this valve could, in addition, have its leaflets designed as defined in original claims 16 and 21, i.e. in claim 1 of auxiliary request 7. This assembly thus provided support for features 1 and 1.1 and for the frame being balloon-expandable in feature 1.2.1. The omission of further features of the assembly did not constitute an unallowable intermediate generalisation as the features relied upon by the opponent were not inextricably linked to the subject-matter of claim 1.

Moreover, it was irrelevant that feature 1.2 specified that the valve of the assembly was merely "adapted to be mounted" on the balloon, and not necessarily mounted on it. It was clear for the person skilled in the art that all valves disclosed in the original disclosure were adapted to be mounted on a delivery apparatus and that they were mounted on the latter at some point before implantation.

The subject-matter of dependent claims 2 to 14 was also directly and unambiguously disclosed in the parent application as filed. The person skilled in the art would understand that the original disclosure related to different aspects of the valve that, although described separately, were fully compatible and intended to be combined. Furthermore, the dependent claims were not based on unallowable intermediate generalisations.

*Extension of the scope of protection*

Auxiliary request 7 complied with Article 123(3) EPC. In feature 1.2.1 of claim 1 as granted, the mounting of the valve on the shaft also encompassed implicitly its mounting on the balloon. Therefore, amendment A-I merely limited the scope of claim 1 by excluding a direct mounting of the valve on the shaft.

*Clarity*

Claim 6 of auxiliary request 7 was clear. Given amendment A-I made in claim 1, on which claim 6 depended, the feature of claim 6 that the valve was radially collapsed on the shaft clearly meant that the valve was radially collapsed on the balloon of the shaft.

*Sufficiency of disclosure*

The invention as claimed in auxiliary request 7 was sufficiently disclosed. On the basis of the technical information provided in the patent, in particular in view of the embodiment described in relation to Figure 30, and common general knowledge, the person skilled in the art would have no difficulty in realising further embodiments of the claimed assembly, thereby disregarding any non-working configurations.

*Novelty in view of D7*

The subject-matter of claim 1 of auxiliary request 7 was novel in view of D7. The opponent's interpretation of Figure 8A of D7 was artificial. D7 did not disclose any secondary side tabs folded as defined in claim 1.

*Inventive step starting from D16, D7 and D14*

The subject-matter of claim 1 of auxiliary request 7 involved an inventive step starting from any of D16, D7 and D14.

The distinguishing features of claim 1 produced the technical effects described in paragraph [0056] of the contested patent, in that the folding of the secondary side tabs back onto the leaflet about a radially extending crease resulted in the formation of a double-layer region of leaflet material in the commissure region of the leaflet. This solved the technical problem of improving the reliability, durability and safety of the valve. The drawings provided by the opponent during the oral proceedings before the Board should not be admitted under Article 13(2) RPBA.

Neither the common general knowledge nor the prior art provided any teaching that would have led the person skilled in the art starting from D16, D7 or D14 to implement secondary side tabs folded in this specific manner. The claimed solution was therefore not obvious.

XII. The opponent's arguments, where relevant to the present decision, can be summarised as follows.

*Main request and auxiliary request 1 to 6 - added subject-matter*

Claim 1 of the main request contained added subject-matter at least for the following reasons.

Feature 1.2 defined the valve as being "adapted to be mounted on the shaft" without specifying that the valve was mounted on the balloon. This wording meant that the claimed valve was to be mounted directly on the shaft, i.e. on a part of the shaft other than the balloon. However, such a mounting mode was not disclosed in the parent application as filed. Feature 1.2 therefore added subject-matter.

Valve embodiments comprising commissure windows defined by axially oriented side struts, as specified in claim 1 as granted, were consistently associated in the original disclosure with the specific configuration of the primary and secondary tabs as defined in the second half of original claim 21. No alternative manner of attaching the primary and secondary tabs to the commissure windows was disclosed in the original disclosure. The omission of this specific configuration from claim 1 as granted was therefore an unallowable intermediate generalisation.

There was no support in the original disclosure for cobalt-chromium alloys as generally defined in claim 15 as granted, i.e. without any restriction that the alloys also contained nickel. The reference to a cobalt-chromium alloy in paragraph [053] only appeared in the context of examples of nickel-based alloys.

Claim 1 of each of auxiliary requests 1 to 6 also contained added subject-matter for at least one of the same reasons.

*Auxiliary request 7*

*Admittance*

Auxiliary request 7 should not be admitted on appeal.

By replacing, in the opposition proceedings, the former auxiliary request 21 with an amended version in which claims 7 and 8 were deleted, the patent proprietor had withdrawn that former request and thus no longer maintained it. On that basis, auxiliary request 7, which corresponded to that former request, should not be admitted in the appeal proceedings pursuant to Article 12(6) RPBA. Allowing the patent proprietor on appeal to revert to a request that had been withdrawn and to pursue again claims that had been deleted would be unfair to third parties and contrary to the principle of procedural economy.

In addition, claim 6 of auxiliary request 7 defined the valve as being "radially collapsed on the shaft". This definition was in contradiction with amendment A-I, according to which the valve was mounted on the balloon of the shaft, and therefore rendered claim 6 unclear.

Consequently, admitting auxiliary request 7 would also introduce additional issues into the proceedings to the detriment of procedural economy.

In any event, the opposition division had exercised its discretion incorrectly when admitting the amended auxiliary request 21, since claims 7 and 8 as granted had been objected to from the outset of the opposition proceedings, namely already in the notices of opposition. The patent proprietor should not be allowed to pursue on appeal a request which expanded on that amended auxiliary request 21.

*Added subject-matter*

Auxiliary request 7 contained added subject-matter despite the introduction of amendments A-I to A-III.

*Claim 1*

The valve of claim 1 corresponded to a large extent to the valve defined by original claims 16 and 21. However, feature 1.2.1 defined "angularly spaced commissure windows", and not "window frame portions" as defined in original claim 21. These terms had different meanings. In any event, angularly spaced commissure windows were disclosed in the original disclosure only in combination with additional features with which they were inextricably linked. The omission of these additional features from claim 1 thus constituted an unallowable intermediate generalisation. In addition, the expression "balloon-expandable annular frame" in feature 1.2.1 lacked a basis in the original disclosure.

Furthermore, the parent application as filed did not disclose the specific combination of the valve of original claims 16 and 21 with a delivery apparatus in the context of an assembly as defined in features 1 and 1.1. The general disclosure of paragraph [007] provided no basis for such a combination. The subject-matter of claim 1 of auxiliary request 7 could only be considered as a combination of original claims 16 and 21 with features extracted from a specific embodiment, such as that shown in Figure 56 and described in paragraph [085]. However, such extraction inherently involved the isolation of the claimed features from other features to which they were inextricably linked. The omission of these other features constituted an unallowable intermediate generalisation. In particular, the embodiment described in paragraph [085] required at least an inflow end portion having an outer diameter smaller than that of the outflow end portion of the frame, V-shaped leaflets, an outer skirt positioned around the inflow end portion of the frame, and leaflets sutured to the side struts of the commissure window frame. These features related to the size and shape of the valve during collapse and expansion and were therefore essential for the successful delivery of the valve using the claimed delivery apparatus. Therefore, they could not be permissibly omitted from claim 1 of auxiliary request 7.

Finally, since the valve was consistently disclosed as being mounted on the balloon in all assemblies of the original disclosure, no basis existed for specifying in feature 1.2 as amended by amendment A-I that the valve was merely "adapted to be mounted" on the balloon.

*Claims 2 to 5*

Claims 2 to 5 corresponded to original claims 17 to 20, which, like original claim 21, depended directly on original claim 16. The original disclosure provided no indication that the subject-matter of these claims could be combined with that of original claims 16 and 21, let alone for forming an assembly as defined in claim 1 of auxiliary request 7. Claims 2 to 5 therefore contained added matter.

*Claims 6 and 7*

A similar objection applied to claims 6 and 7, the subject-matter of which corresponded to that of original claims 9 to 11. The original disclosure provided no indication that this subject-matter could be combined with that of original claims 16 and 21, let alone for forming an assembly as defined in claim 1 of auxiliary request 7.

In any event, paragraph [086] and Figure 56 could not provide a basis for the features of claims 6 and 7 either. Although these passages disclosed radially depressed commissure windows, these were disclosed in combination with several further features, namely a tapered frame, V-shaped leaflets and an outer skirt, which served the same purpose of reducing the crimp profile as the features of claims 6 and 7 and to which they were inextricably linked. Therefore, the omission of these further features from claims 6 and 7 constituted an unallowable intermediate generalisation.

*Claims 8 and 9*

Claims 8 and 9 corresponded to original claims 13 and 14. Original claim 13, which was an independent claim, disclosed an embodiment independent from that of

original claim 16. The original disclosure provided no indication that the subject-matter of these claims could be combined, let alone in an assembly as defined in claim 1 of auxiliary request 7. In any case, contrary to the opposition division's finding, paragraph [015] did not disclose the features of claim 9 and therefore did not provide an adequate basis for that claim.

*Claims 10 to 13*

As indicated below, claims 10 to 13 were based on unallowable intermediate generalisations of various embodiments of the original disclosure, since they omitted various features of those embodiments which were originally disclosed in combination with the claimed features and with which the latter were inextricably linked.

a) Claim 10

The at least one intermediate row of openings defined in claim 10 was inextricably linked to the additional feature that the openings of the inflow row of openings were larger than the openings of the at least one intermediate row of openings, as disclosed in the final sentence of paragraph [012] of the original disclosure. As disclosed in paragraph [061] of the original disclosure, this additional feature aimed at reducing of the crimp profile of the valve, which was the purpose generally sought by the original disclosure as disclosed in paragraph [006].

The "circumferentially extending rows of angled struts arranged end-to-end" defined in claim 10, which were disclosed only in paragraph [054] of the original disclosure, were also inextricably linked to additional

features being a specific frame configuration having five rows of struts, with upper row openings being relatively large and sized to allow portions of the leaflet structure to protrude therethrough, with again the purpose of minimising the crimping profile, as disclosed in paragraph [056].

b) Claim 11

The inner skirt defined in claim 11 was inextricably linked to the presence of an outer skirt, as disclosed in paragraph [050] of the original disclosure. That paragraph did not provide a basis for omitting the outer skirt.

In addition, the feature that the inner skirt was sutured to an inner surface of the frame, which was disclosed only in paragraphs [019] and [073] of the original disclosure, was inextricably linked to the feature that the inner skirt comprised a weave of first and second non-parallel strands and to the suturing taking place at locations away from suture line 154, such that the skirt could be more pliable in that area.

c) Claim 12

The features of claim 12, which were extracted from paragraph [085], were inextricably linked to a number of further features, such as the requirement for the frame to have a tapered shape and the use of V-shaped leaflets 40, for the purpose of compensating for the additional circumferential bulk added by the outer skirt.

d) Claim 13

The wedges defined in claim 13 were inextricably linked to the presence of connector 124 and to a specific shape and position of the primary side tabs outside of the frame, namely that the tabs had portions "located outside of the frame" that "extend[ed] circumferentially away from one another and along an exterior surface of the side struts", as defined in original claim 26, and that, under the action of the wedges, "one of the lower tab portions 116 and a portion of the connector 124 [was] folded against the frame 12", as disclosed in paragraph [080]. Without these features, the wedges could not fulfil their function.

