Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 12 June 2026

Case Number: T 1328/24 - 3.2.02

Application Number: 17837573.9

Publication Number: 3490501

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
PROSTHETIC HEART VALVE

Patent Proprietor:
Edwards Lifesciences Corporation

Opponent:
Boston Scientific Corporation

Relevant legal provisions:
EPC Art. 54(2), 54(3), 56
RPBA 2020 Art. 13(2)

Keyword:
Novelty
Inventive step
Amendment after summons

This datasheet is not part of the Decision
It can be changed at any time and without notice

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 1328/24 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 June 2026

Appellant: (Patent Proprietor)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Appellant: (Opponent)	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752-1234 (US)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Straße 3 80331 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted/ electronically transmitted on 12 September 2024 concerning maintenance of the European Patent No. 3490501 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. Both the patent proprietor and the opponent appealed against the opposition division's interlocutory decision finding that the contested patent as amended on the basis of the request then on file as auxiliary request 3 complied with the requirements of the EPC.

II. Oral proceedings before the Board were held on 12 June 2026, at the end of which the present decision was announced.

III. The **appellants' final requests** at the end of the oral proceedings were as follows.

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, as an auxiliary measure, that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 27, with:
- auxiliary requests 1 to 6 as filed with the patent proprietor's statement of grounds of appeal
- auxiliary requests 7 to 10, 12 and 14 to 27 as filed with the patent proprietor's reply to the opponent's statement of grounds of appeal
- auxiliary requests 11 and 13 as filed at the oral proceedings before the Board

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

IV. The present decision refers to the following documents, which were cited in the decision under appeal:

D2 WO 2017/035487 A1

D3 WO 2014/139545 A1
D4 WO 2012/032187 A1
D7 WO 2012/177942 A2
D9 WO 2005/062980 A2

It also refers to the following documents, which were filed by the opponent with its statement of grounds of appeal:

D11 WO 98/29057 A1
D12 WO 2010/008548 A9
D13 WO 2009/024859 A2

It also refers to the following patent application, from which the contested patent claims priority:

P1a US patent application 62/369,678

V. Claim 1 of the **main request** is claim 1 as granted and reads as follows (using the feature numbering adopted by the parties in the appeal proceedings):

F0 "*A prosthetic heart valve (10; 600; 700; 800; 1100) comprising:*

F1 *an annular frame (12) comprising an inflow end (26) and an outflow end (28) and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, wherein the frame (12) comprises a plurality of struts (22) defining openings (24);*

F2 *a valvular structure (14) mounted within the frame (12) and comprising*

F2.1 *a plurality of leaflets (20) that regulate the flow of blood through the frame (12),*

F2.2 *wherein each leaflet (20) comprises an inflow surface, an outflow surface, and a cusp edge portion (816; 1116) that is fixed relative to the frame (12);*

F3 *a sealing member (16; 602; 702; 802) mounted on the frame (12) and comprising*

F3.1 *an inner layer (34; 604; 704; 804) and*

F3.2 *an outer layer (36; 606; 706; 806), wherein at least the outer layer (36; 606; 706; 806) is mounted on the outside of the frame (12), and*

F3.3 *the inner layer (34; 604; 704; 804) covers at least the openings (24) in the frame (12) between adjacent cusp edge portions of adjacent leaflets (20) and*

F3.4 *the inner layer (34; 604; 704; 804) does not cover one or more openings (24) in the frame (12) at locations facing the outflow surfaces of the leaflets (20) to permit retrograde blood to flow through the one or more uncovered openings (24) in the frame (12) and into space between the outer layer (36; 606; 706; 806) and the frame (12);*

characterized in that

F3.5(i) *(i) the inner layer does not cover any openings in the frame at locations facing the outflow surfaces of the leaflets;*

F3.5(ii) *(ii) the inner layer is formed with one or more openings along the portions of the inner layer that face the outflow surface of the leaflets to allow retrograde blood to flow through the frame at those locations; or*

F3.5(iii) *(iii) the inner layer is formed from a porous material that allows blood to flow through the inner layer and the inner layer is formed from a relatively more porous material than the outer layer.*"

VI. Claim 1 of each of **auxiliary requests 1 to 13** is based on claim 1 as granted and includes one or more of the following amendments A1, B1 to B4, C1 and E, as shown in the table below:

A1: feature F3.5(iii) is amended by adding the requirement that "*the inner layer does not have any of said openings (42)*" and, except in auxiliary request 2, the reference sign "*(42)*" is added after the term "openings" in feature F3.5(ii)

B1: feature F3.5(i) is amended by adding the requirement that "*the inner layer (34; 604; 704; 804) of the sealing member (16; 602; 702; 802) comprises a plurality of triangular shaped portions (608; 708; 808) that are mounted on the frame (12) at locations between adjacent cusp edge portions (816; 1116) of adjacent leaflets (20)*"

B2: feature F3.5(i) is amended by adding the requirement that "*the cusp edge portions (816; 1116) of the leaflets (20) have a curved, scalloped shape*"

B3: feature F3.5(i) is amended by adding the requirements that "*the inner layer (604) is mounted inside of the frame (12)*" and "*the outer layer (606) is secured along its upper edge portion to the struts on the outside of the frame (12)*"

B4: feature F3.5(i) is amended by adding the requirement that "*the outer layer (606) is wrapped around the inflow end (26) of the frame (12)*"

C1: feature F0 is amended by adding the requirement that the valve is "*for implantation in the native aortic valve*"

E: features F3.5(ii) and F3.5(iii), together with the designation "*(i)*" in feature F3.5(i), are deleted

Auxiliary request no.	**A1**	**B1**	**B2**	**B3**	**B4**	**C1**	**E**
1	x						
2	x	x					
3	x	x	x				
4	x			x			
5	x	x	x	x			
6	x	x	x	x	x		
7						x	
8	x					x	
9	x	x				x	
10	x	x	x			x	
11				x		x	x
12	x	x	x	x		x	
13		x	x	x	x	x	x

VII. The **patent proprietor's arguments** relevant to the present decision can be summarised as follows.

Main request and auxiliary requests 1 to 6 - second alternative - novelty in view of D7

The second alternative defined in claim 1 as granted and claim 1 of auxiliary requests 1 to 6 was novel in view of D7. D7 failed to disclose that the prosthetic valve device disclosed in Figures 2F1-A and 2F1-B comprised features F3 to F3.4 and F3.5(ii).

The impermeable cover 151 and the sealing members 160A, 160B could not be regarded as the inner and outer layers of a sealing member as claimed, with the outer layer being mounted on the outside of the frame, particularly in view of the anchors 120, which were part of the support 110 identified by the opponent as the claimed frame.

Even if the impermeable cover 151 was regarded as the inner layer of a sealing member, D7 did not directly and unambiguously disclose that the openings disclosed in paragraph [00208] were provided in that cover and, if so, where they were located. The openings might well be provided in the areas between adjacent cusp edge portions of adjacent leaflets, or all over the cover.

Nor did D7 disclose the geometry or longitudinal position of the leaflets. They could be planar and orthogonal to the longitudinal axis, as suggested by Figure 2I, in which case their outflow surfaces would face an end of the support rather than its inner surface. D7 therefore did not disclose locations of the frame facing the outflow surfaces of the leaflets as required by features F3.4 and F3.5(ii).

Auxiliary requests 7 to 10 - second alternative - lack of inventive step starting from D7

The second alternative defined in claim 1 of auxiliary requests 7 to 10 was novel in view of D7 and, in any event, inventive starting from that document.

The valve of Figures 2F1-A and 2F1-B was specifically designed for replacement of the native mitral valve and was therefore not suitable for implantation in the native aortic valve as required by amendment C1.

In any event, although the devices of Figures 2I and 2J were intended for the aortic valve, D7 did not describe their constructions in sufficient detail, let alone that their constructions were similar. The statement in D7 that the shape, size, stiffness and other aspects of the support and arms disclosed for mitral-valve embodiments could be adapted for the aortic valve did not provide the missing features or prompt the person skilled in the art to transfer them from the embodiment of Figures 2F1-A and 2F1-B. The person skilled in the art starting from Figure 2J would therefore not have arrived at the claimed subject-matter without inventive skill or hindsight.

Auxiliary request 11 - admittance

Auxiliary request 11 should be admitted into the appeal proceedings. The new request streamlined the case by deleting the second and third alternatives, both of which had been challenged, and confined the discussion to the first alternative. Moreover, the Board's finding during the preceding discussion of auxiliary request 7 that amendment C1 rendered the first alternative novel over D2, which departed from the Board's preliminary opinion expressed in the communication under Article 15(1) RPBA, applied similarly to claim 1 of

auxiliary request 11, which likewise contained amendment C1.

Auxiliary request 12 - second alternative - lack of inventive step starting from D7

The second alternative defined in claim 1 of auxiliary request 12 was novel in view of D7 and, in any event, inventive starting from that document, for the same reasons as claim 1 of auxiliary request 7.

Auxiliary request 13

Admittance

Auxiliary request 13 should be admitted into the proceedings. The arguments put forward in connection with auxiliary request 11 likewise applied to auxiliary request 13. Furthermore, the further amendment B4 *prima facie* overcame the inventive-step objection based on D4 in combination with D3. Auxiliary request 13 was therefore *prima facie* allowable and was an appropriate reaction to the Board's departure from its preliminary opinion as to the novelty of the first alternative in view of D2.

Novelty in view of D2

The subject-matter of claim 1 of auxiliary request 13 was indeed novel in view of D2. The general statements in D2 that the concepts disclosed in that document could be applied to the aortic valve did not amount to a direct and unambiguous disclosure that the specific wrapped-liner embodiment of paragraph [0084] was, without further modification, itself suitable for

implantation in the native aortic valve, as required by amendment C1.

Inventive step starting from D4

The subject-matter of claim 1 of auxiliary request 13 involved an inventive step starting from D4, even when combined with D3. D4 and D3 both directed the person skilled in the art towards limiting the amount and thickness of skirt material at the inflow end so as to facilitate crimping. A wrap-around configuration as defined by amendment B4 would add material precisely at that location and was therefore contrary to the teachings of D4 and D3. The person skilled in the art starting from D4 would therefore not have arrived at the subject-matter of claim 1 without inventive skill or hindsight.

D11 to D13 should, in any event, not be admitted into the appeal proceedings.

VIII. The **opponent's arguments** relevant to the present decision can be summarised as follows.

Main request and auxiliary requests 1 to 6 - second alternative - novelty in view of D7

The subject-matter of claim 1 as granted lacked novelty in view of the prosthetic heart valve disclosed in Figures 2F1-A and 2F1-B of D7. Although the openings disclosed in paragraph [00208] were not visible in those figures, the person skilled in the art directly and unambiguously derived from the document that the prosthetic heart valve disclosed in those figures fell within the second alternative defined in claim 1.

The same reasoning applied to auxiliary requests 1 to 6. In any event, auxiliary requests 2 and 4 should not be admitted into the appeal proceedings.

Auxiliary requests 7 to 10 - second alternative - lack of inventive step starting from D7

The second alternative defined in claim 1 of auxiliary request 7 was, in any event, not inventive starting from the aortic-valve embodiment of Figure 2J of D7. That embodiment was indeed structurally and functionally similar not only to the other aortic-valve embodiment of Figure 2I, but also to the more detailed embodiment of Figures 2F1-A and 2F1-B. When putting the valve of Figure 2J into practice and seeking to improve its paravalvular sealing, the person skilled in the art would therefore have obviously applied the teaching relating to the valve of Figures 2F1-A and 2F1-B by providing an impermeable inner cover and openings through that cover and the support to further pressurise the outer sealing members. This was also consistent with the general teaching of D7 that features described in relation to the mitral valve could also be applied to the aortic valve. The resulting valve would fall within the second alternative claimed, including the further limitation introduced by amendment C1.

Auxiliary requests 8 to 10 should not be admitted into the appeal proceedings. In any event, the same reasoning as for auxiliary request 7 likewise applied to those requests.

Auxiliary request 11 - admittance

Auxiliary request 11 should not be admitted at that late stage of the proceedings. In particular, claim 1 of that request was *prima facie* not inventive starting from D4 in combination with D3, as expressed in the Board's communication under Article 15(1) RPBA.

Auxiliary request 12 - second alternative - lack of inventive step starting from D7

Auxiliary request 12 should not be admitted into the appeal proceedings. The subject-matter of claim 1 of auxiliary request 12 was, in any event, not inventive starting from D7 for the same reasons as claim 1 of auxiliary request 7.

Auxiliary request 13

Admittance

Auxiliary request 13 should not be admitted at that late stage of the proceedings. In particular, claim 1 of that request was also *prima facie* unallowable since the novelty objection based on D2 and the inventive-step objection based on D4 in combination with D3 raised against claim 1 as granted remained *prima facie* applicable. Indeed, D2 *prima facie* disclosed the first alternative including amendment C1, while D4 in combination with D3 and the fact that the use of skirts wrapped around the inflow end of a frame was well-known rendered the claimed subject-matter *prima facie* obvious.

Novelty in view of D2

The subject-matter of claim 1 of auxiliary request 13 lacked novelty in view of the alternative embodiment

described in paragraph [0084] of D2, which disclosed a prosthetic heart valve as shown in Figure 3 with the additional limitation defined by amendment B4.

D2 concerned replacement heart valves generally and did not limit the embodiment of Figure 3 to mitral-valve replacement. Paragraph [0078] presented the native mitral valve merely as an example, while paragraph [0041] expressly stated that the disclosed features and concepts could be applied to other valves, including the aortic valve. The embodiment of paragraph [0084] was therefore also disclosed as being suitable for implantation in the native aortic valve, therefore satisfying amendment C1.

Inventive step starting from D4

The subject-matter of claim 1 of auxiliary request 13 did not involve an inventive step starting from D4 in combination with D3.

The subject-matter of claim 1 differed from the prosthetic heart valve disclosed in Figure 1 of D4 in that (a) retrograde blood could flow through uncovered frame openings into a space between the outer skirt and the frame and (b) the outer layer was wrapped around the inflow end of the frame and secured along its upper edge to outer frame struts.

As described in paragraph [0034] of the contested patent, difference (a) improved paravalvular sealing. Difference (b) was a well-known and straightforward design measure, as illustrated, for example, in D2, D9 and D11 to D13. The objective technical problem to be solved starting from D4 could therefore be formulated as being to improve paravalvular sealing.

Starting from D4 and faced with this technical problem, the person skilled in the art would have obviously consulted D3, which disclosed a closely similar valve and also addressed the same problem. In that regard, D3 disclosed the formation of an outer pocket capable of distending under retrograde blood flow by extending the outer skirt towards the outflow end and, where appropriate, securing its upper edge to the outer frame struts. Applying that teaching to D4 would have provided the pocket and flow arrangement defined in claim 1.

Providing, additionally, the outer skirt as a skirt wrapped around the inflow end of the frame was a well-known and straightforward design measure. Combining that measure with the pocket taught by D3 would have led to the subject-matter of claim 1 of auxiliary request 13 without inventive skill.

Further objections

The opponent confirmed at the oral proceedings before the Board that it had no further objections against auxiliary request 13.

Reasons for the Decision

1. Subject-matter of the contested patent

1.1 The contested patent concerns a prosthetic heart valve aimed at reducing paravalvular leakage, as defined in claim 1 as granted.

As illustrated, *inter alia*, in Figures 1A, 3 and 4, reproduced below, the valve (10) comprises:

- a radially collapsible and expandable annular frame (12) having an inflow end (26), an outflow end (28) and a plurality of struts (22) defining openings (24);

- a valvular structure (14) mounted within the frame and comprising leaflets (20) that regulate blood flow through the frame, each leaflet comprising an inflow surface, an outflow surface and a cusp edge portion fixed relative to the frame; and

- a sealing member (16) comprising an inner layer (34) and an outer layer (36), at least the outer layer being mounted on the outside of the frame.

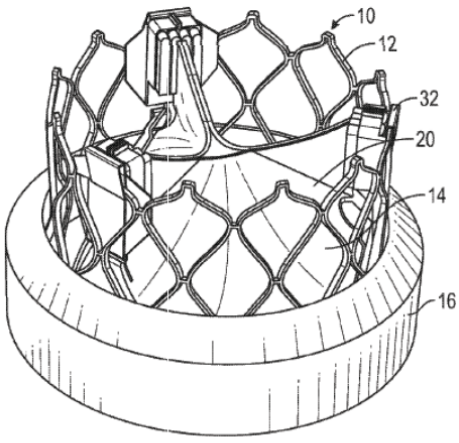


FIG. 1A

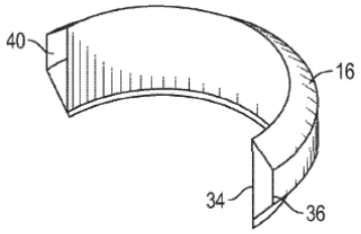


FIG. 3

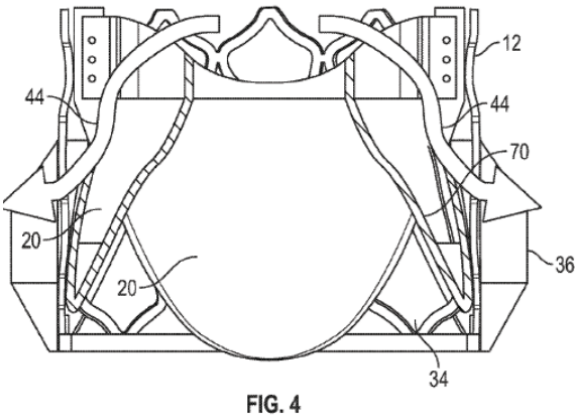


FIG. 4

1.2 Claim 1 as granted requires that the inner layer cover at least the openings in the frame between adjacent cusp edge portions of adjacent leaflets (feature F3.3), but not one or more openings in the frame at locations facing the outflow surfaces of the leaflets to permit

retrograde blood (44) to flow through the one or more uncovered openings into the space (40) between the outer layer and the frame (feature F3.4). As explained in paragraph [0034], this facilitates the outward expansion of the sealing member against the surrounding tissue, thereby improving the peripheral seal.

1.3 Claim 1 as granted requires one of three alternative configurations for enabling the retrograde blood flow:

- first alternative, feature F3.5(i): the inner layer (602) does not cover any openings in the frame at locations facing the outflow surfaces of the leaflets, as shown in Figures 58 and 59, reproduced below:

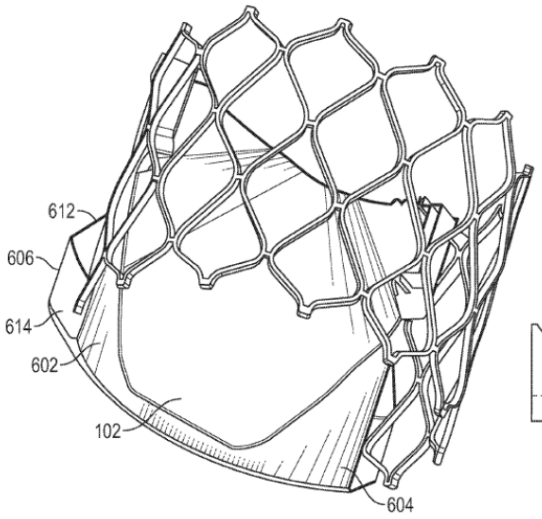


FIG. 58

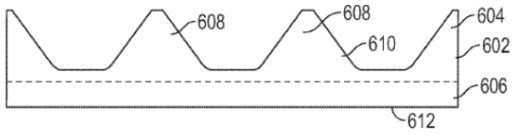


FIG. 59

- second alternative, feature F3.5(ii): the inner layer is formed with one or more openings (42) along the portions of the inner layer (34) that face the outflow surfaces of the leaflets to allow retrograde blood to flow through the frame at those locations, as shown in Figure 5, reproduced below (see paragraph [0034]):

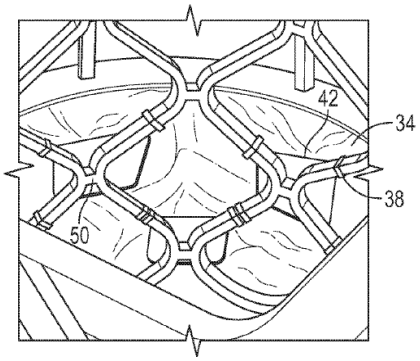


FIG. 5

- third alternative, feature F3.5(iii): the inner layer is formed from a porous material that allows blood to flow through the inner layer and the inner layer is formed from a relatively more porous material than the outer layer (see paragraph [0038])

2. Main request and auxiliary request 1 to 6 - second alternative - novelty in view of D7

2.1 The Board, in confirmation of the preliminary opinion expressed in point 4.2 of its communication under Article 15(1) RPBA, agrees with the opponent that D7 discloses a prosthetic heart valve falling within the second alternative defined in claim 1 as granted.

Accordingly, the subject-matter of claim 1 as granted, i.e. claim 1 of the main request, is not novel in view of D7.

2.2 It is common ground that D7 discloses, in Figures 2F1-A and 2F1-B, both reproduced below, a prosthetic heart valve 100 comprising an annular frame 110 ("support") having an inflow end and an outflow end, and a valvular structure 150 ("valve") mounted within the frame and comprising a plurality of leaflets that regulate the flow of blood through the frame.

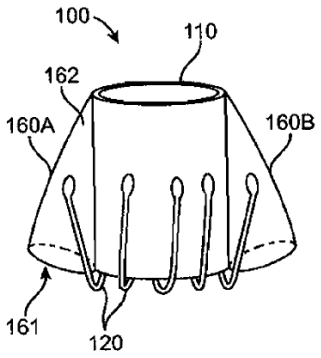


FIG. 2F1-A

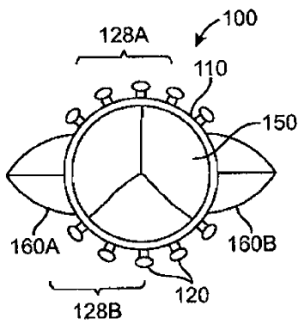


FIG. 2F1-B

By virtue of their function, each of the leaflets has an inflow surface and an outflow surface. In addition, as apparent from Figure 2F1-B, each leaflet has a peripheral cusp edge portion. Since the valvular structure 150 is mounted within the frame 110 and performs the valve function disclosed in D7, the person skilled in the art understands that the peripheral cusp edge portion is implicitly fixed relative to the annular frame 110.

Furthermore, as disclosed in paragraph [00148] and shown, for example, in Figure 2A1, the frame 110 comprises an expandable skeleton 140 formed by a plurality of struts defining openings, and is radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration.

The prosthetic heart valve 100 therefore comprises features F0 to F2.2 of claim 1 as granted. This assessment was not disputed by the patent proprietor.

2.3 The Board agrees with the opponent that the prosthetic heart valve 100 further comprises features F3 to F3.4 and F3.5(ii) and therefore anticipates the second alternative defined in claim 1 as granted. The patent

proprietor's arguments to the contrary are not persuasive.

2.3.1 As described in paragraph [00206], in some embodiments the prosthetic heart valve 100 comprises an impermeable cover 151 disposed on an inner surface of the support 110 so as to prevent blood from flowing from inside the support, through its wall, to the outside of the support, where it could leak. This impermeable cover corresponds to the "covering" disclosed in paragraph [00148] as being disposed, in some embodiments, around the interior wall of the skeleton 140 to block blood flow through the openings defined by the skeleton. By covering these openings, the impermeable cover 151 performs a sealing function.

In addition, as shown in Figures 2F1-A and 2F1-B and described in paragraph [00208], the prosthetic heart valve 100, suitable for mitral replacement, comprises two sealing members 160A, 160B mounted on the outside of the support 110 and configured to be positioned adjacent to the commissures of the native mitral valve. During systole, i.e. when the leaflets are closed and their outflow surfaces are exposed to blood tending to flow in the retrograde (upstream) direction from the left ventricle towards the left atrium, blood is pushed under pressure through the open downstream ends 161 of the sealing members, thereby inflating them and urging them against the native leaflets, and thus enhancing the paravalvular seal.

The Board agrees with the opponent that the inner cover 151 and the outer sealing members 160A, 160B, in combination, constitute a sealing member as defined in features F3 to F3.2, comprising an inner layer and an outer layer, with at least the outer layer being

mounted on the outside of the frame. Claim 1 as granted does not require the sealing member to be of unitary construction. Nor does it exclude additional components, such as the anchors 120, from being coupled to the exterior surface of the annular frame. Therefore, contrary to the patent proprietor's argument, the presence of those anchors does not affect the identification of the inner cover 151 and the outer sealing members 160A, 160B as the claimed inner and outer layers.

2.3.2 D7 further discloses, in the final sentence of paragraph [00208], that openings, not shown in Figures 2F1-A and 2F1-B, may optionally be "provided" between the interior of the sealing members 160A, 160B and the interior of the support 110 to allow blood to flow from within the support into the interior of the sealing members "to further pressurize them". This additional pressurisation supplements the pressurisation already produced, as explained above, by blood entering the sealing members through their open downstream ends 161 during systole.

Contrary to the patent proprietor's argument, the person skilled in the art understands that in the considered embodiment, in which the inner surface of the support 110 is covered with the impermeable cover 151, providing the optional fluid communication between the interior of the support and the interiors of the sealing members necessarily requires providing openings in the impermeable cover 151. Moreover, these openings must be aligned with corresponding openings provided in the support wall, such as openings defined by the skeleton 140, so that the cover leaves those frame openings uncovered. Otherwise, blood could not flow

from the interior of the support 110 into the sealing members 160A, 160B.

Furthermore, since the stated purpose of the optional openings is to "further pressurize" the sealing members during systole, the person skilled in the art understands that these openings must communicate with the ventricular compartment on the outflow side of the valvular structure. The openings in the impermeable cover 151 are therefore necessarily located in the region of the cover exposed to the retrograde pressure acting on the outflow surfaces of the leaflets when the latter are closed, i.e. along the portions of the cover that face the outflow surfaces of the leaflets. Thus, during systole, retrograde blood can flow from the interior of the support 110, through the openings in the cover and the corresponding openings in the support wall, and into the sealing members 160A, 160B, thereby further pressurising them and improving the paravalvular sealing as described.

Conversely, the person skilled in the art understands that the openings in the impermeable cover 151 are confined to the above-mentioned region and that the cover remains uninterrupted in the other regions of the frame, including the regions between adjacent cusp edge portions of adjacent leaflets. Providing openings in those other regions would allow blood to pass through the support wall without contributing to the described pressurisation of the sealing members during systole and would be inconsistent with the stated purpose of the impermeable cover to generally prevent blood from flowing from the inside of the support to the outside of the support.

2.3.3 At the oral proceedings before the Board, the patent proprietor contended that D7 did not disclose the geometry of the leaflets, in particular whether they had a "volcano" shape, or their position along the longitudinal axis of the support. According to the patent proprietor, the leaflets might well be planar and orthogonal to the longitudinal axis of the prosthetic valve, as shown in Figure 2I for a similar prosthetic valve. In such a case, their outflow surfaces would face an end of the support, not the inner surface of the frame. D7 therefore did not disclose directly and unambiguously locations of the frame facing the outflow surfaces of the leaflets, as required by features F3.4 and F3.5(ii).

This argument is not persuasive. As argued by the opponent, the leaflets cannot be strictly planar. They necessarily have a non-zero extent in the longitudinal direction between their fixed cusp edge portions and their free coaptation edges. Consequently, their outflow surfaces, considered as a whole, extend obliquely relative to the longitudinal axis of the prosthetic heart valve and thus face the inner surface of the support 110 located on the outflow side of the valvular structure. Conversely, the locations of the support on that side of the valvular structure face the outflow surfaces of the leaflets within the meaning of features F3.4 and F3.5(ii). These features do not require the openings to be positioned directly radially opposite, or in direct radial alignment with, the outflow surface of a leaflet.

The person skilled in the art thus derives directly and unambiguously from D7 that the impermeable cover 151 covers the frame openings between adjacent cusp edge portions of adjacent leaflets, but is provided with

openings in portions facing the outflow surfaces of the leaflets, thereby permitting retrograde blood to flow through the frame and into the space between the sealing members 160A, 160B and the frame. This embodiment of D7 therefore comprises features F3.3, F3.4 and F3.5(ii) and anticipates a prosthetic heart valve in accordance with the second alternative of claim 1 as granted.

2.4 Claim 1 of each of auxiliary requests 1 to 6 defines the second alternative in the same terms as claim 1 as granted. The addition, in some of those requests, of the reference sign "(42)" after the term "openings" in feature F3.5(ii) does not alter the claimed subject-matter. Consequently, the subject-matter of claim 1 of each of auxiliary requests 1 to 6 likewise lacks novelty in view of D7.

3. Auxiliary request 7 to 10 - second alternative - lack of inventive step starting from D7

3.1 As far as the second alternative is concerned, claim 1 of each of auxiliary requests 7 to 10 differs from claim 1 as granted only by virtue of amendment C1, according to which the claimed prosthetic heart valve is required to be "for implantation in the native aortic valve", i.e. suitable for this purpose.

3.2 The patent proprietor argued that this requirement was not met by the prosthetic valve device 100 disclosed in Figures 2F1-A and 2F1-B, which was instead specifically designed for mitral valve replacement (see paragraph [00208]).

3.3 Even if this argument is accepted, the Board agrees with the opponent that the limitation resulting from

amendment C1 does not, in any event, render the second alternative defined in claim 1 inventive when starting from D7.

3.4 It is common ground that D7 further discloses, in Figures 2I and 2J, both reproduced below, prosthetic heart valve devices explicitly described as suitable for treating the aortic valve (see the respective first sentence of paragraphs [00221] and [00223]).

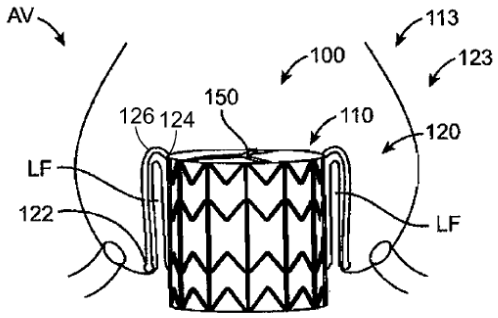


FIG. 2I

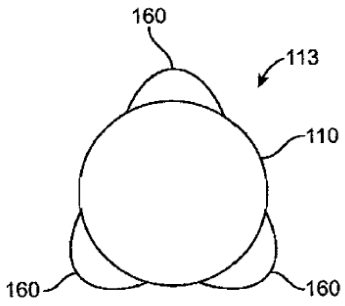


FIG. 2J

As argued by the opponent, the prosthetic heart valve of Figure 2J is similar to that of Figure 2I (see paragraph [00223]: "a prosthetic heart valve device (such as apparatus 100)"), hence likewise having a support 110 comprising an expandable skeleton formed by struts, these struts defining openings. In addition, the prosthetic heart valve of Figure 2J comprises sealing members 160 positioned around the support 110 and configured to extend into, over or under the aortic commissures so as to reduce the risk of paravalvular leaks (see paragraph [00223]).

It is true, as argued by the patent proprietor, that D7 does not describe in detail the construction of the prosthetic heart valves of Figures 2I and 2J. In particular, D7 merely states that "[t]he shape, size, stiffness, and other aspects of support 110 and arms

120 can be adapted as needed for the aortic valve" (paragraph [00221]). D7 is silent on the presence of an impermeable cover 151 and openings between the interior of the sealing members 160 and the interior of the support 110, as explicitly disclosed for the prosthetic heart valve of Figures 2F1-A and 2F1-B.

3.5 However, the prosthetic heart valves of Figures 2I and 2J are closely similar to that of Figures 2F1-A and 2F1-B, in terms of both structure and function. In particular, the support 110 likewise comprises an expandable skeleton comprising struts, these struts defining openings, and the sealing members 160 mounted on the outside of the support 110 as shown in Figure 2J serve the same purpose of improving paravalvular sealing as the sealing members 160A, 160B of Figures 2F1-A and 2F1-B.

3.6 In view of these similarities, the Board concurs with the opponent that the person skilled in the art, when putting the prosthetic heart valve device of Figure 2J into practice and seeking to further improve its paravalvular sealing, would have turned to the more detailed teaching of D7 relating to the embodiment of Figures 2F1-A and 2F1-B.

In accordance with that teaching, the person skilled in the art would have provided an impermeable cover 151 on the inner surface of the support 110 in order generally to seal the openings defined by the skeleton and prevent blood from flowing through the support wall. This would have been a straightforward way of completing the disclosure on the structure of the prosthetic heart valve of Figure 2J.

In addition, faced with the technical problem of further improving the paravalvular sealing provided by the sealing members 160, the person skilled in the art would have provided openings through the support 110 and the impermeable cover 151 to further pressurise the sealing members 160, as disclosed for the embodiment of Figures 2F1-A and 2F1-B.

As argued by the opponent, this reasoning is consistent with the general teaching of D7, for example in paragraphs [0003] and [00147], that, although particular embodiments of D7 may be described with reference to the mitral valve, the corresponding disclosure may likewise be applied to the aortic valve.

The person skilled in the art starting from the prosthetic heart valve of Figure 2J would thereby have arrived at a prosthetic heart valve falling within the second alternative of claim 1 of each of auxiliary requests 7 to 10 without exercising inventive skill. Claim 1 of each of auxiliary requests 7 to 10 therefore does not involve an inventive step starting from D7.

3.7 At the oral proceedings before the Board, the patent proprietor did not provide any further comment on auxiliary requests 8 to 10, but merely referred to its written submissions.

4. Auxiliary request 11 - admittance

4.1 Auxiliary request 11 was filed at the oral proceedings before the Board after the Board had concluded that the subject-matter of the first alternative of claim 1 of auxiliary request 7 was novel over D2. It replaced the previous version of auxiliary request 11 filed with the

patent proprietor's reply to the opponent's statement of grounds of appeal.

The new auxiliary request 11 differs from the earlier one in that the second and third alternatives have been deleted from claim 1. The first alternative remaining in claim 1 differs from the first alternative defined in claim 1 as granted by amendments B3 and C1.

4.2 Auxiliary request 11 constituted an amendment to the patent proprietor's appeal case, which, pursuant to Article 13(2) RPBA, shall, in principle, not be taken into account at such a late stage of the appeal proceedings, unless there are exceptional circumstances, justified with cogent reasons by the party concerned.

4.3 The patent proprietor argued that the new auxiliary request 11 streamlined the case by limiting claim 1 to the first alternative and deleting the second and third alternatives, both of which had been challenged by the opponent. It thereby confined the issues requiring discussion at the oral proceedings to the sole remaining first alternative.

The patent proprietor further relied on the discussion of auxiliary request 7 that had previously taken place at the oral proceedings. In the course of that discussion, the Board had found, departing from its preliminary opinion set out in its communication under Article 15(1) RPBA (see point 5.5), that the first alternative of claim 1 of that request was novel over D2 by virtue of amendment C1. The patent proprietor submitted that this finding meant that the subject-matter of claim 1 of auxiliary request 11, which also included amendment C1, was likewise novel over D2.

4.3.1 These considerations did not, however, justify taking auxiliary request 11 into account under Article 13(2) RPBA. Although the deletion of the second and third alternatives streamlined the case, the request was not *prima facie* allowable, as submitted by the opponent. The limitations defined by amendments B3 and C1 still appeared to the Board to be disclosed in D3 and in both D3 and D4, respectively, as set out in the communication under Article 15(1) RPBA (see points 5.3 and 5.5). Accordingly, as further indicated in the communication (see point 5), these amendments did not appear to overcome the inventive-step objection based on D4 in combination with D3 raised against the first alternative of claim 1 as granted (see point 4.4 of the communication). The patent proprietor did not make any further submissions on that issue when discussing the admittance of auxiliary request 11, and the Board saw no reason to depart from its preliminary opinion on that matter.

It followed that, notwithstanding the Board's finding at the oral proceedings on novelty over D2 in relation to auxiliary request 7, auxiliary request 11 was *prima facie* unallowable for lack of inventive step.

4.3.2 Consequently, the Board decided not to admit auxiliary request 11 into the appeal proceedings.

5. Auxiliary request 12 - second alternative - lack of inventive step starting from D7

5.1 As far as the second alternative defined in claim 1 is concerned, claim 1 of auxiliary request 12 differs from claim 1 of auxiliary request 7 only by the addition of the reference sign "(42)" after the term "openings" in

feature F3.5(ii). As stated above, this addition does not alter the substance of the claim.

Therefore, for the same reasons as set out in point 3. above for auxiliary request 7, the subject-matter of claim 1 of auxiliary request 12 likewise does not involve an inventive step starting from D7.

5.2 At the oral proceedings before the Board, the patent proprietor did not make any further comments on auxiliary request 12, but merely referred to its written submissions.

6. Auxiliary request 13

6.1 Admittance

6.1.1 Auxiliary request 13 was filed at the oral proceedings before the Board, after the Board had decided not to admit auxiliary request 11. It replaced the previous version of auxiliary request 13 filed with the patent proprietor's reply to the opponent's statement of grounds of appeal.

As with auxiliary request 11, the new auxiliary request 13 differs from the earlier one in that the second and third alternatives have been deleted from claim 1. The first alternative remaining in claim 1 differs from the first alternative defined in claim 1 as granted by virtue of amendments C1 and B1 to B4.

6.1.2 Like auxiliary request 11, auxiliary request 13 constituted an amendment to the patent proprietor's appeal case governed by Article 13(2) RPBA. For the following reasons, the Board decided to admit it into the appeal proceedings.

6.1.3 By limiting the scope of claim 1 to the first alternative defined therein, the deletion of claimed subject-matter carried out in the new auxiliary request 13 does not give rise to any new issue extending beyond those previously raised in respect of that alternative.

6.1.4 In addition, accepting the arguments presented by the patent proprietor at the oral proceedings, the Board considered that the combination of amendments C1 and B4 *prima facie* overcame all of the opponent's objections raised against that alternative and that auxiliary request 13 was therefore *prima facie* allowable. This conclusion differed from the Board's preliminary opinion set out in point 5, read in conjunction with points 5.4 and 5.5, of the communication under Article 15(1) RPBA.

Firstly, as put forward by the patent proprietor in support of the admittance of auxiliary request 11, the Board had previously concluded, following the debate on auxiliary request 7 at the oral proceedings, that the first alternative of claim 1 including the further limitation defined by amendment C1 was novel over D2, thereby departing from the preliminary opinion expressed in point 5.5 of the communication under Article 15(1) RPBA. This was because D2 concerns prosthetic heart valves in general but does not disclose directly and unambiguously a prosthetic heart valve both satisfying the first alternative and being suitable for implantation in the native aortic valve. It followed that amendment C1 likewise rendered the subject-matter of claim 1 of auxiliary request 13 *prima facie* novel in view of D2.

Secondly, a sealing member having an outer layer wrapped around the inflow end of the frame, as defined by amendment B4, is disclosed neither in D3 nor in D4. Therefore, even if the person skilled in the art were to combine D4 with D3 as set out in point 4.4 of the Board's communication under Article 15(1) RPBA, they would not arrive at the subject-matter of claim 1 of auxiliary request 13. Arriving at that subject-matter would still require the additional step of wrapping the outer layer around the inflow end of the frame. However, as convincingly argued by the patent proprietor during the oral proceedings, the person skilled in the art would *prima facie* not have considered implementing such a modification without the benefit of hindsight. It followed that the subject-matter of claim 1 of auxiliary request 13 was *prima facie* inventive starting from D4.

Thirdly, the Board considered that the priority claimed from P1a by the contested patent - which had been found to be valid for the first alternative of claim 1 as granted, as set out in point 4.3.1 of the communication under Article 15(1) RPBA - was also *prima facie* valid for the subject-matter of claim 1 of auxiliary request 13. This was because Figures 57 to 60 of P1a, which are identical to Figures 57 to 60 of the contested patent, also *prima facie* disclose the additional limitations defined by amendments C1 and B1 to B4. Consequently, D2 constituted prior art under Article 54(3) EPC for the subject-matter of claim 1 of auxiliary request 13 and could therefore not be taken into account in the assessment of inventive step. In any event, no such inventive-step objection was raised by the opponent.

6.1.5 Since auxiliary request 13 was filed in response to the Board's departure from its preliminary assessment of amendment C1 following the debate on auxiliary request 7, raised no new issues and was *prima facie* allowable, the Board decided to admit it into the appeal proceedings.

6.1.6 As set out in points 6.2 and 6.3 below, the above *prima facie* findings on novelty and inventive step are confirmed following a more detailed assessment.

6.2 Novelty in view of D2

6.2.1 The Board agrees with the patent proprietor that the subject-matter of claim 1 of auxiliary request 13 is novel in view of D2.

6.2.2 The opponent argued that the subject-matter of claim 1 of auxiliary request 13 lacked novelty in view of the prosthetic heart valve disclosed in paragraph [0084] of D2 as an alternative embodiment of the prosthetic heart valve disclosed in Figure 3, reproduced below. The Board disagrees.

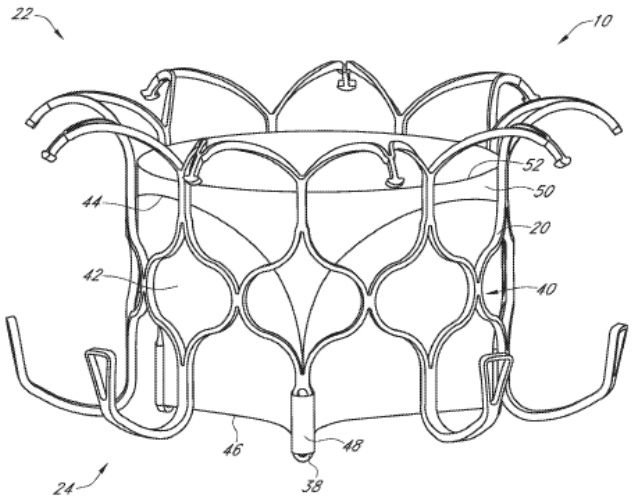


FIG. 3

6.2.3 The prosthetic heart valve shown in Figure 3 comprises an annular frame 20 and a liner 50 attached to the inside of the frame, which the opponent identified as anticipating the claimed sealing member. In the alternative embodiment described in paragraph [0084], the end of the liner 50 extends past the frame 20 and is wrapped around its inflow end, i.e. as defined by amendment B4.

6.2.4 It is true, as argued by the opponent, that D2 is drafted broadly as concerning prosthetic heart valves in general, namely "replacement heart valves" (paragraph [0001]) or valves "such as for replacement of natural heart valves" (paragraph [0041]). In particular, the disclosed valves are not limited to the replacement of the native mitral valve, which is merely presented as an example. Contrary to the patent proprietor's view, this applies to the prosthetic heart valve of Figure 3. This is indicated, *inter alia*, by the use of the expressions "in a manner similar to the native mitral valve" and "a damaged or diseased native heart valve such as a diseased native mitral valve" in paragraph [0078] (emphasis added by the Board).

6.2.5 However, as the patent proprietor had convincingly argued during the oral proceedings before the Board in connection with auxiliary request 7, such general wording merely defines the potential field of application of the concepts generally disclosed in D2. Contrary to the opponent's view, the various references to the aortic valve in D2, such as the disclosure in paragraph [0041] that "the features and concepts discussed herein can be applied to replacing other types of valves including, but not limited to, the aortic valve", merely indicate that the disclosed

features and concepts may be used when developing or adapting a valve for a specific implantation site, for example at the native aortic valve. However, such a general statement does not amount to the direct and unambiguous disclosure that every embodiment described in D2 - including the wrapped-liner configuration described in paragraph [0084] - is suitable, without further modification, for implantation in the native aortic valve, as required by amendment C1.

As argued by the patent proprietor, adapting the embodiment of paragraph [0084] for this purpose would require the person skilled in the art to make further constructional choices, in particular concerning the orientation of the leaflets relative to the direction of blood flow, the dimensions and geometry of the frame, and the configuration of the anchoring structures. D2 does not disclose which of these measures would be adopted or what the resulting aortic valve configuration would be.

For the assessment of novelty, it is not sufficient that the person skilled in the art could adapt the embodiment under consideration for aortic implantation. Such an adaptation may form the basis of an inventive-step objection, but cannot be treated as an implicit disclosure unless the claimed configuration follows directly and unambiguously from D2. As explained above, this is not the case. At most, paragraph [0041] makes an aortic adaptation of the concepts disclosed in D2 conceivable. However, it does not disclose the specific combination of amendments B4 and C1 required by claim 1 of auxiliary request 13.

For these reasons, the subject-matter of claim 1 of auxiliary request 13 is novel in view of D2.

6.3 Inventive step starting from D4

6.3.1 The Board also agrees with the patent proprietor that the subject-matter of auxiliary request 13 involves an inventive step starting from D4.

6.3.2 The opponent submitted that Figure 1 of D4, reproduced below in the colour-annotated form submitted by the opponent on page 10 of its statement of grounds of appeal, discloses a prosthetic heart valve 15 comprising an annular frame 20 ("stent component"), a valvular structure 5 ("valve component") comprising a plurality of leaflets 31, and a sealing member comprising an inner layer 28 ("inner skirt", shown in orange) and an outer layer 29 ("outer skirt", shown in blue), with at least the outer layer being mounted on the outside of the frame.

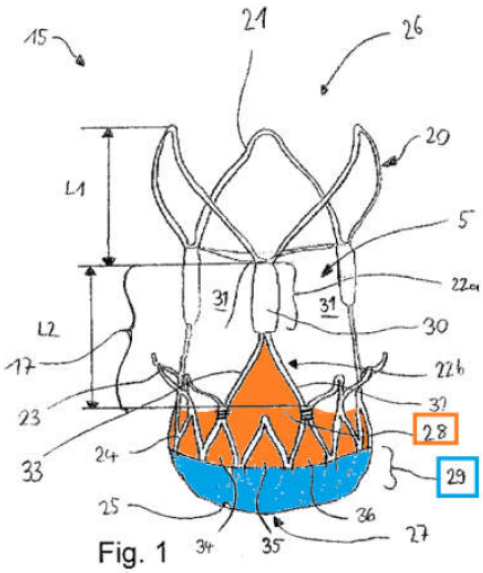


Fig. 1

6.3.3 It is common ground that the subject-matter of claim 1 of auxiliary request 13 differs from that known prosthetic heart valve in that

(a) the inner layer does not cover one or more openings in the frame at locations facing the outflow surfaces of the leaflets *to permit retrograde blood to flow through the one or more uncovered openings in the frame and into space between the outer layer and the frame*, as required by feature F3.4,

and in that

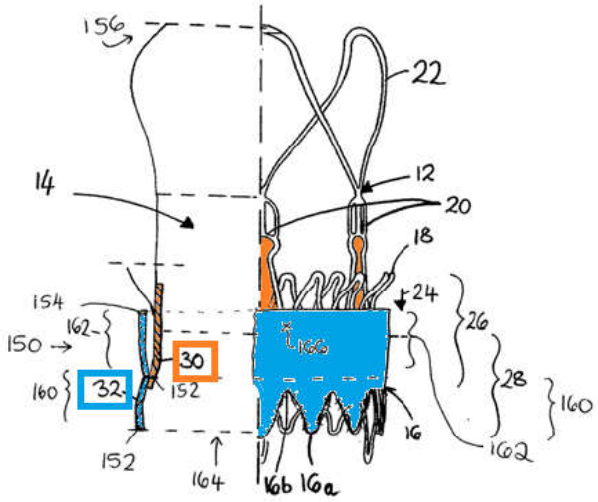
(b) *the outer layer is wrapped around the inflow end of the frame and secured along its upper edge portion to the struts on the outside of the frame*, as required by feature F3.5(i) as amended by amendments B3 and B4.

Indeed, even if retrograde blood were to flow through openings in the frame facing the outflow surfaces of the leaflets 31 and not covered by the inner skirt 28, such as the uncovered openings in the portions of the frame above the outer skirt 29, it would not flow into the space between the outer skirt and the frame, since the outer skirt terminates at a distance from the cusp edge portions of the leaflets.

6.3.4 Referring to paragraph [0034] of the contested patent, the opponent argued that difference (a) improved paravalvular sealing, while difference (b) was merely a well-known and straightforward design measure. The objective technical problem to be solved starting from D4 could therefore be formulated as how to improve paravalvular sealing.

According to the opponent, the person skilled in the art, starting from the prosthetic heart valve known from D4 and faced with this technical problem, would have consulted D3.

D3 discloses in Figure 20, reproduced below in the colour-annotated form submitted by the opponent on page 11 of its statement of grounds of appeal, a prosthetic heart valve closely resembling that of D4. D3 teaches that paravalvular sealing can be improved by configuring the outer skirt 150 to form an outer pocket capable of distending outwardly under backflow of blood (see page 19, second and third paragraphs). For this purpose, D3 discloses that the outflow end 154 of the outer skirt 150 can be positioned at different heights relative to the upper crown 18, including beyond the extremity of the upper crown towards the outflow end of the valve (see Figures 21 to 23 and page 20, first paragraph). In addition, D3 discloses that the outer skirt can be secured along its upper edge portion 154 to the struts on the outside of the frame (see Figure 24 and page 21, second paragraph).



The opponent submitted that this teaching would have provided the person skilled in the art with a motivation to implement a similar pocket in the valve of D4. They would therefore have simply extended the outer skirt 29 towards the outflow end of the frame and, where appropriate, attached its upper edge to the

struts on the outside of the frame. The resulting outer skirt would have defined a pocket capable of being pressurised by retrograde blood flowing through uncovered openings in the frame, thereby providing the arrangement defined in feature F3.4 and feature F3.5(i) as amended by amendment B3.

The opponent further submitted that arranging the outer skirt so as to be wrapped around the inflow end of the frame, as defined by amendment B4, would have been a straightforward design measure, deprived of any inventive skill. Such wrapped configurations were well known in the art, as reflected, for example, in D2, D9 and D11 to D13.

Therefore, according to the opponent, the person skilled in the art would have arrived at the subject-matter of claim 1 of auxiliary request 13 without exercising an inventive step.

6.3.5 This line of argument is not persuasive. Even assuming, in the opponent's favour, that the person skilled in the art would have extended the outer skirt 29 towards the outflow end in accordance with D3, thereby forming a pocket capable of being pressurised by retrograde blood, the Board concurs with the patent proprietor that, without hindsight, the person skilled in the art would not also have implemented the further limitation defined by amendment B4.

Indeed, as argued by the patent proprietor at the oral proceedings before the Board, both D4 and D3 direct the person skilled in the art towards limiting the amount and thickness of skirt material at the inflow end.

While D4 acknowledges that providing both an inner skirt and an outer skirt may improve the overall prevention of leakage, it also explains that the presence of both skirts can add significantly to the thickness of material carried by the frame and thereby increase the difficulty of crimping the valve to a desirably small size. D4 therefore proposes that the skirts overlap only partially in the axial direction. In this way, the sealing benefit afforded by an overlap of the skirts is retained, as compared with an edge-to-edge arrangement of the skirts on the interior and exterior of the frame, while the thickness profile is reduced in the regions in which only one skirt extends (see the paragraph bridging pages 19 and 20).

D3 addresses the same general concern. It suggests, among other things, that the outer skirt 150 have a peripheral zigzag edge substantially matching the zigzag extremity of the lower portion 16 of the frame to avoid excessive material at the inflow extremity and facilitate crimping (see the paragraph bridging pages 18 and 19).

These teachings point away from wrapping the outer skirt 29 of the valve known from Figure 1 of D4 around the inflow end of the frame. Such a wrap-around configuration would indeed require the outer skirt to extend beyond and around the inflow end and then along the inside of the frame, thereby introducing additional skirt material precisely where both D4 and D3 teach that excessive material should be avoided. The Board therefore agrees with the patent proprietor that, without knowledge of amendment B4, the person skilled in the art would not have considered such a modification.

The fact that skirts wrapped around the inflow end of a frame were known as such from other prior art documents does not alter this conclusion. That fact establishes at most that the person skilled in the art could have adopted such a configuration. However, the relevant question is not whether the person skilled in the art *could* have adopted such a configuration, but whether they *would* have done so when starting from D4 and combining it with D3.

6.3.6 It follows that, contrary to the opponent's argument, the person skilled in the art starting from D4 would not have arrived at the claimed subject-matter without exercising inventive skill; doing so would have required the benefit of hindsight. Consequently, the subject-matter of claim 1 of auxiliary request 13 involves an inventive step starting from D4.

6.4 The opponent confirmed at the oral proceedings before the Board that it had no further objections to auxiliary request 13.

7. Admittance issues; conclusion

7.1 It follows from the foregoing that the main request and auxiliary requests 1 to 12 are not allowable. There was therefore no need for the Board to decide on the admittance of auxiliary requests 2, 4, 8 to 10 and 12, as had been requested by the opponent. Auxiliary request 11 was not admitted into the appeal proceedings.

7.2 None of the objections raised by the opponent prejudice the maintenance of the contested patent in amended form on the basis of auxiliary request 13 as filed at the oral proceedings before the Board. As stated above,

this conclusion applies even if D11 to D13 are taken into account despite the patent proprietor's objection to their admittance. There was therefore no need for the Board to decide on the admittance of these documents.

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 with the following claims and a description to be adapted thereto:
   - claims 1 to 11 of auxiliary request 13 as filed at the oral proceedings before the board

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated