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**Datasheet for the decision
of 3 June 2024**

Case Number: T 0308/23 - 3.2.01

Application Number: 13002630.5

Publication Number: 2628464

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

PROSTHETIC VALVE

Patent Proprietor:

Edwards Lifesciences Corporation

Opponent:

Meril GmbH

Headword:

Relevant legal provisions:

RPBA 2020 Art. 12(6), 13(1), 13(2)

EPC Art. 105(1)(a), 84, 83, 76(1), 54, 56

EPC R. 89, 80

Keyword:

Intervention of the assumed infringer - in appeal proceedings
- date of intervention - admissible (no)
Amendment after summons - exceptional circumstances (yes)
Late-filed evidence - should have been submitted in first-
instance proceedings (yes)
Late-filed objection - should have been submitted in first-
instance proceedings (yes)
Claims - clarity main request - clarity after amendment (yes)
Sufficiency of disclosure - main request (yes)
Divisional application - subject-matter extends beyond content
of earlier application (no)
Novelty - main request (yes)
Inventive step - main request (yes) - non-obvious combination
of known features
Requested amendment occasioned by ground for opposition - (no)

Decisions cited:

G 0004/91, G 0001/94, T 1143/00, T 0296/93

Catchword:



Beschwerdekammern

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Case Number: T 0308/23 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 3 June 2024

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 13 December
2022 rejecting the opposition filed against**

European patent No. 2628464 pursuant to Article
101(2) EPC.

Composition of the Board:

Chairman	G. Pricolo
Members:	A. Wagner
	A. Jimenez

Summary of Facts and Submissions

- I. The appeal of the opponent lies against the decision of the opposition division to reject the opposition filed against European patent 2 628 464 pursuant to Article 101(2) EPC.
- II. In its decision, the opposition division held that none of the grounds of opposition raised by the opponent under Article 100(a) EPC in combination with Articles 54 and 56 EPC, Article 100(b) EPC with Article 83 EPC and Article 100(c) with Article 76(1) EPC was prejudicial to the maintenance of the patent as granted.

In order to come to these conclusions the opposition division considered, among others, the following documents:

- D1:** WO 2009/079475 (parent application of the patent in suit)
D4: US 2004/0186563 A1
D5: US 2006/259137 A1
D10: WO 2005/102015 A2
D11: WO 01/76510 A2
D12: Encyclopedia of Biomaterials and Biomedical Engineering: "Heart Valve Failure, Bioprosthetic" by P. Zilla, P. Human, D. Bezuidenhout, pages 711 to 721, July 2004
D13: WO 2006/108090 A2
D14: US 4,501,030

In addition, this decision refers to following documents filed during appeal proceedings:

D25: WO 2005/097003 A1

D26: US 6,558,418 B2

TP-1: High Court of Justice: Particulars of Infringement, 21 February 2020

TP-2: Tribunal judiciaire de Paris: Conclusions Nr°1, 5 June 2020

III. On 15 September 2023, Meril Life Sciences Pvt Ltd. filed a notice of intervention.

IV. Oral proceedings were held before the Board on 3 June 2024.

The appellant (opponent) and the intervener requested that the decision be set aside and the patent be revoked.

The respondent (patent proprietor) requested that the intervention be rejected as inadmissible and that the patent be maintained on the basis of the main request filed as auxiliary request 6" with letter of 24 May 2024.

V. Claim 1 of the main request reads as follows (feature numbering according to the impugned decision):

An implantable prosthetic valve, comprising:

1 a radially collapsible and expandable annular frame (104);

2 a leaflet assembly (102) positioned within the frame (104), the leaflet assembly comprising a plurality of leaflets (106) that are connected to each other to form commissures of the leaflet assembly (102);

3 wherein the frame (104) comprises a pair of vertical struts (404, 406) adjacent each of the commissures, the vertical struts being arranged at an upper area between two frame sections and the struts of each pair being spaced apart from each other so as to define an opening (420) therebetween;

4 wherein at each commissure, two adjacent leaflets (106a, 106b) are positioned between an adjacent pair of vertical struts (404, 406), with one of the leaflets (106a) wrapping around at least a portion of one of the vertical struts (404) at a location outside of the frame and the other leaflet (106b) wrapping around at least a portion of the other vertical strut (406) at a location outside of the frame; and

5 wherein a cloth portion (440) is positioned radially outward of the frame at each pair of vertical struts and positioned over portions (408, 410) of the leaflets (106a, 106b) that extend radially outside of the frame, the cloth portions (440) being sutured to the leaflet portions (408, 410) that are radially outside of the frame,

6 wherein the cloth portion (440) of each commissure comprises a first cloth portion and each commissure further comprises second and third cloth portions (304), the second cloth portion (304) wrapping around one of the vertical struts (404, 406) and the third cloth portion (304) wrapping around the other vertical strut (404, 406), each of the second and third cloth portions (304) being sutured to the first cloth portion (440) and one of the leaflet portions (404, 406) that are radially outside of the frame,

7 characterized in that the leaflet assembly (102) is attached to the frame (104) such that the leaflets (106a, 106b) are not directly sutured to the vertical struts (404, 406).

Granted claims 2, 3, 6 and 10 to 13 are deleted.

VI. The intervener's arguments relevant to the present decision may be summarised as follows:

The intervention was admissible because infringement proceedings relating to the opposed patent have been instituted against them on 16 June 2023 before the Paris Court of First instance. The intervention was filed at 15 September 2023 within the three month time limit stipulated in Rule 89(1) EPC.

VII. The appellant's (opponent's) arguments relevant to the present decision may be summarized as follows:

Admittance of the main request

The main request was late filed after a communication of the Board under Article 15(1) RPBA. The amendments made in the main request addressed objections raised already during opposition proceeding. There were thus no exceptional circumstances as required under Article 13(2) RPBA that could justify the late filing.

Clarity

The amendment "*the vertical struts being arranged at an upper area between two frame sections*" added to feature 3 as granted was not clear because the "upper area" as well as the term "frame section" were ill-defined. It

was not clear to the skilled person where these areas or sections exactly lay and where they extended to. The term "frame section" was also unclear seen together with dependent claim 5, wherein an upper and a lower frame section were defined.

Sufficiency of disclosure

The single embodiment shown in figures 9A, 9B of the patent in suit was not sufficient to enable the skilled person to put the broadly claimed prosthetic heart valve into practice over the whole claimed scope. In particular, the patent in suit (paragraphs [0028] to [0035] and [0043] to [0052]) did not provide any instruction of how the prosthetic valve could be put in practise without the scalloped shape at the lower frame and the specific attachment of the leaflets at said lower frame. To function properly, the attachment of both, the upper and lower end of the leaflets were essential.

Additionally the negative disclaimer in feature 7 was extremely broad. The claimed subject-matter could not be put into practice over its whole scope as claim 1 covered embodiments wherein the leaflets and cloths could freely slide up and down the vertical struts in operation.

Added subject-matter

Compared to the parent application (D1), the claims of the originally filed patent application were completely newly drafted and only based on the description of D1. Contrary to the opposition division's findings, the set of claims contravened Article 76(1) EPC and/or Article 123(2) EPC for the following reasons:

a) The "*two-part foldable frame*" was missing in the claim as the embodiment of figures 9A and 9B - to which claim 1 referred to - was only disclosed in combination therewith.

b) In feature 2 the claim wording "*positioned within*" was broader than the wording "*mounted on*" of the alleged basis in paragraph [040] of D1.

c) The wording "*leaflets that are connected to each other to form commissures*" in feature 2 was only disclosed in combination with "seams" (D1, paragraph [0042]).

d) In feature 3, the wording "*vertical struts arranged at an upper area between two frame sections*" was taken out of the context of paragraphs [010] to [012] wherein each frame section was only described in combination with a lower portion having a scalloped shape and with leaflets being scalloped shaped at the lower portion.

e) The "*cloth portions*" as defined in features 5 and 6 included the possibility of three portions of the same cloth while originally in paragraphs [056] to [059] of D1 only three separate cloths were disclosed.

f) Feature 7 - allegedly based on D1, paragraph [056] - did not include the technical features described in paragraphs [057] to [060] which were relevant to the solution and shown in figure 9B.

g) Dependent claims 2 to 6 constituted unallowable intermediate generalisations with regard to the description of the parent application.

Novelty over D4

The opposition division erred in concluding that features 3 and 7 were not disclosed in D4.

The term "vertical" in feature 3 was to be understood in the broadest technically sensible meaning as "oriented towards the central flow axis". D4, figures 5 and 8, disclosed that the frame 72 had at an upper area (commissure region 76) vertical struts with attachment flanges 106. Furthermore, D4 literally disclosed vertically oriented struts in paragraph [0058] of the description.

With regard to feature 7, in a first line of attack, the wording "*leaflets are not directly sutured*" meant that the leaflets are not in direct contact with the respective frame parts. This was the original idea of the patent in suit and became clear from paragraphs [006] to [014] and paragraph [055] of D1. Also in D4, figure 10, the leaflets 52, 100 were not in direct contact with the struts 72, 106 because of the cloths 114 wrapped around the struts.

A second line of attack was based on the assumption that the wording "*leaflets are not directly sutured*" was understood as requiring the absence of any sutures between the leaflets and the vertical struts. Should the sutures 120, which passed through the attachment holes 108 (D4, figure 10), be seen as a direct attachment, feature 7 was literally disclosed as an alternative in paragraph [0082] wherein it was stated that the attachment holes 108 were only optional.

Novelty over D13

The opposition division erred in concluding that feature 1 was not disclosed in D13.

D13 disclosed in paragraphs [0001] and [0056] a "highly flexible" prosthetic heart valve and mentioned in paragraph [0061] the material Nitinol for the inner stent 70 (figure 4). Such a frame fell under "*a radially collapsible and expandable annular frame*". This also became apparent from D25, a family member of which was cited in D13, paragraph [0064] and "*expressly incorporated by reference*". Therein the same frame as in D13 was shown and described as being implanted percutaneously through a catheter. Features 2 to 7 of claim 1 were disclosed in D13, figure 9.

Admittance of D25 and D26, objections based thereon

D25 and D26 were filed with the statement of grounds of appeal and thus at the earliest moment in time as a direct reaction to the findings of the opposition division during oral proceedings.

Furthermore D25 and D26 were prima facie relevant for the revocation of the patent in suit and did not add any complexity to the appeal case as they were almost identical to D13.

Inventive step

The findings of the opposition division that the subject-matter of claim 1 as granted involved an inventive step starting from D4, D5 or D13 was wrong.

D4 as closest prior art:

Should the Board not follow the novelty objection with regard to D4, claim 1 could only differ in feature 7. The objective technical problem was to provide an alternative attachment of the leaflets.

Omitting the sutures 120 was obvious from D4 alone. The hint in paragraph [0082] that the assembly holes 108 were only "desirable" prompted the skilled person to an attachment in which the leaflets were not directly sutured to the struts.

That the sutures through the attachment flanges were not necessary was also part of the skilled person's general knowledge, as e.g. shown in D11, figure 11, or D13, figure 9.

Feature 7 was also known from D5, figures 5 and 7, wherein leaflets were attached to the frame without suturing through assembly holes.

Omitting the sutures 120 in figure 10 of D4 was also obvious in combination with either D12, D13 or D14. D12 and D14 taught that that stitches in the leaflets produced a number of failures. D13 provided a perfect example for an attachment according to feature 7.

Finally, D10 disclosed on page 17, lines 16 to 20 an attachment e.g. by adhering.

D5 as closest prior art:

Claim 1 differed in features 5 and 6 (first, second and third cloth portion).

In order to solve the problem of how to exactly realise the attachment of the leaflets at the commissures, the skilled person would consider D4 or D13, both teaching

an attachment at the commissure region including features 5 and 6. The skilled person would apply the teaching of D4 or D13 to the prosthetic valve of D5 and arrive at the claimed subject-matter without becoming inventive.

D13 as closest prior art:

Should the Board share the view of the opposition division that claim 1 differed from D13 in feature 1, the objective technical problem was to provide a valve that could navigate through the passages of a patient's vasculature to the implantation site within the patient's body.

D13 itself suggested Nitinol, known by the skilled person as being a suitable material for collapsible and expandable frames for transcatheter aortic valve implantation. Thus D13 alone or D13 with common general knowledge prompted the skilled person to the subject-matter of claim 1.

VIII. The respondent's (patent proprietor's) arguments relevant to the present decision may be summarised as follows:

Admissibility of the intervention

The attempted intervention was to be rejected as it was not filed within the time limit set out in Rule 89(1) EPC. Documents TP-1 and TP-2 demonstrated that the 2023 French proceedings relied on in the notice of intervention were not the first infringement proceedings as required according to T 1143/00 and T 0296/93.

Admittance of the main request

Claim 1 of the main request was identical to claim 1 of auxiliary request 6 filed with the reply to the opponent's statement of grounds of appeal. The only difference was the deletion of granted claims 2, 3, 6 and 10 to 13. It was considered procedurally inefficient at that stage to provide explicit claim sets for all possible combinations of deleted claims.

Clarity

In the context of a prosthetic heart valve and the claim wording itself, the terms "upper area" of a frame and "frame sections" were clear for a skilled person.

Sufficiency of disclosure

The opposition division's reasoning given in the impugned decision, points 36.3 and 37 was to be confirmed. Essential features were an issue of clarity and not a ground of opposition. The patent as a whole showed a detailed embodiment of a prosthetic heart valve with all necessary features such that the skilled person was able to put the invention into practice.

Added subject-matter

The main request did not contravene Article 76(1) EPC or Article 123(2) EPC. The objected features all found basis in D1.

ad a) The "*two-part foldable frame*" was originally disclosed as being "*desirable*" (paragraph [004] in D1).

ad b) The wording in feature 2 "*positioned within the*

frame" found basis in figure 1. Seen together with feature 7, requiring the leaflet assembly being attached to the frame, the teaching of "mounted on the frame" as described in paragraph [040] of D1 was included in the claim.

ad c) The wording "*leaflets that are connected to each other to form commissures*" in feature 2 found basis in paragraph [056], defining the commissures as the area where two leaflets come together. A seam as mentioned in paragraph [042] was not an essential requirement.

ad d) The wording "*vertical struts arranged at an upper area between two frame sections*" defined in feature 3 could be isolated from the teaching of paragraphs [010] to [012] of D1. The aspect of the attachment of the leaflets at the outflow (upper) end of the frame was independent from the scalloped shape of the frame and the leaflets at the inflow (lower) end.

ad e) Basis for the first, second and third "*cloth portions*" as defined in features 5 and 6 was provided by paragraph [012] of D1.

ad f) Feature 7 found basis in paragraph [056] of D1. Features 4 to 6 defined how the attachment was made.

ad g) Dependent claims 2 to 6 all found basis in D1, in particular in figures 9A, 9B and figure 3, as well as in paragraphs [047], [057], [062] and claims 1 and 2.

Novelty over D4

The opposition division correctly found that D4, figure 5 and paragraph [0082], disclosed only slanted struts - contrary to feature 3. These struts did not fall under

the wording "vertical struts" which required the pair of struts being in parallel arrangement.

The opposition division was also right with regard to feature 7. The sutures 120 in D4, figure 10, attached the leaflets directly to the struts 106. The term "*desirably*" in D4, paragraph [0082], did not include an attachment wherein the sutures 120 were omitted. Seen in the context of the whole paragraph, "*desirably include a plurality of holes 108*" meant that at least one hole 108 was required or that the sutures 120 wrapped around the struts.

Novelty over D13

The opposition division was correct in finding that D13 only related to surgical valves. However feature 1 required a radially collapsible and expandable frame implying a transcatheter aortic valve implantation.

Admittance of D25 and D26, objections based thereon

D25 and D26 were filed to show that the frame disclosed in D13 implicitly was suitable for percutaneous implantation. However, feature 1 was already part of claim 1 as granted and disputed from the beginning. Neither the documents nor the new attacks based thereon were admissible under Articles 13(1) and 12(6) RPBA.

Inventive step

D4 as closest prior art

The term "*desirably*" in D4, paragraph [0082], did not prompt the skilled person to omit the sutures 120. Instead the skilled person was guided by paragraph

[0084] to use sutures 120 to allow tensile forces to be transferred as much as possible to the frame. Therefore neither D4 alone, nor D4 combined with either common general knowledge (D11, D13), D5, D12, D13, D14 or D10 rendered the claimed subject-matter obvious. Additionally, the frame structure and the delivery method of D5, D13, D14 or D10 were totally incompatible with those of D4.

D5 as closest prior art

The disclosure of D5 was not compatible with the one of D4. In paragraph [0117], it was described that the prosthetic valve of figure 6A - having the frame of figure 5 - had a sewing cuff ring 37, 38 that allowed to reduce "*the sutures necessary to sufficiently anchor and implant the anchoring structure and valve*". The prosthetic valve was thus implanted in an open heart surgery.

As also D13 only disclosed surgical valves, the anyway not obvious combination of the two completely differently designed frame structure could not result in the claimed prosthetic valve.

D13 as closest prior art

D13 related to a valve which is implanted in an open heart surgery. D13 was thus not an appropriate starting point and could neither alone nor combined with common general knowledge render feature 1 obvious.

Reasons for the Decision

1. Admissibility of the intervention

1.1 The intervention filed on 15 September 2023 is rejected as inadmissible because it does not comply with the time limit specified in Rule 89(1) EPC.

1.2 While the intervener referred to infringement proceedings relating to the opposed patent instituted against them on 16 June 2023 before the Paris Court of First instance, the patent proprietor demonstrated that previous infringement proceedings by the patent proprietor based on the opposed patent were initiated against the intervener Meril Life Sciences Pvt Ltd. more than three months prior to the notice of intervention.

Specifically, there were infringement proceedings before the High Court of Justice of England and Wales, commenced on 26 February 2020 (TP-1), and infringement proceedings before the Paris Court of First Instance (TP-2) filed on 5 June 2020, with the infringement claims based on the opposed patent.

1.3 According to T1143/00 and T0296/93, the three-month time limit for filing an intervention is always triggered by the date on which the first proceedings were instituted. As there were at least in 2020 already relevant infringement proceedings, the intervention filed on 15 September 2023 is to be rejected as inadmissible.

1.4 The intervener did not dispute that there were earlier infringement proceedings instituted. However, they were of the opinion that neither Article 105(1)(a) EPC nor Rule 89(1) EPC stipulated that the three month's time

limit according to Rule 89(1) EPC could be triggered only once with first proceedings or that it was always triggered by the date on which the first proceedings were instituted. With just two very old decisions (T1143/00 and T0296/93), there was no established Case Law on this topic. Furthermore, the cited case law was of no relevance for the present case.

1.5 The Board does not agree.

1.5.1 The cited case law dealt with very similar situations. In both cases the attempted intervention was rejected as inadmissible because it was not filed within the three month limit specified in Rule 89(1) EPC.

1.5.2 In T0296/93, an intervention was filed on 29 December 1992 with reference to proceedings instituted according to Article 105(1), second sentence EPC 1973 (corresponding to Article 105(1)(b) EPC) on 30 September 1992. However, proceedings for infringement according to Article 105(1), first sentence EPC 1973 (corresponding to Article 105(1)(a) EPC) were instituted on 1 July 1992. The board held (decision, reasons point 2.5) that the principle behind Article 105 EPC is that, as soon as any court action has been brought, the sole available period for intervention starts running. Any other interpretation would open the possibility of abuse of the intervention opportunity by the filing of national invalidity actions in order simply to trigger a new time limit under Article 105 EPC, regardless of earlier circumstances.

Even though in T0296/93, there were not two infringement proceedings according to the same paragraph of Article 105 EPC, namely (1)(a), the general principle that the first proceedings,

independent of whether there are instituted under Article 105(1)(a) or (b) EPC, triggers the time limit of Rule 89(1) EPC also applies to the present case.

1.5.3 In T1143/00, an intervention was filed on 3 July 2001 with reference to infringement proceedings instituted on 25 May 2001 in Austria. However, earlier infringement proceedings were instituted on 23 June 2000 in Germany. In this case, the board held (decision, reasons point 2.2) that from the purpose of the possibility of intervention to have the validity of a European patent reviewed within the framework of the centralised European opposition proceedings, it follows that an intervention can only be filed on the basis of the first infringement action. These general considerations also apply to the present case.

1.5.4 The Board also disagrees with the intervener's argument that interpreting the 3-month time limit in Rule 89(1) EPC as always being triggered by the date of the first proceedings would violate the principle of equality of arms and would open the door to potential procedural abuses.

1.5.5 The provisions of Article 105 EPC are intended to allow the alleged patent infringer to defend themselves by challenging the validity of the patent within the centralised procedure before the EPO rather than through separate national proceedings (see G4/91, reason 4 and G1/94, reason 7). This purpose is achieved by enabling the alleged infringer to intervene in opposition proceedings, even at the appeal stage, as soon as they are informed of infringement case against them. This implies that the intervention can only be initiated based on the first infringement proceedings,

even if there are separate national infringement proceedings underway in different EPC contracting states.

If the alleged infringer were able to choose at will the infringement procedure allowing them to intervene in the opposition proceedings, it would be theoretically possible for them to deliberately delay the opposition proceedings by intervening at a later stage on the basis of a subsequent infringement procedure, which would run counter to the objective pursued by Article 105 EPC and Rule 89(1) EPC.

The different interests of the alleged infringer in one or other of the national proceedings or its subjective assessment of the economic importance of a territory cannot play a role in this context.

- 1.5.6 Furthermore, in the case at hand, the Board underlines that some of the multiple infringement proceedings against the intervener were instituted while the opposition period was still running (see TP1, particulars of infringement before the UK High Court of Justice deemed served on 24 February 2020). The intervener would have been free to file an opposition against the patent themselves during that time to become a party to the proceedings.

2. Admittance of the main request

- 2.1 The main request was filed as auxiliary request 6" with letter of 24 May 2024 and falls under the provision of Article 13(2) RPBA. The Board admitted the main request into the proceedings.

- 2.2 Claim 1 of the main request is identical to claim 1 of auxiliary request 6 filed for the first time on 4 March 2022 during opposition proceedings and submitted again with the patent proprietor's reply to the opponent's statement of grounds of appeal. The only difference in the main request on file is the deletion of granted claims 2, 3, 6 and 10 to 13.
- 2.3 In the present case, numerous objections of added subject-matter were raised by the appellant against the complete set of claims. The respondent (patent proprietor) was aware of these objections, filed already 43 auxiliary requests with their reply and indicated therein on page 95 (fifth paragraph), that *"one or more claims may be deleted depending the course of the appeal proceedings"*, but that it was *"considered procedurally inefficient to provide explicit claim sets for all possible combinations of deleted claims"* already with the reply.
- 2.4 Under these circumstances the Board considered that the patent proprietor was justified in not filing auxiliary requests for all possible combinations of deleted claims with their reply to the opponent's statement of grounds of appeal. Furthermore, the main request complies with the need of procedural economy by rendering unnecessary the discussion of several issues of added subject-matter in connection with the patent as granted.
- 2.5 The Board judged these circumstances to be exceptional and duly justified by the patent proprietor according to Article 13(2) RPBA.

3. Clarity

3.1 Claim 1 of the main request meets the requirements of Article 84 EPC.

3.2 The appellant was of the opinion that the wording "*at an upper area between two frame sections*" added from the description to feature 3 as granted was unclear.

3.3 The Board does not agree. Seen in the context of a prosthetic heart valve, the skilled person knows that a frame has an upper area (usually the outflow area) and a lower area (usually the inflow area). Furthermore, the claim defines that the upper area is the part of the frame where the pair of vertical struts is arranged to attach the commissures of the leaflet assembly. Therefrom, the skilled person understands what and where the upper area of the frame is.

Also the feature "*two frame section*" is clear. From the wording of feature 3 the skilled person understands that the frame sections are defined in circumferential direction by the pairs of vertical struts. Therefrom it is also clear that the upper and lower frame section defined in claim 5 and referred to by the appellant in their clarity objection are different from those defined in claim 1.

3.4 The appellant further argued in their written submissions that the wording of feature 2 "*leaflet assembly positioned within the frame*" was unclear as to whether the leaflet assembly had to be completely or partly inside, or within the circumferential or axial dimension of the frame. The wording was also unclear seen together with feature 4 wherein it was defined that a part of the leaflets needs to be positioned

outside the frame to wrap around the struts.

However, as brought forward by the respondent, these objections refer to clarity issues with regard to claim 1 as granted which is not a ground for opposition.

4. Sufficiency of disclosure

4.1 The Board confirms the opposition division's findings with regard to the patent as granted that the requirements of Article 83 EPC are met (impugned decision, points 36, 37).

4.2 The appellant (opponent) was of the opinion that without the essential feature of a scalloped shape at the lower frame area and without defining the leaflet attachment at the lower frame in claim 1, the patent in suit did not provide any instruction of how the heart valve could be put in practise. Because of the essentiality of these features, there was also no guidance for the skilled person on how to solve the problem of reducing abrasion of the leaflets without the details of attachment of the lower leaflets.

4.3 First of all, it is noted that, in general, the lack of essential features is an issue of clarity, which is not a ground of opposition.

Secondly, the skilled person would not - when trying to implement the prosthetic valve as such - limit the prosthetic valve to the features included in claim 1. That additional features are required for the prosthetic valve to be functional is generally known.

Furthermore the Board agrees with the respondent (patent proprietor) that the heart valve as claimed solves the problem posed by providing a specific

solution for reduced abrasion at the commissures of the leaflets. Concerning the specific attachment at the upper frame area, it was not disputed that the patent provides sufficient disclosure. Indeed, in particular paragraphs [0055] to [0060] with figures 9A and 9B - disclose an embodiment according to claim 1 such that the skilled person can put the invention into practice. That the patent in suit additionally provides a specific solution for the lower end of the leaflets is not relevant for an enabling disclosure of the invention which is directed to the specific attachment at the upper area.

- 4.4 Feature 7 was objected as allegedly being too broad to be put into practice over its whole range.
- 4.5 The Board does not agree as claim 1 itself describes in features 4 and 6 how the leaflets are attached to the frame to be held in place without being directly sutured to the vertical struts. Furthermore, the patent clearly shows, in the embodiment of figure 9B, how the leaflet assembly can be attached to the frame. Seen together with the design of the pair of vertical struts as shown in figure 9A, the skilled person also knows how to prevent the leaflets from sliding off the struts when not directly sutured to the latter. An insufficiency of disclosure is therefore not apparent.

5. Added subject-matter

- 5.1 The patent in suit is a divisional of the international application WO 2009/079475 A2 (D1). The description of the A1-publication of the patent in suit is the same as that of the parent application D1. The claims of the parent application are added at the end of the description of the originally filed patent application.

The originally filed claims of the patent application are newly drafted compared to the claims of the parent application.

5.2 The main request meets the requirements of Article 76(1) EPC and Article 123(2) EPC.

5.3 **Article 123(2) EPC**

5.3.1 Claim 1 of the main request on file is a combination of originally filed claims 1 and 4 with feature 7 added from paragraph [056] and with the wording "*the vertical struts being arranged at an upper area between two frame sections*" added from paragraph [012] to feature 3, both passages are the same in the originally filed application and in the parent application.

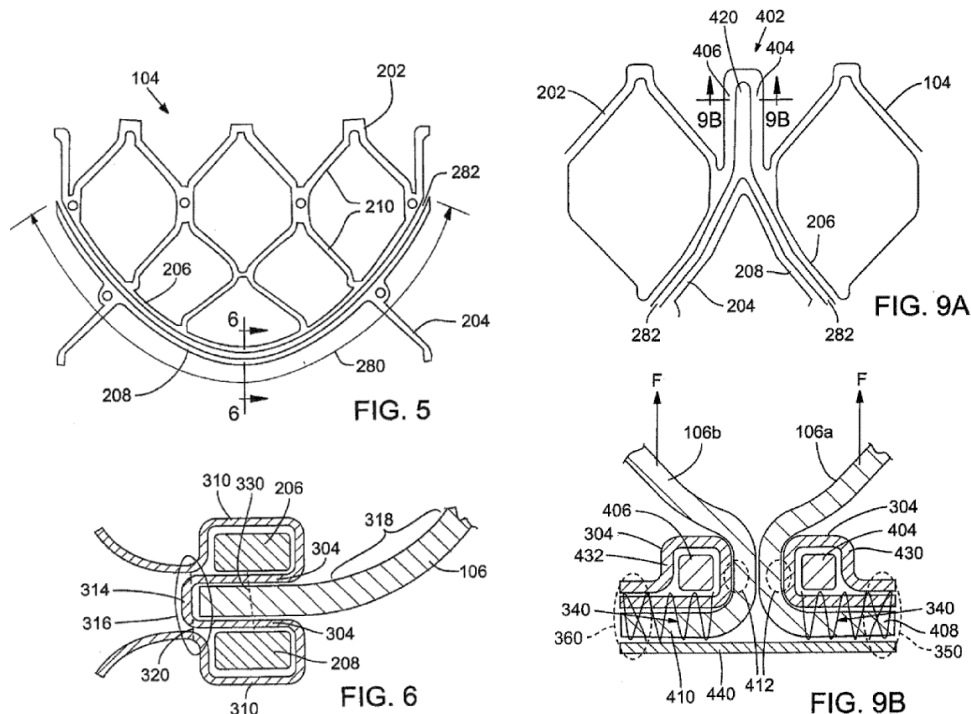
5.3.2 The objections under Article 123(2) EPC and under Article 76(1) EPC with regard to feature 7 and amended feature 3 are the same and therefore dealt with in the following with regard to the parent application D1 (see points 5.5 below, issue d and f).

5.4 **Disclosure of D1**

5.4.1 The disclosure as a whole is about attaching the leaflets to the stent frame. On the one hand, the attachment at the lower arc-shaped or scalloped frame edge is described and shown in
- paragraphs [004] to [011], [013], [014], [047], [049] to [054] and
- figures 3 to 8 (figures 5, 6 reproduced below at the left hand side).

On the other hand, the attachment at the upper frame area is described and shown in

- paragraphs [012], [055] to [061] and
- figures 9A, 9B, 10 (figures 9A, 9B reproduced below
at the right hand side).



5.4.2 While the claims of the parent application address the attachment at the scalloped lower frame portion 206, 208 (figure 5, first core teaching), the patent in suit addresses the attachment at vertical struts 404, 406 at the upper frame area (figure 9A, second core teaching).

5.4.3 From the overall disclosure of D1 it is per se appropriate to provide a set of claims directed only to said second core teaching of D1 without contravening Article 76(1) EPC - contrary to the appellant's opinion.

5.5 **Article 76(1) EPC**

5.5.1 The appellant (opponent) submitted numerous objections summarized under issue a to g as follows:
a) "two-part frame"

- b) feature 2: "mounted on" versus "positioned within"
- c) feature 2: "connected to each other to from commissures"
- d) feature 3: "vertical struts arranged at an upper area between two frame sections"
- e) features 5, 6: "cloth portions"
- f) feature 7: "not directly sutured"
- g) dependent claims 2 to 6.

None of the objections is convincing for the following reasons.

- 5.5.2 ad a - "*two-part frame*" (impugned decision, point 17.4, penultimate paragraph, last sentence)

The Board confirms the opposition division's findings that basis for the omission of the feature "*two-part frame*" can be found in paragraph [004] of D1, reciting that "*The valve prosthesis desirably includes a two-part foldable frame.*"

The appellant argued that omitting the two-part frame constituted an impermissible intermediate generalisation. In particular features 3, 5 and 6 of claim 1 - allegedly based on paragraphs [012] and [056] to [060] - were only disclosed in combination with the two-part frame. Paragraph [012] read (emphasis added by the Board): "*In other specific implementations, the frame **further** comprises...*" and thus referred back to the frame with the two parts described before in paragraph [011]. Furthermore claim 1 was clearly directed to the embodiment depicted in figure 1 with figures 9A, 9B being described in paragraphs [056] to [060] and having a two-part frame 202, 204 with an upper and lower arc portion 206, 208. Thus the definition of the two-part foldable frame was

inextricably linked to the features of claim 1. Further reference was made to paragraph [064] wherein D1 described a combined effect of the two-part frame and the specific attachment.

The Board is not convinced. From paragraphs [010] and [012], which are reflected in claims 8 and 11 of D1, the skilled person is taught that the two-part form is not obligatory for the frame.

The two-part form is defined in dependent claim 9 which corresponds to paragraph [0011]. Claim 11, which relates to features 3, 4 and 6, corresponds to paragraph [012], and is only dependent on independent claim 8 and not on claim 9. Consequently, paragraph [012] is to be read together with paragraph [010], not obligatorily with paragraph [011].

It is a fact that independent claim 8 (paragraph [010]) is directed to a frame with a lower edge portion having a scalloped shape to which a lower leaflet edge, which likewise has a scalloped shape, is attached. However, the attachment of the leaflets at the vertical struts (being one of the core teachings of D1, see point 5.4 above) is not inextricably linked to the attachment at the lower edge of the leaflets (being another core teaching of D1) due to the spatial separation.

Therefore the additional features of claim 8 concerning the lower attachment ("scalloped shape") can be omitted without contravening Article 76(1) EPC.

5.5.3 ad b - "*mounted on*" versus "*positioned within*"
(impugned decision, point 17.1)

The Board agrees with the opposition division that paragraph [040] and figure 1 provide sufficient support for a leaflet assembly "*positioned within a frame*".

The appellant argued that "mounted on" referred to a mechanical arrangement while "positioned within" defined a spacial constraint. Furthermore the term "mounted on" referred to the overall attachment of the leaflet assembly while the broader term "positioned within" completely omitted the idea of attachment. The wording "positioned within" did not find any literal basis and was not directly and unambiguously disclosed.

The Board does not agree. Throughout the parent application, the leaflet assembly is disclosed as being positioned within the frame. For a prosthetic valve, it is even inherent that the leaflets are somehow positioned within the frame to guarantee proper functioning. Additionally, also the idea of mounting or attaching the leaflets on the frame is reflected in claim 1. Features 4 to 7 define how the leaflets are wrapped around vertical struts of the frame and attached to the frame via cloths. The claim wording therefore does not broaden the original technical teaching of paragraph [040].

5.5.4 ad c - "*leaflets connected to each other to form commissures*" (impugned decision, point 17.2)

The Board agrees with the opposition division's findings that omitting the term "seams" does not constitute an intermediate generalisation.

The appellant was of the opinion that paragraph [056] could not provide basis for the feature wording as therein no connection at the commissures was mentioned, but only a "coming together". Connected leaflets were only disclosed in paragraph [042] together with the mechanical means of seams.

The Board is not convinced. The term "commissures" is generally known in the art and defines the part of the valve where the leaflets come together to be attached to the frame. This corresponds to the teaching of paragraph [056] of D1, wherein it is disclosed that "*two leaflets come together in the valve (e.g. the commissure)*" without qualifying this feature as having seams to connect the leaflets.

Paragraph [040] rather refers to a specific example of a leaflet assembly as shown in figure 1 wherein the "*leaflets 106 **can** comprise three pieces of pliant material that are connected to each other at seams*" (emphasis added by the Board).

5.5.5 ad d - "*vertical struts arranged at an upper area between two frame sections*"

This feature was added to granted claim 1 during opposition proceedings. Similar to objection a), the appellant was of the opinion that the alleged basis of paragraph [012] or, alternatively, of claims 8 and 11, disclosed the vertical struts at an upper area only in combination with a frame and leaflets that both have a lower portion with a scalloped shape.

The Board however agrees with the respondent that the disputed feature wording finds sufficient basis in claim 11. It is true that claim 11 depends on claim 8 wherein it is defined that "*a frame comprising a plurality of frame sections, each frame section having a lower portion with a scalloped shape; and a flexible membrane comprising a plurality of flexible leaflets, each flexible leaflet having a lower portion with a scalloped shape; wherein the lower portion of each flexible leaflet is attached to the lower portion of each frame section*".

However, the Board refers to point 5.5.2 above (last paragraph). Accordingly, the Board does not see any need of adding the features concerning the lower portions to claim 1. These features refer to the aspect of the lower attachment which is not inextricably linked to the aspect of the upper attachment (see also point 5.4.3). The fact that the lower edge of the leaflets also needs to be attached somehow to the frame, is implicit for the skilled person and does not need to be mentioned in the claim.

5.5.6 ad e - cloth portions (impugned decision, point 17.4, penultimate paragraph)

The Board agrees with the opposition division that features 5 and 6, wherein the cloth portions are defined, do not add subject-matter. Basis can be found in paragraphs [057] to [059] and figure 9B.

The appellant argued that in paragraphs [057] to [059] no "cloth portions" were disclosed but three separate cloths. Cloth portions were disclosed in paragraph [012] but not in the context of feature 7.

The Board is not convinced. Even if paragraphs [057] to [059] use the wording "cloth 304" and "piece of cloth 440", it is clear that the embodiment described therein (and shown in figure 9B) refers to paragraph [012] of the general description of D1 wherein first, second and third "cloth portions" are described. The terminology is not identical, but what is meant is the same such that no technical information is added.

5.5.7 ad f - feature 7 (impugned decision, point 17.5)

The Board agrees with the opposition division that feature 7 finds support in paragraph [056].

The appellant argued that paragraphs [056] to [059] had to be seen as one disclosure. Feature 7 was just an open statement without the relevant structural features that solved the problem posed. Claim 1 omitted that

- the leaflets were attached to a cloth at one area while at another area the leaflets were not attached to the cloth,
- the unattached portion of the leaflets extended radially inwards into the interior of the frame,
- an unattached portion of the cloth formed an excess cloth portion that extends radially inward into the frame and wraps back around the strut.

The Board can agree that the teaching of paragraphs [0056] to [059] is about the solution of how to not directly suture the leaflets to the posts. However, as brought forward by the respondent, feature 7 has to be seen together with features 3 to 6. Therein structural features are defined which describe how the leaflets are attached to the struts via cloths so that the leaflets are attached to the frame without being sutured directly to the struts. These structural features correspond to those described in paragraphs [0056] to [059].

The definition of an attached or unattached area of the leaflets or of the cloths is not necessary and rather implicit. Feature 6, defining that the second and the third cloth portion 304 is sutured to one of the leaflet portions that are radially outside of the frame, describes that the leaflets create there an attached area. All the remaining portions of the leaflet, e.g. portions that are included by feature 2,

create an area that is not attached to the cloth 304. Likewise feature 5 defines an attachment portion of the leaflets with the first cloth portion. Furthermore, it is clear from feature 6 that the second and the third cloth portion 304 are sutured to leaflet portions outside of the frame. As feature 6 further defines that the second and third cloth portion 304 wrap around a vertical strut, it is clear that all portions of the cloth not outside of the frame form an unattached or excess portion. Nothing else is disclosed in paragraphs [0057] to [059].

5.5.8 ad g - dependent claims (impugned decision, point 19f)

Claim 2 defines that *"each of the second and third cloth portions (304) of each commissure comprises an attached portion (408, 410) that is attached to one of the leaflets (106a, 106b) and an excess cloth portion (430, 432) that extends inward into the frame and wraps back around one of the vertical struts (404, 406), the first cloth portion (440) being sutured to the attached portions (408, 410) and the excess cloth portions (430, 432)."*

Claim 2 corresponds to claim 4 as granted. The wording of claim 2 is supported by paragraphs [057] and [058] of D1.

The argument of the appellant that the wording of claim 2 was not identical to the wording of the description and therefore introduced subject-matter is not convincing. The changes are of purely linguistic nature such that the technical information of the wording of claim 2 is the same as in paragraphs [057] and [058] of D1.

Claim 3 defines that "*the vertical struts (404, 406) of each pair are connected to each other at their upper ends.*"

Claim 3 corresponds to claim 5 as granted. The wording of claim 3 finds basis in figures 3 and 9A showing the vertical struts of each pair being connected as claimed.

The argument of the appellant that the feature of claim 3 was abstracted from the figures showing a specific frame structure is not followed. All relevant features of the frame concerning the attachment at the upper frame area are included in claim 1 (see also point 5.5.5 above).

Claim 4, that corresponds to claim 7 as granted, defines that "*each pair of vertical struts (404, 406) are connected to adjacent pairs of vertical posts by a row of circumferentially extending angled struts.*"

The appellant argued that no literal basis could be found and that contrary to the opposition division's opinion the figures could not provide support for the feature "angled struts".

The Board does not agree. Figure 3 and paragraph [062] sufficiently support the claimed features. While figure 3 (reproduced below) clearly shows angled struts connecting adjacent pairs of vertical struts, paragraph [062] discloses that the shape and number of the angled struts 210 can vary, see also figures 11 to 13. Claim 4 thus does not add subject-matter.

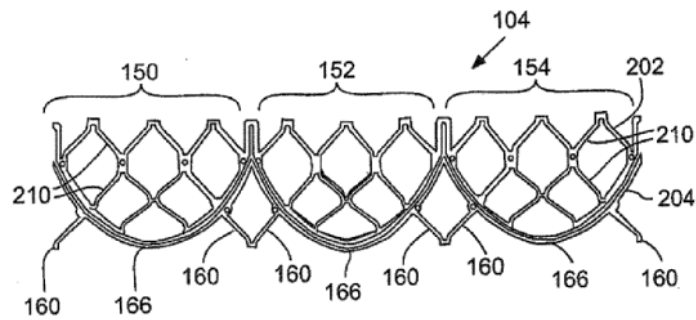


FIG. 3

Claims 5 and 6, corresponding to claims 8 and 9 as granted, incorporate all features of claims 1 and 2 of D1.

Claim 5 defines that *"the frame comprises an upper frame section and a lower frame section, the upper frame section having a plurality of struts and a first leaflet receiving surface at a lower portion of the upper frame section, the lower frame section having a second leaflet receiving surface at an upper portion of the lower frame section; each leaflet comprises a lower edge portion disposed between the first and second leaflet receiving surfaces."*

Claim 6, which is dependent on claim 5, specifies that *"the first and second leaflet receiving surfaces are scalloped shaped."*

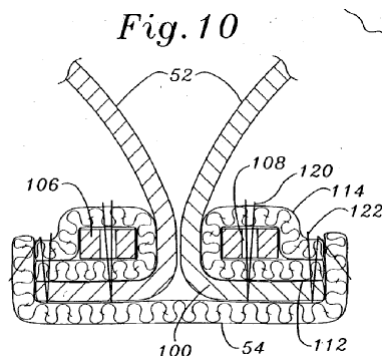
The appellant argued that the features were not disclosed in that broad fashion.

However, the wording of claims 5 and 6 finds literal basis in claims 1 and 2 of D1. The subject-matter was thus disclosed in an even broader context, i.e. without the features of claim 1 of the main request on file.

6. Novelty over D4

6.1 The Board confirms the opposition division's decision (point 22) that the subject-matter of claim 1 of the main request on file is new over D4 because feature 7 is not disclosed. While the opposition division's findings referred to the patent as granted it is noted that feature 7 of claim 1 of the main request on file is the same as in the patent as granted.

6.1.1 In a first line of attack it was argued that the wording "*leaflets are not directly sutured*" only meant that the leaflets are not in direct contact with the respective frame parts. Also in figure 10 of D4 (reproduced below), the leaflets 52, 100 were not in direct contact with the struts because of the cloths 114 wrapped around the struts.



6.1.2 The Board does not agree. The skilled person understands from the wording "*not directly sutured*" - seen together with features 4 and 6 - not only that the leaflets are not in direct contact with the struts, but also that no suture directly connects the leaflets with the vertical struts. This is obviously not the case in the embodiment shown in figure 10 of D4. The suture 120 passes through assembly holes 108 of the frame and directly connects the leaflets 52 to the attachments flanges 106 of the frame.

6.1.3 In a second line of attack the appellant referred to D4, paragraph [0082]. Therein feature 7 allegedly was literally disclosed as the assembly holes 108 were described as only being optional ("*Attachment flanges 106 are formed adjacent the tip 104 and desirably include a plurality of assembly holes 108...*"). An alternative embodiment was thus disclosed without holes 108 that inevitably resulted in feature 7.

6.1.4 The Board is not convinced. Neither an attachment without any assembly hole nor an attachment in which direct suturing simply is omitted is directly and unambiguously derivable from D4. As brought forward by the respondent, there are numerous alternatives to the meaning of "desirably" in the context of paragraph [0082], e.g. providing just a single assembly hole 108 or having direct suturing to the attachment flanges 106 without the plurality of suture holes. Furthermore, as acknowledged by the appellant, simply omitting the sutures 120 would lead to a less robust attachment, which gives the skilled person reason to doubt whether this actually is meant with "desirably" in paragraph [0082]. On that basis D4 can not be considered as disclosing directly and unambiguously no direct suturing.

6.2 The respondent further disputed the disclosure of vertical struts in D4. D4 described in paragraph [0081] with reference to figure 8 clearly non-vertical struts because "*the commissure region 76 of the leaflet frame 72 tapers down in the outflow direction to a tip 104*".

6.2.1 However, contrary to the respondent's opinion, the wording "vertical" does not imply a perfect vertical orientation resulting in the pair of struts being parallel. Instead, the skilled person understands the

wording "vertical struts" in its broadest technical meaning including generally or substantially vertical orientations.

6.2.2 Furthermore, in the general part of the description, D4 discloses in paragraph [0058] that the frame has "*three upstanding and generally axially-oriented arcuate or U-shaped commissure regions on the outflow end*". The skilled person understands the wording "*upstanding and generally axially-oriented arcuate or U-shaped*" as falling under the term "vertical" - even if the commissure region is slightly tapering in the outflow direction to a tip 104 as shown in figure 8 of D4.

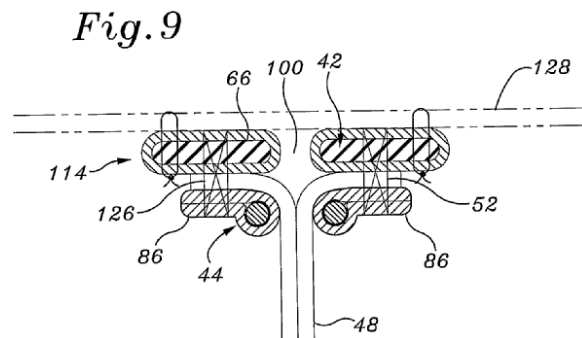
6.2.3 Consequently, the attachment flanges 106 of the frame adjacent to the leaflet tabs 100 can be considered as a pair of struts being "vertical" according to feature 3.

7. Novelty over D13

7.1 The Board confirms the opposition division's decision (point 23) that the subject-matter of claim 1 of the main request on file is new over D13 because feature 1 is not disclosed. Feature 1 of the main request on file is the same as in the patent as granted on which the opposition division decided.

7.2 In particular, the Board agrees with the respondent (patent proprietor) that in the technical field of heart valves a "*collapsible and expandable frame*" is understood by the skilled person as implying a percutaneous implantation of the prosthetic valve. Contrary to the appellant's opinion, no further definition of these terms is necessary for this understanding.

7.3 Having said that, D13 can not take away novelty of the claimed subject-matter because the prosthetic valve shown in figures 3 to 10 - to which the appellant referred to - is a surgical valve. This is not even disputed by the appellant and actually disclosed e.g. in paragraph [0015], wherein it is described that the prosthetic valve comprises a sewing ring or connecting band 42 and *"is connected to the natural tissue along the undulating connecting band using conventional techniques, such as sutures"*. As the connecting band 42 in the commissure region needs to be sutured to the aortic wall 128 as shown in figure 9 (reproduced below) and further described in paragraph [0076], the valve indeed requires a surgical method.



7.4 The argument of the appellant that a *"highly flexible"* frame as disclosed in D13, e.g. paragraph [0001] or claim 1, was radially collapsible and expandable and therefore suitable for percutaneous implantation could not convince the Board.

The high flexibility of the frame in D13 only relates to the ability of the prosthetic valve to follow the natural movements at the implantation site in use. This is e.g. described in D13, paragraph [0057]: *"a highly flexible prosthetic valve of the present invention accommodates the in-and-out movements of both the annular region 34 and the sinus region 36."* and further *"relative movement in the annulus and sinus regions*

during systole and diastole does exist, and the highly flexible prosthetic heart valve of the present invention accommodates such movement."

7.5 Even if D13, paragraphs [0061, 0062], discloses that *"the stent 70 comprises a single element of Nitinol..."*, a material that is indeed known in the field as one possible material for expandable and collapsible frames, it can not be concluded that therewith, implicitly, the prosthetic valve as such is suitable for percutaneous implantation. This is obviously not the case (see point 7.3 above).

7.6 Finally, the appellant argued that D13, paragraph [0064] incorporated by reference the disclosure of D25 by referring to a family member US 2005/0228494 A1. Therein (D25, paragraph [0034]) it was disclosed that *"If the support frame 40 of the heart valve is made of a highly flexible material such as Nitinol, the valve may be compressed to a relatively small package and inserted using a minimally-invasive technique, such as percutaneously through a catheter passed up through the femoral artery."*

7.7 However, according to established case law, in the assessment of novelty, a document, here D13, must be considered in isolation. The incorporation is only allowed if the first document (here D13) contains a specific reference to the second document (here D25) for detailed information on certain features. This is not the case as nowhere in D13 a specific reference to the passage disclosing a percutaneous implantation is provided.

8. Admission of D25, D26

8.1 D25 and D26 were not admitted into the appeal proceedings pursuant to Article 12(4), (6) RPBA.

8.2 Article 12(6) second sentence RPBA expresses the principle that each party should submit all requests, facts, objections or evidence that appear relevant as early as possible so as to ensure a fair, speed and efficient procedure.
D25 and D26, both filed for the first time with the opponent's statement of grounds of appeal, were not admitted into the appeal proceedings as these documents should have been submitted already during opposition proceedings.

8.3 According to the appellant, the filing of D25 and D26 was a direct reaction to the findings of the opposition division during oral proceedings that D13 did not disclose feature 1. The interpretation that feature 1 allegedly implied a percutaneous implantation was only discussed during oral proceedings.
Furthermore D25 and D26 were prima facie highly relevant as they took away novelty of, or at least rendered obvious, the subject-matter of claim 1.

8.4 However, feature 1 in claim 1 of the patent as granted is the same as in claim 1 of the main request on file. The patent proprietor disputed the disclosure of feature 1 in D13 already from the beginning of the opposition proceedings. The opinion that D13 did not disclose feature 1 was also shared by the opposition division in their preliminary opinion dated 24 September 2021 (page 5). At this stage already, there would have been reason for the opponent to submit D25 and D26 to support their arguments for lack of

novelty over D13, in particular as the opponent actually provided two further submissions with letters dated 4 March 2022 and 21 April 2022 after the opposition division's preliminary opinion and before the date of oral proceedings.

The filing of D25 and D26 with the statement of grounds of appeal can thus not be considered as a direct reaction to the opposition division's final conclusions with regard to novelty over D13.

- 8.5 The same reasoning applies for the novelty attack with regard to D25 and the inventive step attack combining D25 and D26, both attacks submitted only with letter dated 29 November 2023. The admission falls under the provision of Article 13(1) RPBA according to which Article 12(6) RPBA applies *mutatis mutandis*.

The new attacks are directed in particular to feature 1 of claim 1 and would have likewise applied to claim 1 as granted. Consequently, these attacks based on D25 and D26 should have been submitted already during opposition proceedings.

- 8.6 The appellant further argued that D25 and D26 were already implicitly in the proceedings as they were mentioned in D13, paragraphs [0006], [0061], [0064] and [0074] and "*incorporated by reference*".

However, according to established case law, only features of a second document that are specifically referred to can be incorporated in a first document. A mere statement "*incorporated by reference*" is not a specific reference and therefore can not result in the incorporation of the whole disclosure of the second

document as such.

9. Inventive step

9.1 The Board confirms the opposition division's decision (point 26) that claim 1 involves an inventive step over the cited prior art. While these findings were related to the patent as granted, it is noted that the features concerned in the discussion of inventive step in appeal are identical in claim 1 as granted and claim 1 of the main request.

9.2 D4 as closest prior art

9.2.1 Claim 1 differs from D4 in feature 7 (see point 6 above).

9.2.2 The appellant formulated the objective technical problem as providing an alternative leaflet attachment. The alleged contribution to the prior art that feature 7 would reduce stresses on the leaflets was already achieved with the prosthetic valve of D4. With regard to figure 10, paragraph [0084] of D4 disclosed that *"the construction shown in FIG. 10 causes tensile forces imparted by the leaflets 52 to be transferred as much as possible from the sutures 120, 122 to the frame 72, thus helping to prevent tearing of the flexible leaflets and rendering the valve 22 more durable."*

9.2.3 While this formulation of the technical problem was disputed by the respondent, the Board concludes that even if the underlying problem were to find an alternative leaflet attachment, the claimed subject matter is not obvious when starting from D4.

9.2.4 The appellant argued that feature 7 was obvious in view of

- (a) D4 alone because paragraph [0082] prompted the skilled person to an attachment without direct suturing by omitting the suture 120 passing through the assembly holes 108.
- (b) D4 with common general knowledge. A lack of a suture between the leaflet and the stent struts at the commissure location was common in the field of prosthetic valves as was apparent from D11 (figure 11) or D13 (figure 9). The skilled person was thus hinted by paragraph [0082] of D4 to omit the assembly holes 108 and therewith the suture 120 passing there through.
- (c) D4 with D5 because D5 motivated the skilled person to implement an attachment without direct suturing the leaflets to the attachment flanges 106. D5 disclosed in figures 5 and 7 frames in which leaflets were attached without suturing through bore holes. The assembly holes 108 in D4 were thus dispensable.
- (d) D4 with either D12, D13 or D14. D12 and D14 emphasized that high stresses on the leaflets represented a major problem for prosthetic valve durability and that any suture line caused additional stress (D12, page 717, right column, second paragraph, and page 718, left column, second paragraph; D14, column 1, lines 34 to 41). Thus the skilled person got a clear teaching to implement the alternative embodiment of D4 in which no assembly holes 108 were present. Feature 7 was thus an obvious modification to avoid sutures between leaflet and frame struts. D13, figure 9, provided

an example of indirect leaflet attachment.

- (e) D4 with D10 because D10 (page 17, lines 16 to 20) described alternative ways of attachment, e.g. adhering, such that no sutures were provided.

9.2.5 None of the attacks could convince the Board. In accordance with point 6.1.4 above, paragraph [0082] of D4 neither itself prompts the skilled person to an attachment according to feature 7 nor renders feature 7 obvious in combination with common general knowledge or any of the documents D5, D12, D13, D14 or D10.

- (a) As explained above with regard to novelty, the disclosure in paragraph [0082] that "*Attachment flanges 106 are formed adjacent the tip 104 and desirably include a plurality of assembly holes 108 sized to permit passage of sutures therethrough.*" is to be seen in the context. As held by the opposition division (decision point 29.2, last paragraph), the teaching of D4 is to suture the leaflets to the attachment flanges - with or without assembly holes. That the sutures 120 can not simply be omitted becomes apparent from the teaching of paragraph [0084]. Therein it is disclosed that "*the construction shown in figure 10*" - with sutures 120 - "*causes tensile forces imparted by the leaflets 52 to be transferred as much as possible from the sutures 120, 122 to the frame 72, thus helping to prevent tearing of the flexible leaflets and rendering the valve 22 more durable.*"

The appellant acknowledged that omitting the disputed sutures 120 results in a less robust attachment. The Board is not convinced that the person skilled in the technical field of prosthetic

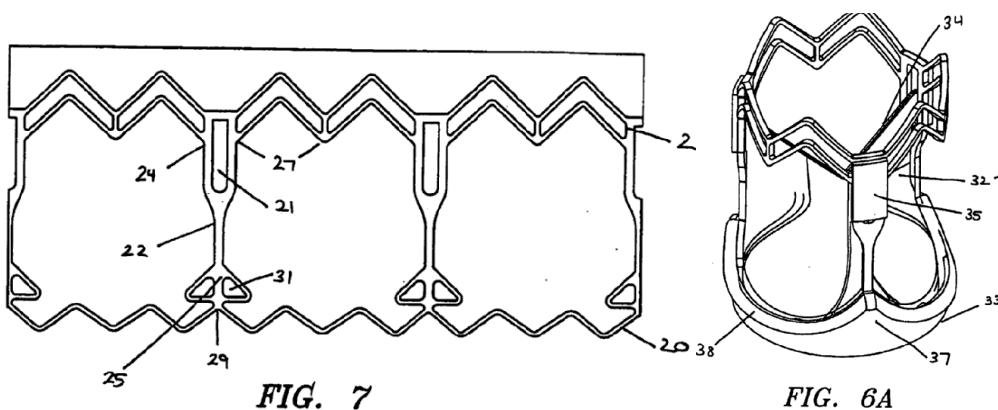
heart valves would take the risk of a less robust attachment at the commissure region, in particular as paragraph [0084] explicitly describes that the sutures 120 help to prevent tearing of the flexible leaflets.

- (b) The teaching of D4 as described in previous sub-point (a) is not changed when considering the common general knowledge. Notwithstanding the fact that D11 and D13 are both patent literature and therefore can not provide evidence of common general knowledge, it can be agreed that the skilled person knows that specific solutions for the attachment at the commissure region exist wherein the leaflets are not directly sutured to vertical struts. However, these specific solutions are part of an overall solution for a prosthetic heart valve disclosed together with a specific frame structure (see e.g. D11, figures 6 and 10; D13, figure 4), a specific method of implantation (see e.g. D13, surgical method with connecting band 42 sewed to the aortic wall) and/or specific means for attachment (D11, insert 166, see figures 7 and 11; D13, connecting band 42, figure 9). The skilled person would not simply pick, from their common general knowledge, a single feature that is only applied under specific circumstances, and implement it to the prosthetic valve of D4. This line of argumentation is based on hindsight.
- (c) The combination of D4 with the teaching of D5 does not result in the claimed subject-matter as also D5 does not disclose feature 7.

D5 discloses in figure 5 and figure 7 (reproduced below) a frame with vertical struts that define an

opening ("*axially extending slots 21*"). The leaflets are secured via commissural tabs 35 (figure 6A, reproduced below) that are threaded through the openings 21 (paragraph [0104]). No further details are provided in D5 with regard to this attachment. Therefrom it can not be concluded that D5 teaches to not directly suture the leaflets to the vertical struts.

Furthermore, the skilled person would not even consider D5, as D5 does not disclose a solution to the problem posed. D5 does not disclose an alternative attachment at the commissures in such manner that it could be implemented in the prosthetic valve of D4.



Even if D5, figure 7, may prompt the skilled person to apply the teaching of D4, paragraph [0082], in a way that the assembly holes are omitted, the skilled person is not hinted to additionally omit in D4 the disputed suture 120. D5 only discloses a directly sutured leaflet assembly. This becomes apparent from paragraph [0106] describing that the leaflet assembly is positioned in the frame with only "*the fabric of the commissural mounting tabs (35) of the valve (32) contacting the support posts (22) at the distal outflow annulus of the valve*". Consequently the leaflet assembly is in direct

contact with the struts. As argued by the opponent themselves with regard to the disclosure of D4, such an arrangement is excluded by feature 7 (see points 6.1.1 and 6.1.2 above).

- (d) While the prosthetic valve disclosed in D4 is not combinable with the teaching of D13, the passages of D12 or D14 cited by the appellant do not hint to feature 7.

The skilled person is aware that the attachment at the commissure region requires increased attention with regard to abrasion and durability. D4 provides a specific solution to this aspect (see paragraph [0084] as mentioned herein above in sub-point (a), figure 10).

The cited passages of D12 does not add anything different to D4 as what the skilled person anyway already knows with regard to the problems at the commissure region.

D14 summarizes the same problems (column 1, lines 34 to 41) and provides its own specific solution. As explained in sub-point (b), also this specific solution is part of an overall solution for a prosthetic heart valve. This solution requires specific attachment means (see figure 12, valve leaflet support 49). Therefrom the skilled person does not get any hint to omit the direct sutures 120 of the specific attachment disclosed in D4. With regard to D13, reference is made to sub-point (b).

- (e) D10, page 17, indeed discloses that the valve assembly can be attached to the support stent in different ways, not necessarily by sewing. However, the skilled person knows that several means for the

attachment exits. Nevertheless, also D10 only discloses a direct attachment such that the leaflets are in direct contact with the struts, be it by sewing, pinning, adhering, etc. Thus also D10 does not teach to omit the suture 120. The skilled person does not get any incentive from D10 to deviate from the embodiment of D4, figure 10.

9.2.6 Hence, the claimed subject-matter involves an inventive step in view of D4 alone, combined with common general knowledge or any of the cited prior art.

9.3 D5 as closest prior art

9.3.1 Claim 1 differs from D5 at least in features 5 to 7.

9.3.2 Feature 6 was acknowledged by the appellant as not being explicitly disclosed in D5. With regard to feature 7, reference is made to point 9.2.5 (c) above. Concerning feature 5, it was argued that the commissure tab 35 constituted a cloth portion positioned radially outward of the frame.

However, the commissure tabs 35 are part of the leaflets and not an additional cloth sutured to the leaflet portions that extends radially outside of the frame. This becomes apparent from paragraph [0106] ("*commissural mounting tabs (35) of the valve (32)*", the term "valve" being used for the leaflet assembly) and corresponds to what a skilled person understands from the term "commissure tab" (see e.g. D4, figure 7, tabs 100). Feature 5 is thus not disclosed in D5.

9.3.3 According to the appellant, the objective technical problem was to attach the leaflets at the commissure and thereby reduce stress on the leaflets. D5 itself

taught in paragraph [0011], that securing into position should be possible with minimal suturing and in paragraph [0106], that the leaflets should avoid any contact with the frame. The skilled person would thus look for an attachment that met these objectives.

D4 disclosed in figure 10 an appropriate attachment including features 5 and 6. An attachment without assembly holes 108 was described in paragraph [0082]. Also D13, figure 9, taught an appropriate attachment for the leaflets including features 5 and 6.

- 9.3.4 The Board is not convinced. The teaching of D5 with regard to the embodiment shown in figures 5, 6A and 7, is to provide a valve assembly "*in which there is minimal or no contact between the valve and anchoring structure.*" (paragraphs [0015], [0106]). To achieve this goal, D5 proposes a specific frame design without any lattice structure between the outflow rim 23 and the inflow rim 20. The leaflet assembly is directly secured to the frame.

Even if, inspired by D4, figure 10, or D10, figure 9, the skilled person may consider to implement a second and a third cloth that wrap around the vertical struts forming the opening 21 to avoid direct contact to the commissure tabs of the leaflet assembly, it is not obvious to additionally provide a cloth portion that is positioned radially outward of the frame as required by feature 5.

- (a) Combined with D4

In D4, the panel of fabric 54 which covers the complete outer frame (see figure 6B and paragraph [0066]) was seen by the appellant as being the

cloth portion that is positioned radially outward of the frame (D4, figure 10). However, contrary to the appellant's opinion, such an outer cloth is not applicable to the prosthetic valve disclosed in D5.

Applying a panel of fabric as disclosed in D4 to the prosthetic valve of D5 would contradict the teaching of D5. D5 already discloses a cloth positioned radially outwards of the frame ("*sewing cuff rings 37, 38*") which is presented as being advantageous for the specific frame structure (paragraphs [0105], [0106], figure 6B). However, this cloth only covers the inflow rim 20 of the frame and avoids there contact of the leaflet assembly with the frame.

An additional cloth at the outflow (upper) rim would not provide any additional benefit as according to paragraph [0106], "*with only the fabric of the commissural mounting tabs (35) of the valve (32) contacting the support posts (22) at the distal outflow annulus of the valve (34)*", and with the lower edge of the valve being "*separated from the inflow rim (20) of the anchoring structure by the sewing cloth (37)*," it is ensured "*that no part of the valve (32) is contacted by the anchoring structure during operation of the valve (32), thereby eliminating wear on the valve (32) that may be occasioned by contact with mechanical elements.*"

(b) Combined with D13

In D13, the connecting band 42 which is sewed to the aortic wall was seen by the appellant as being the cloth portion that is positioned radially outward of the frame (figure 9). However, according to D5, paragraph [0011] - which, contrary to the

appellant's argumentation, is not directed to the attachment of the leaflets at the commissures - this document aims to secure the prosthetic valve assembly into position at the implantation site with minimal or no suturing. D5 thus explicitly wants to avoid or minimize suturing of a connecting band to the aortic wall (paragraph [0008]) and proposes therefore sewing cuff rings 37, 38 (paragraph [0117], figure 6B). These cuff rings only cover the inflow rim (paragraph [0105], figure 6A). It would thus be contrary to the teaching of D5 to implement the connecting band 42 of D13.

9.3.5 The claimed subject-matter involves thus an inventive step in view of D5 combined with D4 or D13.

9.4 D13 as closest prior art

9.4.1 Claim 1 differs from D13 in feature 1 implying a percutaneous implantation of the prosthetic valve (see point 7 above).

9.4.2 The appellant formulated the objective technical problem as providing a valve that can navigate through the narrow passages of a patient's vasculature to the treatment site.

The skilled person would be prompted to use Nitinol for the frame by D13, paragraph [0061], thereby arriving at the claimed subject-matter.

9.4.3 The Board does not agree for the reasons given under point 7.2 and 7.5 above. Even if the skilled person would make the frame of D13 from Nitinol motivated by D13 alone or by the common general knowledge, the prosthetic valve of D13 is not suitable for percutaneous implantation because the connecting band

42 needs to be sewed to the aortic wall to fix the valve in position (D13, e.g. paragraphs [0069] and [0076]).

9.4.4 The claimed subject-matter involves thus an inventive step when starting from D13.

10. Adaptation of the description

10.1 The description of the patent as granted forms a suitable basis for the maintenance of the patent in amended form. No amendments are necessary to bring the description into conformity with the claims of the main request on file.

10.2 The appellant was of the opinion that paragraph [0012] was not in conformity with claim 1 as e.g. features 5 and 6 were still described as being optional.

10.3 However, the requested amendments are not caused by amendments made to claim 1 during opposition or appeal proceedings. All features mentioned as optional in paragraph [0012] were already in claim 1 as granted. The requested amendment would therefore contravene Rule 80 EPC, as submitted by the respondent, as they would not be occasioned by a ground for opposition under Article 100 EPC.

Order

For these reasons it is decided that:

1. The intervention is rejected as inadmissible.
2. The decision under appeal is set aside.

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

Description:

Paragraphs 1-54 of the patent specification

Claims:

No. 1 - 6 according to the auxiliary request 6'' filed with letter of 24 May 2024

Drawings:

Figures 1-17 of the patent specification

The Registrar:

The Chairman:



M. Schalow

G. Pricolo

Decision electronically authenticated