*Claim 14*

Amendment A-III did not overcome the added subject-matter objection raised against to claim 15 as granted.

A "nickel-based cobalt-chromium alloy" as specified by amendment A-III was broader than the "nickel-based alloy (e.g., a cobalt-chromium or a nickel-cobalt-chromium alloy)" originally disclosed in paragraph [053] of the original disclosure.

Furthermore, the disclosure of a nickel-based cobalt-chromium alloy in paragraph [053] was inextricably linked with the requirement that such a material fell within the category of "suitable plastically expandable materials" disclosed in that paragraph. Claim 14 failed to specify that the nickel-based cobalt-chromium was plastically-expandable.

*Extension of the scope of protection*

Amendment A-I extended the scope of protection conferred by claim 1 as granted. By specifying that the valve was adapted to be mounted on the shaft of the delivery apparatus, feature 1.2.1 of claim 1 as granted required it to have features that allowed it to be mounted on a rigid shaft, as shown in Figure 46. In contrast, amendment A-I required the valve to have features allowing it to be mounted on a balloon, i.e. a highly flexible and expandable diaphragm, as shown in Figure 56. The adaptations required for mounting a valve upon these two different substrates of differing diameters were not identical. Therefore, the scope of the amended claim had shifted to encompass subject matter lying outside of the scope claimed by the patent as granted.

#### *Clarity*

Claim 6 of auxiliary request 7 was unclear. It defined the valve as being "radially collapsed on the shaft", which was in direct contradiction with amendment A-I according to which the valve was mounted on the balloon of the shaft.

#### *Sufficiency of disclosure*

The invention as claimed in auxiliary request 7, in particular in claims 1 and 13, was not sufficiently disclosed across the whole scope of the claims.

The contested patent disclosed only a single embodiment with leaflets comprising primary and secondary side tabs, namely the embodiment shown in Figure 21 and described in paragraph [0049], in which the lower and upper tabs corresponded to the claimed primary and secondary tabs, respectively. However, the terms

"primary side tabs" and "secondary side tabs" used in claim 1 did not impose any positional limitations on the tabs, with the result that claim 1 encompassed various further embodiments other than the single embodiment disclosed in Figure 21 and paragraph [0049]. The patent failed to provide sufficient information enabling the person skilled in the art to realise such further embodiments.

Claim 13 referred to the wedge being "urged radially inwardly against the primary side tabs" but did not define any feature capable of producing such an urging action. Connector 124 and sutures 148, as disclosed in paragraph [0054] and Figures 23 and 29, were necessary to achieve this effect. Since these features were absent from claim 13, the disclosure was not sufficient across the full scope of the claim. This objection was raised for the first time in the opponent's statement of grounds of appeal (see point 109).

*Novelty in view of D7*

The subject-matter of claim 1 of auxiliary request 7 was not novel in view of D7. As shown in the annotated figures on page 10 of the opponent's reply, the leaflet 36 shown in Figure 8A comprised the same tab structure and folding configuration as claimed.

*Inventive step starting from D16*

The subject-matter of claim 1 of auxiliary request 7 did not involve an inventive step starting from D16.

The subject-matter of claim 1 differed from the disclosure of D16 only by features 1.2.2.3.3 to 1.2.2.5 and 1.2.2.6.2 relating to the secondary side tabs.

These distinguishing features, which did not define the specific configuration shown in Figures 29 and 30 and described in paragraph [0056] of the patent, failed to produce any technical effect. Therefore, the objective technical problem to be solved could only be regarded as to provide an alternative means of attaching a leaflet to a commissure window.

In fact, these features amounted to nothing more than a mere arbitrary, non-functional modification of the prior art. In line with the established case law, as set out *inter alia* in T 2044/09, T 1289/22, T 885/20 and T 294/89, any such arbitrary, non-functional modification was to be disregarded in the assessment of inventive step. As stated in T 2044/09 (Reasons 4.6), this applied even in the absence of a pointer or suggestion in the prior art towards this modification.

In any event, numerous leaflet attachment and folding configurations were known in the art and formed part of the common general knowledge, as reflected, for example, in D12 (see Figures 1a and 1b), D20 (see Figures 3 and 4), D29 (see Figures 1 and 2), D8 (see Figures 3A and 4A) and D14 (see Figure 9B). The person skilled in the art, seeking an alternative means of attaching a leaflet to a commissure window, would, using common general knowledge or prompted by D17 (see Figures 25A and 25B) or D8 (see Figures 3A and 4A), have arrived at the subject-matter of claim 1 as a matter of mere routine design, without exercising inventive skill.

*Inventive step starting from D7 and D14*

The subject-matter of claim 1 of auxiliary request 7 also lacked an inventive step when starting from D7 or D14, for substantially the same reasons.

## Reasons for the Decision

### Subject-matter of the contested patent

1. The contested patent relates to an assembly comprising a balloon-expandable prosthetic aortic valve and a corresponding delivery apparatus having an elongated shaft with an inflatable balloon for minimally invasive implantation of the valve.

1.1 As shown in Figures 2 and 4, reproduced below, the prosthetic valve (10) comprises a balloon-expandable annular frame (12) including a plurality of angularly spaced commissure windows (30), each comprising an opening (20) enclosed between first and second axially oriented side struts (feature 1.2.1). A leaflet structure (14) comprising a plurality of leaflets (40) is positioned within the frame and secured to the commissure windows (features 1.2.2 to 1.2.2.2).

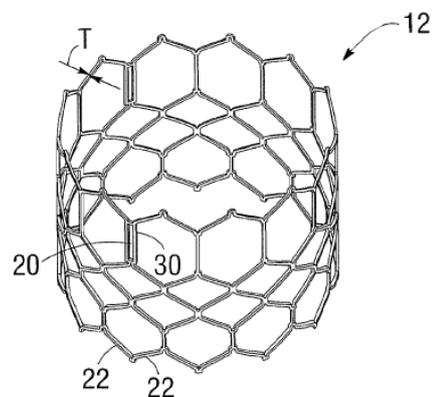
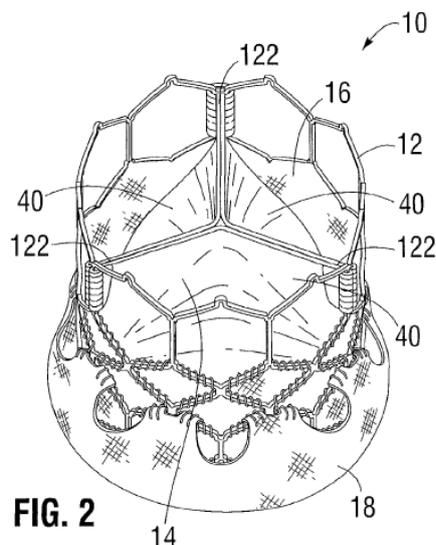
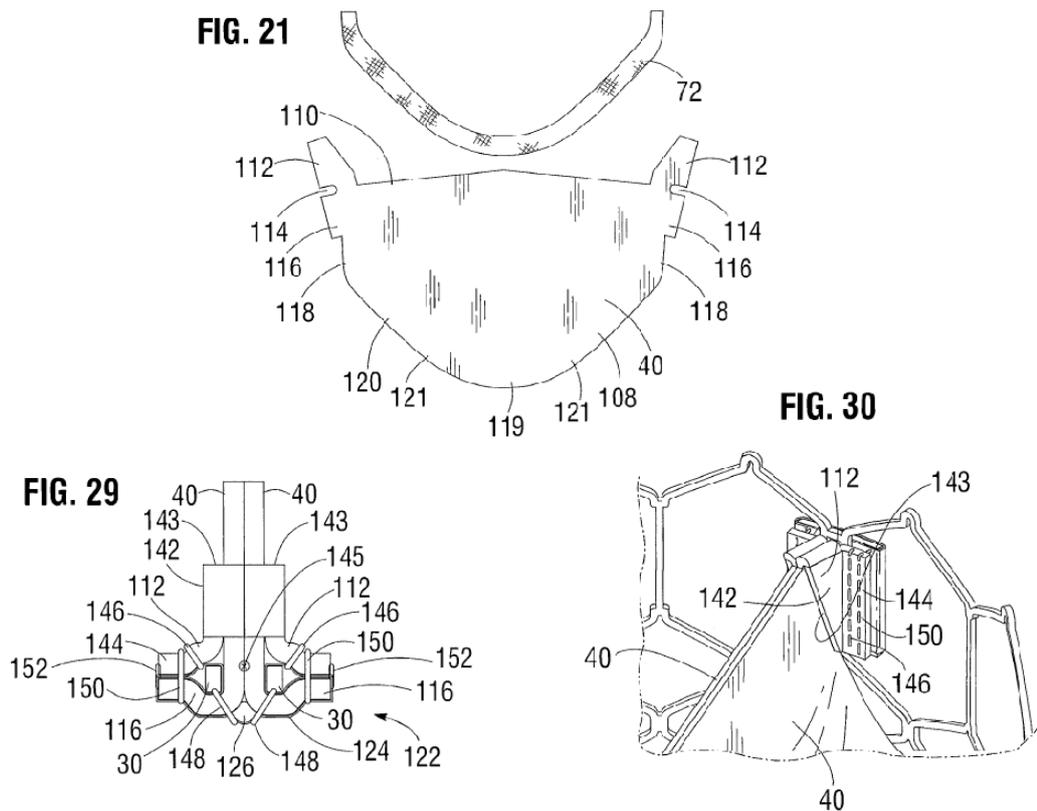


FIG. 2

FIG. 4

1.2 Claim 1 of the various claim requests defines more specifically the manner in which the leaflets (40) are secured to the commissure windows (30). This aspect is described, *inter alia*, in paragraphs [0049] to [0056] with reference to Figures 21, 29 and 30, reproduced below.



As claimed and shown on these figures, each leaflet (40) comprises a body portion, two opposing primary side tabs (116) extending from opposite sides of the body portion (feature 1.2.2.3.2), and two opposing secondary tabs (112) extending from the body portion adjacent to the primary side tabs (feature 1.2.2.3.3).

The primary side tabs (116) extend radially outwardly through the commissure windows (30) to a location outside of the frame and are sutured to the secondary

tabs (112), thereby securing the leaflets (40) around the side struts (features 1.2.2.6.1 and 1.2.2.6.2).

The secondary tabs (112) are folded about a radially extending crease such that a first portion (142) lies flat against the body portion of the respective leaflet, and further folded about an axially extending crease such that a second portion (144) extends in a different plane than the first portion (features 1.2.2.4.1, 1.2.2.4.2 and 1.2.2.5).

As explained in paragraph [0056], the folding configuration illustrated in Figures 29 and 30 results in the commissures (122) comprising four layers of leaflet material in their region immediately radially inward of the commissure windows (30). This configuration is described to increase the leaflets' resistance to bending in this region and cause their articulation to occur radially inward of the commissure windows. As a result, contact between the moving portions of the leaflets and the frame is reduced, which may otherwise lead to damage of the leaflet structure.

**Main request and auxiliary requests 1 to 6 - added subject-matter**

2. The descriptions and drawings of the parent and divisional applications as filed are substantially identical, with the claims of the parent application being included as a list of embodiments in paragraph [0115] of the description of the divisional application. Consequently, the content of the parent application as filed, which corresponds to the content of D2, constitutes the relevant disclosure for the assessment of added subject-matter under both

Articles 76(1) and 123(2) EPC. This content is referred to as "the original disclosure" in the following.

3. At the oral proceedings before the Board, the parties did not make any further comments on whether the main request and auxiliary requests 1 to 6 contained added subject-matter, but relied on their written submissions. The Board therefore sees no reason to deviate from its preliminary view on this issue as set out in its communication under Article 15(1) RPBA (see points 3.2 to 3.2.3 and 4) and reiterated in substance below, according to which claims 1 and 15 as granted contain added subject-matter, with the result that the main request is not allowable.

### 3.1 *Claim 1 as granted*

It is common ground that the parent application as filed does not disclose explicitly an embodiment comprising all features of claim 1 as granted in combination. Rather, claim 1 as granted is based on the combination of original independent claim 16 and the first half of dependent claim 21, with the additional features 1, 1.1, 1.2 and 1.2.1 being taken from the original description (see Reasons 20). The opponent's objections to features 1.2 and 1.2.1 are convincing.

#### 3.1.1 *Feature 1.2: valve adapted to be "mounted on the shaft"*

Although feature 1.1 specifies that the shaft of the claimed assembly has a balloon, feature 1.2 states that the valve of the assembly is adapted to be "mounted on the shaft" without any reference to the balloon. This conveys to the person skilled in the art the technical teaching that the valve is not restricted to be mounted on the balloon, but that it can be mounted on a part of

the shaft other than the balloon, for example directly on the shaft, as argued by the opponent. The fact that the frame of the valve is defined as balloon-expandable in feature 1.2.1 does not change this interpretation since the balloon-expandable valve could be initially crimped onto the shaft off the balloon and subsequently moved onto the balloon for expansion and deployment (see in this regard the decision under appeal, Reasons 20.1.1).

However, the teaching that the valve can be adapted to be mounted on a part of the shaft other than the balloon is neither explicitly nor implicitly disclosed in the original disclosure. On the contrary, as argued by the opponent, for all the disclosed assemblies in which, as in the assembly of claim 1 as granted, the delivery apparatus is a balloon catheter and the valve is balloon-expandable, the original disclosure consistently describes that the valve is mounted *on the balloon* of the shaft. This applies also to the embodiment illustrated in Figure 56 and described in paragraph [085]. The patent proprietor's contrary assertion that the original disclosure is not limited, for such assemblies, to mounting the valve directly on the balloon is thus not convincing.

It follows that feature 1.2 presents the person skilled in the art with technical information which is not directly and unambiguously derivable from the original disclosure. This confirms the opposition division's corresponding conclusion in the decision under appeal (see Reasons 20.1 to 20.1.2).

*3.1.2 Feature 1.2.1: omission of the second part of original claim 21*

The opponent submitted that feature 1.2.1 cannot allowably define "commissure windows (30) each comprising an enclosed opening between first and second axially oriented side struts", as defined in the first half of original claim 21, without also defining that "the primary side tabs extend radially outwardly through respective 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", as defined in the second half of original claim 21, which has been omitted from claim 1 as granted.

It is true, as argued by the patent proprietor, that original claim 16, on which original claim 21 depends, already specifies that the leaflet structure is "secured to the leaflet attachment portions of the frame" without detailing the specific role of the primary and secondary tabs in this attachment.

However, as argued by the opponent, the parts of the original disclosure relating to valve embodiments in which the leaflets comprise such sets of primary and secondary tabs (both in original claim 21 and in the corresponding passages of the original description) consistently disclose that, where the leaflet attachment portions of the frame are constituted by "commissure windows each comprising an enclosed opening between first and second axially oriented struts" (as specified by feature 1.2.1 and originally disclosed in the first part of original claim 21), the primary (or lower) side tabs extend radially outwardly through respective window frame portions to a location outside of the frame and are sutured to the secondary (or upper) tabs to secure the leaflets around the side struts (as defined in the second part of original

claim 21; see also paragraphs [0079]-[0081] and Figures 29-30).

Contrary to the patent proprietor's argument, this configuration of the primary and secondary side tabs is not optional for the embodiments with commissure windows in accordance with original claim 21. Rather, the person skilled in the art would regard it as inextricably linked to the presence of commissure windows with axially extending struts. The original disclosure does not disclose any alternative manners of attaching the primary and secondary tabs to the side struts of said commissure windows.

It follows that the omission from claim 1 as granted of the features defined in the second part of original claim 21 constitutes an unallowable intermediate generalisation. This also confirms the opposition division's corresponding conclusion in the decision under appeal (see Reasons 20.2 to 20.2.3).

### 3.2 *Claim 15 as granted: "cobalt-chromium alloy"*

The second alternative in claim 15 as granted defines the frame as comprising "a cobalt-chromium alloy", without any further limitation. On a plain reading, the wording of claim 15 thus relates to a cobalt-chromium alloy *in general*, i.e. one that may not contain nickel. The Board agrees with the opponent that this alternative is not disclosed in the original disclosure.

Contrary to the patent proprietor's argument, the mention of a cobalt-chromium alloy in paragraph [053] of the original disclosure does not provide a basis for this alternative. The examples given in parentheses in

paragraph [053], namely "e.g., a cobalt-chromium or a nickel-cobalt-chromium alloy", are merely examples (as indicated by the term "e.g.") of the "nickel based alloy" genus disclosed immediately before. Therefore, the "cobalt-chromium alloy" example must be understood as referring to a cobalt-chromium alloy that itself contains nickel, contrary to the patent proprietor's view. The Board notes in this respect that, in metallurgical practice, alloys marketed as cobalt-chromium alloys frequently also contain nickel.

It follows that cobalt-chromium alloys *in general*, i.e. alloys not necessarily containing nickel, are not directly and unambiguously disclosed in the original disclosure, with the result that claim 15 as granted contains added subject-matter. This also confirms the opposition division's corresponding conclusion in the decision under appeal (see Reasons 30 to 30.2).

4. Auxiliary requests 1 to 6 differ from the main request only in that they include one or two of amendments A-I, A-II and A-III. However, they do not include all three amendments (see point IX. above), with the result that at least one of the objections discussed above for claims 1 and 15 as granted still applies. These requests are therefore also unallowable.

#### **Auxiliary request 7**

#### **5. Admittance**

- 5.1 Auxiliary request 7 corresponds to auxiliary request 21 as originally filed by the patent proprietor in the opposition proceedings and subsequently replaced during the oral proceedings before the opposition division by an amended auxiliary request 21 in which claims 6 and 7

were deleted (see Minutes 9 and Reasons 39 of the decision under appeal).

The opponent submitted that the original auxiliary request 21, i.e. auxiliary request 7, had not been maintained and should therefore not be admitted in the appeal proceedings pursuant to Article 12(6), first sentence RPBA.

- 5.2 It is undisputed that by replacing the former auxiliary request 21 with an amended request deleting claims 6 and 7, the patent proprietor formally withdrew the former request.

However, claims 6 and 7, which correspond to claims 7 and 8 as granted, remained part of the patent proprietor's main request pursued in the opposition proceedings, namely the request for maintenance of the patent as granted. The deletion of these claims from the amended auxiliary request 21 therefore did not prevent the opposition division from deciding upon them, which the opposition division actually did, finding them to contain added subject-matter (see Reasons 24). This objection prompted the filing of the amended auxiliary request 21 deleting these claims, consistent with the patent proprietor's earlier statement made when filing the original auxiliary request 21 that it would be prepared to delete dependent claims if necessary and that it refrained from filing further auxiliary requests with such reduced sets of claims for reasons of procedural economy.

In view of these circumstances, the replacement of the original auxiliary request 21 by the amended version during the opposition proceedings does not amount to an

abandonment of the subject-matter of claims 7 and 8 as granted.

- 5.3 Claims 7 and 8 as granted are also pursued in the main request in the appeal proceedings, which is identical to the main request underlying the decision under appeal.

As indicated in the communication under Article 15(1) RPBA (see points 3.3.1 and 3.3.2), the Board did not find the opposition division's added subject-matter objections against these claims and the other dependent claims to be convincing.

Moreover, as further indicated in the communication (see points 5.2 and 6), the amendments A-I, A-II and A-III introduced in auxiliary request 7 *prima facie* overcome all added subject-matter objections against claim 1 as granted which the Board had found convincing. In addition, claim 1 of auxiliary request 7 is identical to claim 1 of auxiliary request 21 as underlying the decision under appeal, which the opposition division found to be allowable.

Furthermore, the Board also found *prima facie* unconvincing the alleged lack of clarity raised by the opponent in its reply to the patent proprietor's statement of grounds of appeal against claim 6 of auxiliary request 7 - on which the opponent did not comment again when discussing the admittance of auxiliary request 7 at the oral proceedings before the Board.

Therefore, auxiliary request 7 appeared *prima facie* to be allowable.

Finally, contrary to the opponent's view, the question of whether the opposition division correctly exercised its discretion in admitting the amended auxiliary request 21 has no bearing on the assessment of the admittance of auxiliary request 7.

For these reasons, and in line with its preliminary opinion expressed in the communication pursuant to Article 15(1) RPBA (see point 5.2), the Board considered that the circumstances of the appeal case justified the admittance of auxiliary request 7 into the appeal proceedings (Article 12(6), first sentence RPBA).

## **6. Added subject-matter**

6.1 Auxiliary request 7 differs from the main request in that it includes all three amendments A-I, A-II and A-III.

The opponent's added-matter objections raised against auxiliary request 7, including those objections raised against the claims as granted and likewise applying to the corresponding claims of auxiliary request 7, are not convincing, for the reasons set out below. This conclusion is consistent with the Board's preliminary opinion expressed in the communication under Article 15(1) RPBA (see points 3.3.1, 3.3.2 and 6 to 6.2).

### *6.2 Claim 1*

6.2.1 The Board is satisfied that, by adding features 1.2.2.6.1 and 1.2.2.6.2, corresponding to the second part of original claim 21, into claim 1, amendment A-II

overcomes the objection raised in point 3.1.2 above against feature 1.2.1 of claim 1 as granted.

The opponent maintained that, notwithstanding this amendment, feature 1.2.1 still contained added subject-matter for several reasons, which are addressed below.

- 6.2.2 The opponent argued that the features specified by feature 1.2.1 according to which the frame of the valve comprises "commissure windows" and these are "angularly spaced", both terms being absent from original claims 16 and 21, resulted in added subject-matter. The Board does not agree.

Although certain passages of the original disclosure distinguish between the expressions "window frame portion" and "commissure window" (see e.g. paragraphs [054] and [079]), the person skilled in the art would recognise that these terms are used interchangeably throughout the original disclosure, in some instances even within the same paragraph (see e.g. paragraph [086]). In all cases, they designate a portion of the frame defining an opening between first and second axially oriented side struts, through which portions of the leaflets - such as the primary side tabs of original claim 21 - extend outwardly to a location outside of the frame for attaching the leaflet structure to the frame.

The opponent's contention that the term "commissure window" has a narrower meaning, requiring i) that the opening of the window be such that the leaflet tabs were able to protrude through the opening and ii) that the opening was small enough in circumferential direction to allow an easy and secure positioning of the leaflet tabs, is not convincing. These requirements

are equally implied by the term "window frame portion" as used e.g. in claim 21. The assertion that the person skilled in the art would regard the hexagonal cells 40 shown in Figure 5 of the original disclosure as window frame portions is also not convincing. Moreover, contrary to the opponent's argument, the mere fact that commissure windows are described in the embodiments of the original disclosure along with other features (not mentioned in original claim 21) does not in itself demonstrate any inextricable link between these features which would make the omission of these features from claim 1 unallowable. The opponent did not convincingly show any such inextricable link, and the Board does not see any. No reason has been identified why the further features would be necessary for the function of the commissure windows as defined.

Accordingly, referring to "commissure windows" in feature 1.2.1 instead of "window frame portions" as used in original claim 21 does not add subject-matter.

Furthermore, in the various embodiments disclosed in the original description (see e.g. paragraphs [011], [052], [096] and [098]) and in most of the original claims (see e.g. claims 4 and 9) that include such features, the commissure windows or window frame portions are consistently described as being "angularly spaced", "radially spaced" or "circumferentially spaced". In the technical context of the contested patent, the person skilled in the art would understand these terms as having the same meaning. The angular spacing of the commissure windows enables the formation of commissures when the leaflets are attached to the frame. Such commissures are implicit in the type of prosthetic heart valves disclosed in the original application and claimed in auxiliary request 7, in

which the closing of the valve is achieved by the coaptation of a plurality of leaflets.

The person skilled in the art therefore regards the leaflet attachment portions and window frame portions of original claims 16 and 21 as being implicitly angularly spaced, as a necessary requirement allowing the claimed leaflets to form commissures. Explicitly specifying in feature 1.2.1 that the commissure windows are angularly spaced therefore does not result in added subject-matter. For the same reason, the opponent's contention that additional features allegedly inextricably linked to the commissure windows had been omitted from claim 1 cannot succeed.

Similarly, since commissures implicitly result from the claimed attachment of the leaflet structure to the frame at the commissure windows, the absence of an explicit reference to commissures in claim 1 of auxiliary request 7 does not add matter either.

- 6.2.3 The opponent further objected to the expression "balloon-expandable annular frame" in feature 1.2.1, arguing that this expression was not disclosed in original claims 16 and 21, or more generally in the original disclosure, and that it therefore added matter. The opponent further contended that the original disclosure provided no basis for an assembly that combined the claimed valve with a delivery apparatus as defined in features 1 to 1.2. These objections are not convincing.

It is common ground that original claims 16 and 21 relate in substance to the specific approach for securing the leaflet structure to the frame of the valve described in paragraphs [079] to [082] and

illustrated in Figures 29 to 36 of the original disclosure (see points 1. and 1.2 above).

The person skilled in the art understands from paragraph [079] that this approach generally applies to all the embodiments of valves previously disclosed in the original disclosure in which the frame comprises commissure windows for attaching portions of the leaflets. This includes, in particular, the valve 10 shown in Figures 1 to 3, which comprises commissure window frame portions 30 (see paragraph [055]).

Paragraph [052] discloses that the valve 10 can be designed to be expanded by means of an inflatable balloon, i.e. that it can be balloon-expandable, when the frame is constructed of a plastically-expandable material. The person skilled in the art recognises that, in the context of such prosthetic heart valves, balloon-expandability of the frame is a functional property enabling expansion of the frame of a balloon-expandable valve by a balloon, and is not inextricably linked to a specific material. Accordingly, defining the frame as balloon-expandable without specifying the material of which it is made, in particular a plastically-expandable material, does not extend beyond the content of the original disclosure. This applies all the more since, as noted by the opponent, a balloon-expandable frame could, in principle - although not disclosed in the original disclosure - be made of a material which is not plastically expandable.

Limiting the valve of original claims 16 and 21 to a balloon-expandable valve comprising a balloon-expandable frame, as defined by feature 1.2.1, therefore does not add subject-matter.

6.2.4 Paragraph [085] of the original disclosure explicitly discloses a "delivery assembly" comprising the valve 10 mounted on the balloon of an elongated shaft of a delivery apparatus. The Board is satisfied that this disclosure provides a basis for the assembly of claim 1 of auxiliary request 7, especially in view of amendment A-I.

The opponent conceded that the subject-matter of claim 1 of auxiliary request 7 could be considered as a combination of original claims 16 and 21 with additional features extracted from this "delivery assembly". However, it argued that the omission from claim 1 of several further features of this assembly constituted an unallowable intermediate generalisation, alleging that these features were inextricably linked to the subject-matter of claim 1. This is not convincing.

One of the features to which the opponent referred is the feature that the leaflets are sutured to the side struts of the commissure window, as disclosed in paragraph [086] for that assembly. However, with amendment A-II requiring the primary side tabs to be sutured to the secondary tabs to secure the leaflets around the side struts, claim 1 already implicitly includes this feature.

As regards the remaining features relied upon by the opponent (an inflow end portion of the frame that has an outer diameter smaller than the outer diameter of the outflow end portion of the frame, V-shaped leaflets, an outer skirt positioned around the inflow end portion of the frame, an inner skirt), the opponent did not provide convincing reasons, nor does the Board see any, why these features would be inextricably

linked to the subject-matter of claim 1. The feature that the commissure windows are depressed radially inwardly, as further disclosed in paragraph [086], is also not inextricably linked to the subject-matter of claim 1. Although such features may, as described, be advantageous for the delivery and operation of the valve, they are not indispensable for balloon expansion of the frame, contrary to the opponent's argument, or for securing the leaflet structure in the manner defined in claim 1 of auxiliary request 7.

Finally, the Board agrees with the patent proprietor that amendment A-I overcomes the objection raised against claim 1 as granted in point 3.1 above.

Amendment A-I requires the valve to be adapted to be mounted on the balloon of the shaft, consistently with paragraph [085] and Figure 56, which disclose that the valve is "positioned over the deflated balloon". Contrary to the opponent's view, it is irrelevant that claim 1 of auxiliary request 7 does not specify this exact positioning but merely requires that the valve is "adapted to be mounted" on the balloon of the shaft. The person skilled in the art understands, in particular from paragraph [007], that the original disclosure also encompasses, at least implicitly, the disclosed assemblies in a state in which the valve is not yet mounted or positioned on the balloon of the delivery shaft. Even in that state, the valve must be adapted to be mounted on the balloon of the shaft, otherwise it could not be subsequently mounted on the balloon for delivery and implantation.

- 6.2.5 It follows that claim 1 does not extend beyond the content of the original disclosure.

6.3 *Claims 2 to 5 (corresponding claims 2 to 5 as granted)*

Claims 2 to 5 correspond in substance to original claims 17 to 20. The opponent contended that the original disclosure did not provide any indication that the subject-matter of these claims should be combined with that of original claim 21, nor with an assembly as defined in claim 1 of auxiliary request 7.

The Board agrees that the dependencies of the original claims do not support the combination of original claims 17 to 20 with original claim 21, since claims 17 to 20, like claim 21, directly depend on claim 16.

However, the basis in the original disclosure for claims 2 to 5 need not necessarily be found in the original claims. As argued by the patent proprietor, original claims 17 to 20 disclose further features of the primary and secondary side tabs which are all disclosed in Figure 30 and the corresponding description of the original disclosure (see in particular paragraph [081]) in combination with the further features of the valve of original claims 16 and 21. This was not disputed by the opponent.

Given the considerations for claim 1 in point 6.2 above, an assembly according to claim 1 comprising the further features defined in claims 2 to 5 is therefore directly and unambiguously derivable from the original disclosure. Accordingly, claims 2 to 5 do not extend beyond the original disclosure.

6.4 *Claims 6 and 7 (corresponding to claim 7 and 8 as granted)*

The features defined in claims 6 and 7, in particular that the commissure windows are depressed radially inwardly relative to portions of the frame between adjacent commissure windows when the prosthetic aortic valve is radially collapsed on the shaft, are disclosed in original claims 9 to 11. The Board agrees with the opponent that, following a similar line of argument as for claims 2 to 5, original claims 9 to 11 alone cannot provide a basis for claims 6 and 7 at least because they are not dependent on original claims 16 and 21.

However, as argued by the patent proprietor, the features of claims 6 and 7 are literally disclosed in paragraph [086] and Figure 56 of the original disclosure for the valve 10 of Figures 1 to 3, on which the valve of claim 1 of auxiliary request 7, on which claims 6 and 7 depend, is based (see points 6.2.3 and 6.2.4).

The Board does not accept the opponent's further argument that the subject-matter of claims 6 and 7 would be an unallowable intermediate generalisation of the disclosure of paragraph [086] and Figure 56. It is true that the features of claims 6 and 7 are disclosed in paragraph [086] side by side with other features, such as a tapered frame, V-shaped leaflets and an outer skirt. However, this juxtaposition does not render these features inextricably linked to each other. The Board notes that the depression of the commissure windows is not inseparable from these other features, since it is disclosed in original claims 9 to 11 in the absence of these other features.

For these reasons, the Board concludes that - contrary to the opposition division's conclusion for granted claims 7 and 8, to which claims 6 and 7 correspond, in

the decision under appeal (see Reasons 24 to 24.2) - claims 6 and 7 do not contain added subject-matter.

6.5 *Claims 8 and 9 (corresponding to claims 9 and 10 as granted)*

The features of claims 8 and 9, related to the presence of an annular outer skirt positioned around an outer surface of the frame, are disclosed in original claims 13 and 14. The Board agrees with the opponent, following a similar line of argument as for the preceding dependent claims, that original claims 13 and 14 alone cannot provide a basis for claims 8 and 9 at least because they are not dependent on original claims 16 and 21.

However, as argued by the patent proprietor and accepted by the opposition division (see Reasons 25.2), the features of claim 8 are disclosed literally in paragraph [015]. The person skilled in the art understands from the wording of paragraph [015] that its disclosure applies to all valves of the invention, including the valve 10 of Figures 1 to 3 in combination with the specific approach for securing the leaflet structure to the frame disclosed in Figure 30, on which the valve of claim 1 of auxiliary request 7 is based. Claim 8 therefore does not contain added subject-matter.

It is true, as argued by the opponent, that paragraph [015] does not disclose the features of claim 9. However, these features are disclosed in original claim 14. From the dependency of original claim 14 from original claim 13, the person skilled in the art infers that an annular outer skirt as defined in claim 13 - to which the annular outer skirt defined

in claim 8 corresponds - can further include the additional features of original claim 14. Therefore, since the subject-matter of claim 8 is originally disclosed, as discussed above, original claim 14 provides support for claim 9.

6.6 *Claim 10 (corresponding to claim 11 as granted)*

The features defined in claim 10 are not disclosed in the original claims but can be found in the original description.

- 6.6.1 The claimed general structure of the frame comprising an inflow row of openings at an inflow end portion of the frame, an outflow row of openings at an 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 is disclosed literally in the first sentence of paragraph [012] of the original disclosure.

The opponent submitted that this specific structure was inextricably linked to the additional feature, disclosed in the second sentence of paragraph [012], that the openings of the inflow row of openings were larger than the openings of the at least one intermediate row of openings. Paragraph [061] of the original disclosure disclosed that this additional feature enabled the crimp profile of the valve to be reduced, which was the purpose generally sought by the original disclosure as disclosed in paragraph [006]. For this reason, the person skilled in the art would not construe the two sentences of paragraph [012] separately from each other.

The Board does not share this view.

The person skilled in the art does not infer any inextricable link from the mere juxtaposition of these two sentences in paragraph [012]. Nor do they derive such a link from the specific disclosure in paragraph [061] that the inflow openings 36 are larger than the openings 38 of the two intermediate rows of openings. From this, they merely conclude that designing the inflow openings to be larger than those of the intermediate rows enables the valve to adopt a tapered shape when crimped, making it easier to accommodate an outer skirt - which is not claimed in claims 1 or 10 of auxiliary request 7 - at the inflow end of the valve, without increasing its overall crimp profile. The person skilled in the art thus understands that this option is not inextricably linked with the remaining features of the disclosed frame.

In addition, contrary to the opponent's view, the fact that paragraph [006] generally emphasises the advantages of a reduced crimp profile for the valve does not mean that all embodiments of the original disclosure must necessarily include a feature implementing this purpose. For example, the valve of original claim 16, on which the valve of claim 1 of auxiliary request 7 is based, does not comprise any such feature. The person skilled in the art therefore understands that the original disclosure is not directed only at prosthetic heart valves having a reduced crimp profile.

As argued by the patent proprietor, the person skilled in the art recognises instead that the frame structure defined in claim 10 generally reads on the embodiments disclosed in the original disclosure. This includes in particular the other frame 50 of Figure 12, although

the corresponding description does not disclose it literally. The fact that the openings of the inflow row in this other frame are not larger than those of the intermediate rows of openings confirms that there is no inextricable link between the two sentences of paragraph [012]. The Board notes that this also applies to the frame of the valve 10 of Figures 1 to 3, on which the valve of claim 1 of auxiliary request 7 is based.

- 6.6.2 Claim 10 also specifies that this frame structure is formed by "circumferentially extending rows of angled struts arranged end-to-end".

The opponent objected that this wording was disclosed only in paragraph [054] of the original disclosure, side by side with additional features to which it was inextricably linked, namely a specific frame configuration having five rows of struts, with upper row openings being relatively large and sized to allow portions of the leaflet structure to protrude therethrough, with again the purpose of minimising the crimping profile, as disclosed in paragraph [056].

This is also unconvincing.

As argued by the patent proprietor, the person skilled in the art also regards the formation of the frame by "circumferentially extending rows of angled struts arranged end-to-end" as a general teaching of the original disclosure found throughout the various embodiments. They also recognise that the specific design of the frame in paragraph [054], including the number of intermediate rows of openings, is merely exemplary, with paragraph [054] merely describing "the illustrated embodiment" shown in Figure 5.

Furthermore, designing the openings 40 of the outflow row as "relatively large and [...] sized to allow portions of the leaflet structure 14 to protrude, or bulge, into and/or through the openings 40 when the frame 12 is crimped" is merely described in paragraph [056] as a way of minimising the crimping profile of the valve. The person skilled in the art recognises this as an advantageous feature, albeit one not inextricably linked with the formation of the frame by "circumferentially extending rows of angled struts arranged end-to-end" or with the further features of claim 1 of auxiliary request 7, on which claim 10 depends. Not sizing the outflow openings 40 as explained in paragraph [056] would just have resulted in a larger crimping profile.

The Board therefore concludes that claim 10 does not contain added subject-matter.

6.7 *Claim 11 (corresponding to claim 12 as granted)*

Claim 11 requires that the valve comprises an inner skirt for securing the leaflet structure to the frame, the inner skirt being sutured to an inner surface of the frame.

The opponent did not contest that paragraph [050] provides support for claiming that the valve of Figures 1 to 3 (on which the valve of claim 1 of auxiliary request 7 is based) comprises an inner skirt, as considered by the opposition division in the decision under appeal (see Reasons 27.3), but contended that this paragraph did not disclose the outer skirt as being optional. Therefore, the outer skirt could not be permissibly omitted from claim 11.

The Board does not agree. As submitted by the patent proprietor, the person skilled in the art would see no inextricable link between the inner skirt and the outer skirt of the valve. In particular, the original disclosure contains several embodiments of a valve comprising an inner skirt secured to the inside of the frame but no outer skirt, such as in original claim 22 and paragraph [019].

The opponent further argued that suturing the inner skirt to an inner surface of the frame was disclosed only in paragraphs [019] and [073] of the original disclosure, albeit only in combination with further additional features, namely (i) that the inner skirt comprises a weave of a first set of strands with a second set of strands, both the first and second sets of strands being non-parallel with the axial direction of the valve (paragraph [019]) and (ii) that the inner skirt is sutured to the frame at locations away from a suture line 154 so that the skirt is more pliable in that area (paragraph [073]). Since these additional features are absent from claim 11, the opponent submitted that claim 11 was in any event based on an unallowable intermediate generalisation.

This is also not convincing. Contrary to the opponent's assertion, suturing the inner skirt to an inner surface of the frame is not disclosed only in paragraphs [019] and [073] of the original disclosure. The Board notes that paragraph [064] also discloses that the inner skirt can be generally "secured to the inside of frame 12 via sutures 70", without any reference to features (i) and (ii). The person skilled in the art therefore understands that features (i) and (ii) only represent preferred features of exemplary embodiments

and are not inextricably linked with the attachment of the inner skirt to the frame via sutures. Moreover, the original disclosure further discloses that the inner skirt can alternatively be formed from woven elastic (see paragraph [072]), which indicates that feature (i) related to the weave of non-parallel strands is merely optional.

The Board therefore concludes that claim 11 does not contain added subject-matter.

6.8 *Claim 12 (corresponding to claim 13 as granted)*

Claim 12 specifies that an outer diameter of an inflow end portion of the frame is smaller than an outer diameter of an outflow end portion of the frame.

The opponent argued that this feature had been extracted from paragraph [085] where, however, it was disclosed as being inextricably linked to a number of further features, such as the requirement for the frame to have a tapered shape and the use of V-shaped leaflets, for the purpose of compensating for the additional circumferential bulk added by the outer skirt.

The Board does not share this view. As argued by the patent proprietor and also held by the opposition division (see Reasons 28.2), the feature of claim 12 is also disclosed in paragraph [008] of the original disclosure without the features referred to by the opponent. Rather, paragraph [008] discloses that "[t]he reduced diameter of the inflow end can be due to a reduced amount of materials positioned within the inflow end portion of the frame". The person skilled in the art therefore understands that the features

referred to by the opponent are merely optional ways to achieve the difference in diameters defined in claim 12. Therefore, the omission of these features from claim 12 does not add subject-matter. This is all the more so as neither claim 12 nor claim 1 on which claim 12 depends define an outer skirt.

The Board therefore concludes that claim 12 does not contain added subject-matter.

6.9 *Claim 13 (corresponding to claim 14 as granted)*

Even if the subject-matter of claim 13 is not literally disclosed in the original disclosure with regard to the specific embodiment shown in Figure 29, the person skilled in the art directly and unambiguously reads this subject-matter in this figure and its description in paragraph [080], with each "pair of primary side tabs" corresponding to a pair of two adjacent lower tab portions 116 of two adjacent leaflets 40 as depicted in Figure 29, and each of the claimed plurality of wedges corresponding to a wedge 126, as being illustrated in the same figure. Accordingly, the subject-matter of claim 13 is originally disclosed.

The opponent contended that the wedges defined in claim 13 were disclosed in the original disclosure as being inextricably linked to the presence of connector 124 and to a specific shape and position of the primary side tabs outside of the frame, namely that the tabs had portions located outside of the frame that "extend[ed] circumferentially away from one another and along an exterior surface of the side struts", as defined in original claim 26, and that, under the action of the wedges, "one of the lower tab portions 116 and a portion of the connector 124 [was] folded

against the frame 12", as disclosed in paragraph [080]. According to the opponent the wedges could not fulfil their function without these features. The omission of these further features from claim 13 constituted an unallowable intermediate generalisation.

This is not convincing. The person skilled in the art understands that the locking function of the wedge results from the wedge being urged radially inwardly against the primary side tab 116, as defined in claim 13, resulting in the tab being frictionally secured against the corresponding side strut of the commissure window. This is achieved regardless of the presence of a connector 124 between the wedge and the primary side tab 116 and regardless of the configuration of the portions of the primary side tabs extending beyond the commissure windows. The absence of the further features referred to by the opponent from claim 13 therefore does not add matter.

Furthermore, as argued by the patent proprietor, the locking function of the wedges is disclosed in original claim 26 for a valve using a similar attachment mechanism of the leaflet structure to commissure windows of the frame, however without any reference to the further features relied upon by the opponent. This further confirms that the wedges are not inextricably linked to these further features.

The Board therefore concludes that claim 13 does not contain added subject-matter.

*6.10 Claim 14 (mostly corresponding to claim 15 as granted)*

6.10.1 The opponent contended that the original disclosure did not disclose a "nickel-based cobalt-chromium alloy" as

specified in amendment A-III. The Board disagrees. A "nickel-based cobalt-chromium alloy" corresponds to the first example of a nickel-based alloy disclosed in the parenthetical phrase in paragraph [053] of the original disclosure.

- 6.10.2 In addition, the opponent also objected in its reply to the patent proprietor's statement of grounds of appeal (see points 58 and 59 on pages 17 and 18) that specifying a nickel-based cobalt-chromium alloy while omitting that it is "plastically expandable" still extended the scope of the claim beyond the original disclosure.

This objection differs from the objection against claim 15 as granted dealt with in the decision under appeal and reiterated on appeal (see point 3.2 above and the preceding paragraph), which solely related to the nickel content of the cobalt-chromium alloys.

As set out in the communication under Article 15(1) RPBA (see point 6.1.3), this new objection could and should have been filed in the opposition proceedings. In line with its preliminary opinion, the Board therefore decided not to admit this further objection pursuant to Article 12(6), second sentence RPBA. At the oral proceedings before the Board, the opponent did not provide any further submissions on this issue.

## **7. Extension of the scope of protection**

- 7.1 The opponent submitted that auxiliary request 7 did not comply with Article 123(3) EPC because amendment A-I extended the scope of protection conferred by the patent as granted.

Claim 1 as granted defines the valve as being "adapted to be mounted on the shaft" of the delivery apparatus. According to the opponent, this wording required the valve to have features allowing it to be mounted directly on a rigid shaft, as allegedly illustrated in Figure 46 of the patent. By contrast, amendment A-I specifies that the valve is adapted to be mounted on the balloon of the shaft, which, in the opponent's view, required different adaptations. The opponent therefore submitted that amendment A-I resulted in a shift of the scope of protection to configurations not covered by the patent as granted.

7.2 The Board does not agree for the reasons already set out in the Board's communication under Article 15(1) RPBA (see point 7).

Feature 1.2.1 of claim 1 as granted does not exclude mounting of the valve on the balloon of the shaft (see point 3.1.1 above). On the contrary, since the balloon forms part of the shaft of the delivery apparatus, the definition that the valve is adapted to be mounted on the shaft necessarily encompassed mounting on the balloon. Amendment A-I merely restricts this broader definition by specifying that the mounting takes place on the balloon, excluding any other possible mounting locations on the shaft. The amendment thus constitutes a limitation of the scope of protection and claim 1 of auxiliary request 7 complies with Article 123(3) EPC.

7.3 The opponent's reliance on Figures 46 and 56 does not alter this conclusion.

Figure 56 illustrates an embodiment in which the valve is explicitly positioned over a deflated balloon of the delivery apparatus. As explained in paragraph [063] of

the patent, Figure 46 merely illustrates that the openings 206 of the frame are dimensioned such that portions of the leaflet structure 204 are able to protrude outwardly through these openings. This disclosure concerns the interaction between the leaflet structure and the frame and does not define any feature relating to the mounting of the valve on a delivery apparatus. In particular, neither Figure 46 nor paragraph [063] discloses any structural adaptation of the valve that would be specific to mounting on a rigid shaft or that would render the valve incompatible with mounting on a balloon. In any event, the existence of different exemplary delivery configurations in the patent does not imply that the scope of claim 1 as granted is limited to one of them. Rather, claim 1 as granted encompasses all configurations in which the valve is adapted to be mounted on the shaft, including mounting on the balloon.

## **8. Clarity**

- 8.1 Contrary to the opponent's view, claim 6 of auxiliary request 7 is clear.
- 8.2 In the opponent's view, the definition that the valve is "radially collapsed on the shaft" in claim 6 was in contradiction with feature 1.2 as amended by amendment A-I in claim 1, according to which the valve is mounted on the balloon of the shaft.
- 8.3 The Board does not agree. Claim 6 depends on claim 1 and must be interpreted in the light of all the features defined therein. Claim 1 explicitly requires that the valve is adapted to be mounted on the balloon of the shaft. In this context, the reference in claim 6 to the valve being "radially collapsed on the shaft"

can therefore only be understood by the person skilled in the art as meaning that the valve is radially collapsed on the balloon of the shaft.

8.4 The Board notes that this interpretation is technically meaningful and consistent with the disclosure of the patent, in particular with embodiments such as that shown in Figure 56, in which the valve is crimped onto the deflated balloon of the delivery apparatus. No alternative technically sensible interpretation arises in which the valve would be radially collapsed on a different part of the shaft.

8.5 Accordingly, claim 6 does not contain a contradiction with claim 1 and is clear within the meaning of Article 84 EPC.

## **9. Sufficiency of disclosure**

9.1 The opponent's objections that the contested patent did not disclose the invention as claimed in auxiliary request 7 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art are not convincing.

9.2 At the oral proceedings before the Board, the parties did not make any further submissions on this issue but merely referred to their written submissions. The Board therefore sees no reasons for deviating from its preliminary opinion set out in the communication under Article 15(1) RPBA (see point 8), which is reiterated in substance below.

9.3 *Claim 1*

The opponent did not dispute that the contested patent sufficiently discloses the specific embodiment of the claimed invention in which the leaflets are designed as shown in Figure 21 and described in paragraph [0049] (see point 1.2 above). In this embodiment, the lower and upper tabs clearly correspond to the claimed primary and secondary tabs, respectively.

Furthermore, contrary to the opponent's argument, the person skilled in the art would have no difficulty in conceiving embodiments other than that shown in Figure 21 using the information contained in the patent and common general knowledge. This applies even if the terms "primary side tabs" and "secondary tabs" used in claim 1 do not contain any positional constraints, as contended by the opponent. As pointed out by the patent proprietor, the person skilled in the art would be aware that the folding of the secondary tabs must not interfere negatively with the leaflet geometry. They would therefore exclude any non-working embodiments in which the design of the tabs would hinder the valve's proper function.

#### 9.4 *Claim 13*

The opponent also objected to the feature of a "wedge being urged radially inwardly against the primary side tabs" of claim 13 of auxiliary request 7, arguing that connector 124 and sutures 148 as disclosed in paragraph [0054] and Figures 23 and 29 of the patent were required to enable the wedge to be "urged". However, such features were absent from claim 13. This claim was therefore not supported across its breadth.

This objection is based on a different line of argument to that used in the objection to claim 1 above. The

opponent did not dispute that this objection was filed for the first time in the opponent's statement of grounds of appeal.

However, as claim 13 of auxiliary request 7 is identical to claim 14 as granted, the opponent could and should have raised this objection in the opposition proceedings. Therefore, pursuant to Article 12(6), second sentence RPBA, the Board decided not to admit this objection.

## **10. Novelty in view of D7**

10.1 At the oral proceedings before the Board, the parties did not make any further submissions on the issue of novelty in view of D7 but merely referred to their written submissions. The Board therefore sees no reasons for deviating from its preliminary opinion set out in the communication under Article 15(1) RPBA (see point 9), which is reiterated in substance below, according to which the subject-matter of claim 1 of auxiliary request 7 is novel in view of D7.

10.2 D7 discloses a prosthetic heart valve comprising a frame (stent 12) to which a plurality of leaflets 14 are attached (see Figures 1 and 4 reproduced below). As explained in paragraphs [0075] and [0076], the leaflets 14 can be formed by double-coaptation leaflets 36, each formed from a single sheet of material shaped with the planar pattern 38 shown in Figure 8A and folded in the middle into two plies 14a and 14b. A first ply 14a coapts centrally with the corresponding plies of other leaflets, and a second ply 14b coapts peripherally with the stent 12 (see Figure 4).

FIG. 1

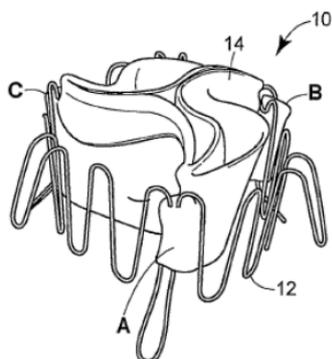
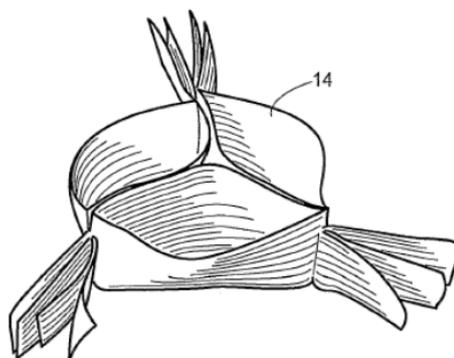
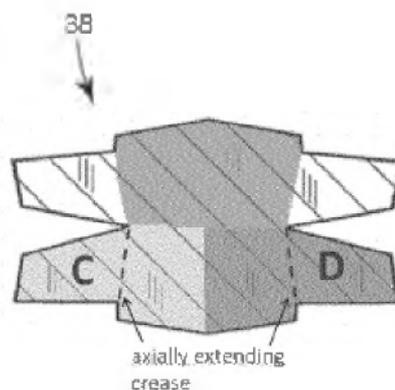
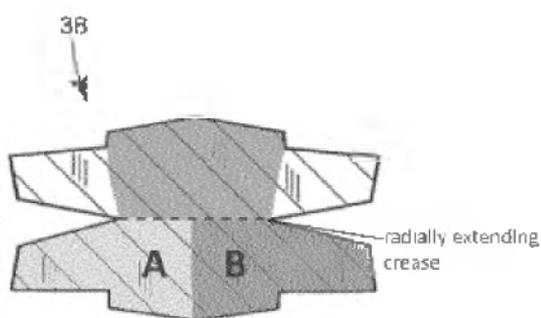


FIG. 4

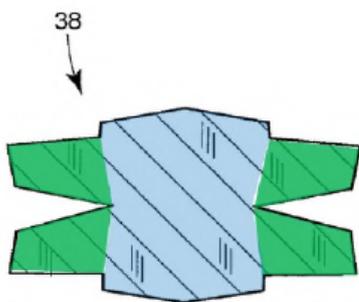


10.3 Referring to the annotated copies of Figure 8A submitted in its reply (see page 10), reproduced below, the opponent argued that this embodiment disclosed the specific tab structure and folding configuration defined in claim 1 of auxiliary request 7, with two opposing primary side tabs (in white), two secondary side tabs forming the lower portion of the leaflet (below the line marked "radially extending crease"), and a body portion (above that line and between the two primary side tabs). Each of the secondary side tabs comprised a first portion (marked "A" and "B") and a second portion (marked "C" and "D"), and was folded about both an axially extending crease and a radially extending crease, as indicated in the annotated figures. In view of this interpretation, the subject-matter of claim 1 of auxiliary request 7 was not novel in view of D7.

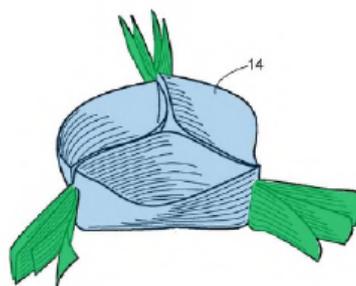


10.4 This is not convincing. The opponent's mapping of the wording of claim 1 onto the leaflet 36 disclosed in Figure 8A of D7 is artificial. As argued by the patent proprietor, the person skilled in the art would - if at all - view the leaflet 36 as comprising, as indicated in the coloured figures on page 16 of the patent proprietor's reply, reproduced below, four symmetrically protruding portions forming "tabs" (in green in the patent proprietor's reply), and the rest of the leaflet at the centre forming a "body portion" (in blue in the patent proprietor's reply). Indeed, the leaflet 36 is a double-coaptation leaflet, meaning that the entire central body portion, on both sides of the middle crease, contributes to the valve function of the leaflet structure. Therefore, the opponent's interpretation that the lower ply is not part of the body portion but consists of two secondary side tabs is not convincing.

**FIG. 8A**



**FIG. 4**



10.5 Furthermore, D7 does not clearly disclose how the tabs are secured to the frame and/or to each other (see area A in Figure 1). Although Figures 1 and 4 may suggest that some tabs extend outwardly between two struts of the frame, these tabs appear to be at most folded about what the opponent itself considered an axially extending crease (see annotated figures above).

10.6 The opponent argued in its written submissions that the term "extending" in the expression "radially extending crease" broadened the meaning of this expression to encompass any creases that had a component of extension in the radial extension. This was all the more so, according to the opponent, since the valve was a radially collapsible valve, wherein the leaflet structure underwent significant changes during radial collapse and expansion.

However, the Board notes that claim 1 itself explicitly distinguishes between the "radially extending" and "axially extending" creases about which the portions of the secondary side tabs are folded (features 1.2.2.4.1 and 1.2.2.5). The same clear distinction is made for the struts defining the commissure windows, which are "axially oriented" (feature 1.2.1), whereas the primary side tabs "extend radially" outwardly through the commissure windows (feature 1.2.2.6.1). This clear distinction would not make any sense if the opponent's interpretation above were adopted.

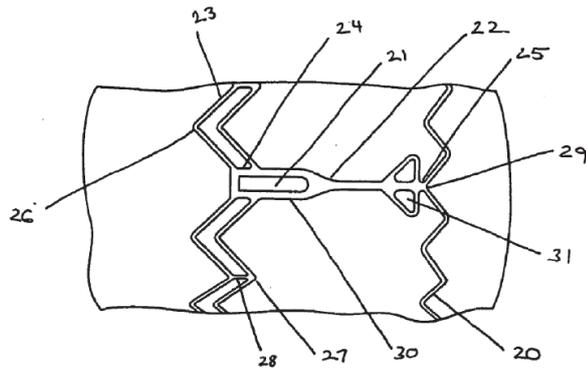
Therefore, even if the tabs were folded, in the zone marked "A" in Figure 1 of D7, about an axis having locally some extension deviating from the axial direction, the person skilled in the art would still not consider them to be folded about a radially extending crease.

10.7 Therefore, even if the four tabs of the design of Figure 8A are considered to constitute two opposing primary side tabs and two opposing secondary side tabs, D7 still does not directly and unambiguously disclose secondary tabs being folded twice as defined by features 1.2.2.4.1, 1.2.2.4.2 and 1.2.2.5, in particular about a radially extending crease. The Board

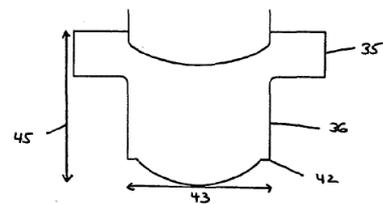
thus concludes that the subject-matter of claim 1 of auxiliary request 7 is novel in view of D7.

**11. Inventive step starting from D16**

11.1 D16 discloses a prosthetic heart valve comprising a frame (anchoring structure) to which a plurality of leaflets are attached. As shown for example in Figure 5, reproduced below, the frame comprises axially extending slots 21 through which portions of the leaflets can extend, these slots corresponding to commissure windows as defined in claim 1 of auxiliary request 7. Figure 9 of D16, also reproduced below, illustrates a preferred leaflet shape. Each leaflet comprises a body portion from which two opposing commissural tabs 35 extend, which correspond to primary side tabs as defined in claim 1. As disclosed in paragraph [0099], these tabs can be threaded through the axially extending slots 21 of the frame in order to attach the leaflet to the frame.



**FIG. 5**



**FIG. 9**

It is common ground that the subject-matter of claim 1 of auxiliary request 7 differs from this disclosure at least by the features relating to the secondary side tabs, namely features 1.2.2.3.3 to 1.2.2.5 and 1.2.2.6.2.

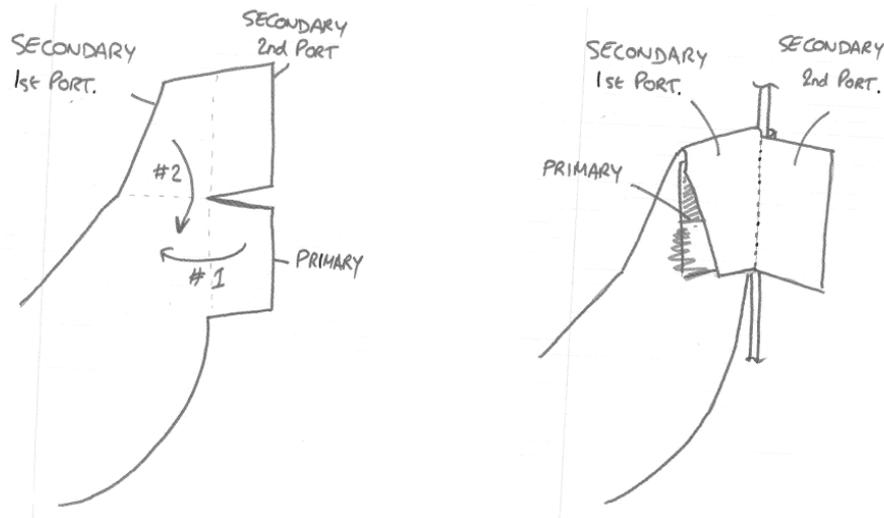
11.2 The opponent submitted that these distinguishing features did not render the subject-matter of claim 1 inventive.

11.2.1 While conceding that the specific tab configuration described in paragraph [0056] and Figures 29 and 30 of the contested patent may solve a technical problem, the opponent argued that the distinguishing features of claim 1 did not define that specific configuration. The technical effects discussed in paragraph [0056] could only be achieved if four layers of leaflet material were provided at the commissures radially inward of the frame. However, according to the opponent, the distinguishing features did not define any such multilayer structure radially inward of the frame. They did not even require the secondary side tabs to be positioned within the frame. More generally, claim 1 merely required the presence of a leaflet structure having a plurality of leaflets and did not specify the relative positioning of the leaflets, let alone of the primary and secondary side tabs, with respect to one another.

Consequently, in the opponent's view, the distinguishing features of claim 1 did not produce any technical effect, let alone over the full scope of the claim. The technical problem to be solved could therefore only be formulated as providing an alternative way of attaching a leaflet to a commissure window.

11.2.2 According to the opponent, the distinguishing features in fact amounted merely to an arbitrary, non-functional modification of the valve disclosed in D16. The opponent illustrated this assertion by providing at the oral proceedings before the Board several drawings,

reproduced below, showing an arrangement in which a portion of the secondary side tab was dangling, thus serving no technical purpose. Since, according to the analysis provided below, these drawings do not alter the assessment of inventive step by the Board, the question of their admittance under Article 13(2) RPBA raised by the patent proprietor does not need to be addressed.



According to the opponent, in line with the case law set out *inter alia* in T 2044/09, T 1289/22, T 885/20 and T 294/89, any such arbitrary, non-functional modification was to be disregarded in the assessment of inventive step. In particular, as stated in T 2044/09 (see Reasons 4.6), this applied even in the absence of a pointer or suggestion in the prior art towards this modification. The opponent therefore concluded that, on this basis alone, the subject-matter of claim 1 was not inventive starting from D16.

11.2.3 The opponent further submitted that, in any event, numerous leaflet attachment and folding configurations were known in the art and formed part of the common general knowledge, as reflected, for example, in D12 (see Figures 1a and 1b), D20 (see Figures 3 and 4), D29

(see Figures 1 and 2), D8 (see Figures 3A and 4A) and D14 (see Figure 9B). According to the opponent, the adoption of minor variations in leaflet folding or tab arrangement did not require inventive skill, nor did it result in any unexpected technical effect. The person skilled in the art was familiar with attachment mechanisms for the leaflet structures of prosthetic heart valves. D17 (see Figures 25A and 25B) and D8 (see Figures 3A and 4A) also provided evidence of the widespread use of folded leaflets in commissure regions in the prior art. Consequently, when merely seeking an alternative way of attaching a leaflet to a commissure window, the person skilled in the art starting from D16 would have arrived at the distinguishing features by routine design choices, using common general knowledge or in view of the teachings of D17 or D8, without exercising an inventive step.

- 11.3 This is not convincing, as already stated in the Board's communication under Article 15(1) RPBA (see point 10.1.2).
- 11.3.1 The Board agrees with the patent proprietor that the distinguishing features credibly produce a technical effect - even if, as set out below, this technical effect results primarily from some of these features only.

Features 1.2.2.4.1 and 1.2.2.4.2 specify that the secondary side tabs are folded such that a first portion of the secondary side tabs lies flat against the body portion of the respective leaflet. From this the person skilled in the art directly and unambiguously derives that, at least in the region of this first portion of the secondary side tab, a double-layer structure is formed, comprising part of the

leaflet body portion and the folded first portion of the secondary side tab lying flat thereagainst. The distinguishing features therefore define, at least locally, a double-layer region of leaflet material.

The person skilled in the art, interpreting claim 1 in a technically sensible manner, understands - as is the case for this type of prosthetic heart valve - that the body portion of the respective leaflets is located within the frame. This follows from the fact that the primary side tabs extend from the leaflet body portion and are inserted through the commissure windows to the outside of the frame. Consequently, the leaflet body portion, and thus the double-layer region mentioned above, is necessarily located within the frame, radially inward of the commissure windows.

In addition, from the fact that the primary side tabs extend radially outwardly through the respective commissure windows (feature 1.2.2.6.1), that the secondary side tabs extend from the body portion adjacent to the primary side tabs (feature 1.2.2.3.3) and that the secondary side tabs are folded about a radially extending crease (feature 1.2.2.4.1) to create the double-layer region, the person skilled in the art understands that this double-layer region is necessarily located radially inward of the commissure windows, adjacent to the inner surface of the frame.

Accordingly, the configuration defined by the distinguishing features 1.2.2.3.3, 1.2.2.4.1 and 1.2.2.4.2 necessarily gives rise, at least in this commissure-adjacent region, to a double-layer region of leaflet material of the type described in paragraph [0056].

While claim 1 does not necessarily requires that two adjacent leaflets have their double-layer regions adjacent so as to form, together, a four-layer region as disclosed in Figures 29 and 30 of the patent, the Board notes that the technical effects disclosed in paragraph [0056], namely increased resistance to bending of the leaflets in the commissure region and displacement of the leaflet articulation radially inwardly away from the frame, are already achieved, for each leaflet, as a result of this double-layer region. Moreover, these technical effects are achieved by the distinguishing features over the full scope of the claim.

The fact that the remaining distinguishing features 1.2.2.5 and 1.2.2.6.2 leave open the exact configuration or orientation of the second portion of the secondary side tabs, and whether the primary side tabs are sutured to the secondary tabs at this second portion - as disclosed in Figures 29 and 30 of the contested patent and potentially also advantageous - or at another portion of the secondary side tabs does not call this conclusion into question. Indeed, the formation of the double-layer region radially inward of the commissure windows, which is responsible for the stated technical effects, already results from the other distinguishing features referred to above. Any additional folding or positioning of a further portion of the secondary side tabs, or its possible attachment to a primary side tab, may influence the resulting geometry of the leaflet structure, but does not negate the presence of the double-layer region nor the technical effects associated therewith.

In this context, the Board also notes that even the configuration invoked by the opponent during the oral

proceedings, as illustrated in the drawings reproduced above, does not contradict the existence of these technical effects. In that configuration, the first portion of the secondary side tab likewise lies against the body portion of the leaflet (albeit not in direct contact, which is not required by claim 1).

Accordingly, even in that configuration, a double-layer region of leaflet material is formed adjacent to the commissure region. This configuration therefore also achieves the technical effect discussed above. This further confirms that the technical effect credibly results from the distinguishing features 1.2.2.3.3, 1.2.2.4.1 and 1.2.2.4.2 across the full scope of the claim.

- 11.3.2 Consequently, at least these distinguishing features are not mere arbitrary, non-functional modifications of the valve known from D16, contrary to the opponent's assertion. The opponent's line of argument based on this assertion therefore cannot succeed already for this reason.

There is thus no need to assess in detail whether, as suggested by the opponent referring to decisions T 294/89, T 2044/09, T 885/20 and T 1289/22, inventive step can, even where a distinguishing feature has technical character, indeed already be denied for the only reason that there is a lack of improvement over the prior art by that distinguishing feature in the form of a particular technical effect or functionality. See on this matter, however, point 11.3.4 below.

- 11.3.3 In view of the technical effects discussed above, the Board accepts the formulation of the objective technical problem proposed by the patent proprietor,

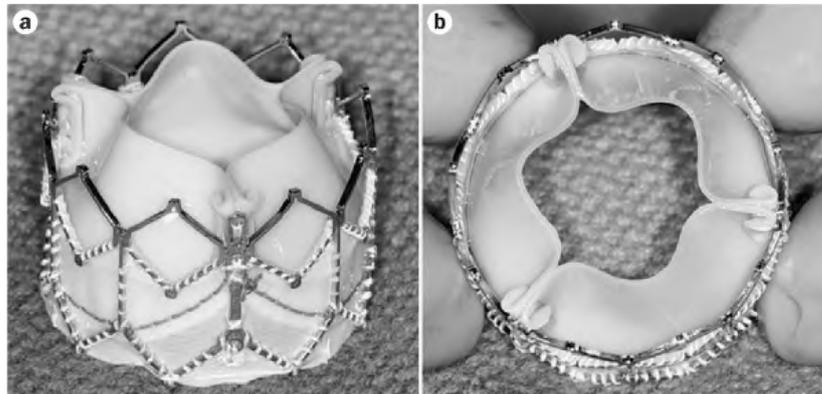
namely to improve the reliability, durability and safety of the prosthetic heart valve.

- 11.3.4 In any event, even if, to the opponent's benefit, the objective technical problem starting from D16 were formulated in the least ambitious way as merely providing an alternative means of attaching a leaflet to a commissure window, the person skilled in the art starting from that document would still not arrive at the claimed subject-matter in an obvious manner.
- 11.3.5 D16 itself provides no teaching or suggestion of secondary side tabs extending adjacent to the primary tabs and folded about a radially extending crease so as to form such a double-layer region.

Using only common general knowledge, the person skilled in the art starting from D16 would not implement such secondary tabs - let alone secondary tabs folded about a radially extending crease as claimed - in addition to the commissural tabs 35 without hindsight.

The fact that numerous leaflet attachment mechanisms are known in the prior art, as put forward by the opponent, does not in itself render the specific solution defined by the distinguishing features of claim 1 obvious. Inventive step cannot be denied merely because multiple alternative attachment techniques are known in the art; what matters is whether common general knowledge or the prior art provides a teaching or motivation that would lead the person skilled in the art, starting from D16 and faced with the above objective technical problem, to adopt the specific configuration claimed.

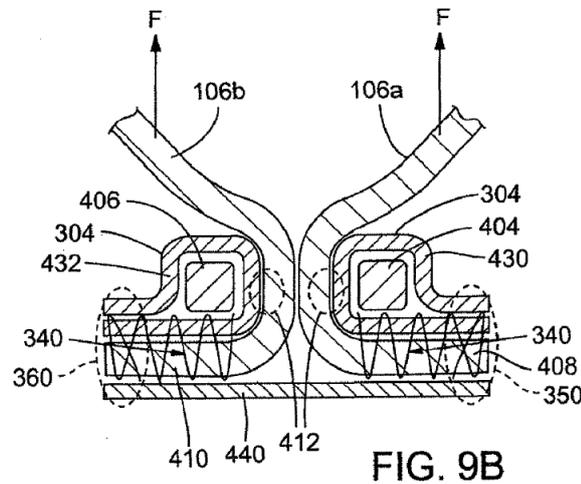
The opponent submitted, in particular, that the concept of a multi-layer reinforcement at the commissure region was part of the common general knowledge. In this regard, reference was made *inter alia* to D12, which described the patent proprietor's SAPIEN XT valve. As shown in Figures 1a and 1b, reproduced below, this valve comprises a four-layer structure positioned radially inwards of the leaflet attachment which, according to the opponent, acts as a buffer to the frame and alters the articulation of the leaflets.



However, this disclosure neither shows nor suggests secondary side tabs extending from the leaflet body portion and folded about a radially extending crease as defined by the distinguishing features. The same applies to the other documents D20, D29 and D14 relied upon by the opponent to illustrate the alleged common general knowledge, which likewise do not disclose or suggest these features either.

In particular, concerning D14, even if the cloth portion 304 shown in Figure 9B (reproduced below) is regarded as a secondary side tab, the fact that it is folded only about an axially extending crease, parallel to struts 404 and 406, does not provide any motivation for the person skilled in the art starting from D16 to

implement an additional tab folded about a radially extending crease.



11.3.6 The opponent more specifically referred to D17 and D8. Contrary to the opponent's argument, neither of these documents would motivate the person skilled in the art to implement secondary tabs with the claimed folding about a radially extending crease.

Figures 25A and 25B of D17, reproduced below, disclose side flaps 62 having a slit 200 splitting them into upper and lower portions. However, both portions are intended to be folded about an axially extending crease, represented by a dotted line in these figures (see also paragraph [0136]). In this respect, the Board notes that the slight deviation from the vertical axis visible in these figures, which show the flattened-out shape of the leaflets, is removed when the leaflets are mounted to the frame.

Therefore, even if the person skilled in the art modified the commissural tabs 35 in D16 to include such a slit to form a primary tab and a secondary tab, they would have no incentive, without the benefit of hindsight, to fold the resulting secondary tab about a radially extending crease as argued by the opponent,

instead of an axially extending crease as taught in D17.

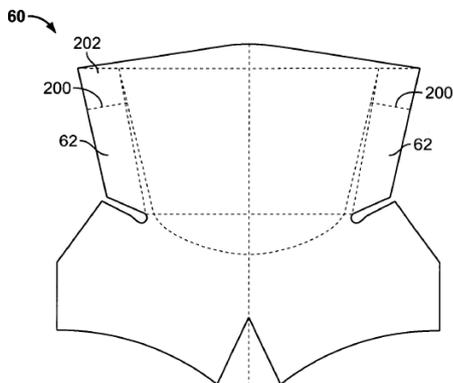


FIG. 25A

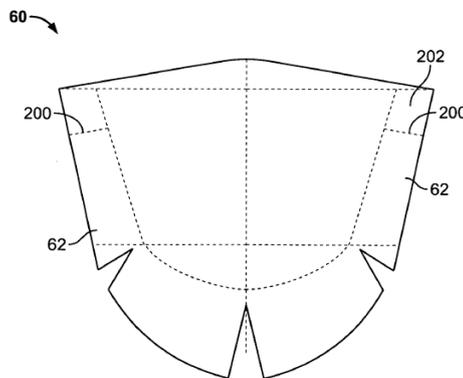


FIG. 25B

Similarly, the flaps 34, 35 and 36 disclosed in D8, Figures 3A and 4A, reproduced below, are all folded along an axially extending crease. Therefore, even if the person skilled in the art added such additional flaps to the commissural tabs 35 in D16, this would not result in a secondary tab being folded along a radially extending crease.

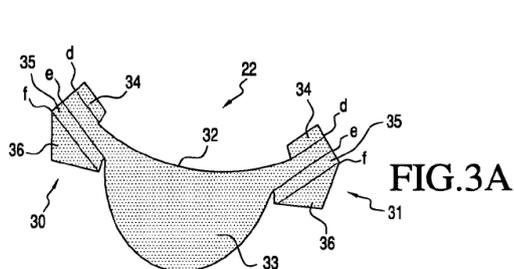


FIG. 3A

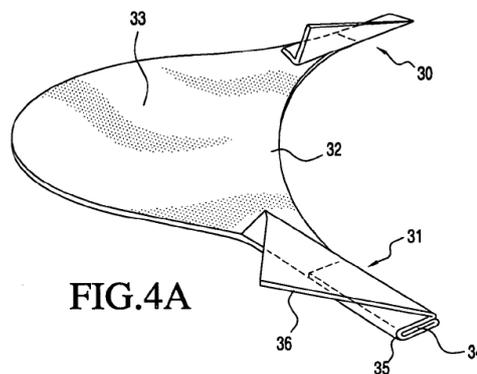


FIG. 4A

11.4 The Board therefore concludes that the subject-matter of claim 1 of auxiliary request 7 involves an inventive step starting from D16.

12. **Inventive step starting from D7 and from D14**

12.1 At the oral proceedings before the Board, the parties did not make any further submissions on the issue of inventive step starting from D7 and from D14, but merely referred to their written submissions. The Board therefore maintains its preliminary opinion set out in its communication under Article 15(1) RPBA (see points 10.2 and 10.3) and reiterated in substance below, according to which these objections are not convincing.

12.2 *Starting from D7*

12.2.1 The opponent's inventive-step objection starting from D7 is based on an artificial interpretation of Figure 8A (see point 10.3 above) and is unconvincing for this reason alone.

12.2.2 Furthermore, as set out in point 10.7 above, the subject-matter of claim 1 of auxiliary request 7 differs from the disclosure of D7 at least by features 1.2.2.4.1 and 1.2.2.4.2.

Therefore, similar considerations to those for D16 also apply. Without hindsight, the person skilled in the art starting from D7 would not, even in view of the common general knowledge, have modified the tabs of the design shown in Figure 8A, nor added further tabs extending from the body portion adjacent to the existing tabs, so as to implement secondary side tabs which 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, as defined in features 1.2.2.4.1 and 1.2.2.4.2.

The Board therefore concludes that the subject-matter of claim 1 of auxiliary request 7 involves an inventive step starting from D7.

### 12.3 *Starting from D14*

12.3.1 The opponent's inventive-step objection starting from D14 was originally raised by opponent 2 in its notice of opposition. The opponent reiterated this objection in its statement of grounds of appeal (see points 98 to 103), *inter alia* by referring to pages 26 to 36 of opponent 2's notice of opposition.

12.3.2 The patent proprietor submitted that such reference did not meet the substantiation requirement. However, the Board notes that the opponent further developed its argument beyond this reference in points 100 to 103 of its statement of grounds of appeal. In any event, since, as set out below, this objection is not convincing, the question concerning the substantiation of this objection raised by the patent proprietor does not need to be addressed.

12.3.3 The opponent submitted that the edges of the leaflet 106 and one of the cloth portions 304 in the valve disclosed in D14 (see Figure 7 and Figure 9B, reproduced above) formed a primary side tab and a secondary tab, respectively, both of which extended from the body portion of the leaflet 106. The two end portions of cloth portion 304 could also be considered as forming both a primary and a secondary tab.

Even when accepting these arguments, the person skilled in the art would not, without hindsight, have folded the cloth portion 304 about a radially extending crease or replaced it with a differently designed cloth

portion folded along an radially extending crease. This would have departed from the arrangement shown in Figure 9B where the folds extend along an axially extending crease parallel to the struts 404 and 406, and would have required substantial modifications going beyond routine design choices. This applies even when considering D7, since D7 does not directly and unambiguously disclose secondary tabs being folded twice as defined by features 1.2.2.4.1, 1.2.2.4.2 and 1.2.2.5, in particular about a radially extending crease (see point 10. above).

The Board therefore concludes that the subject-matter of claim 1 of auxiliary request 7 involves an inventive step starting from D14.

**13. Description**

Neither the parties nor the Board had objections against the specification of the patent as granted.

**14. Conclusion**

It follows from the foregoing that none of the opponent's objections to auxiliary request 7 taken into account in the appeal proceedings prejudices the maintenance of the contested patent in amended form on the basis of that claim request.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

- claims 1 to 14 of auxiliary request 7 filed with the patent proprietor's statement of grounds of appeal
- description and drawings of the patent specification

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated