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**Datasheet for the decision
of 11 February 2025**

Case Number: T 0447/23 - 3.2.02

Application Number: 19154368.5

Publication Number: 3501455

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

LOW PROFILE TRANSCATHETER HEART VALVE

Patent Proprietor:

Edwards Lifesciences Corporation

Opponent:

Abbott Cardiovascular Systems, Inc.

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 76(1), 83, 123(2)

Keyword:

Divisional application - extension beyond the content of the
earlier and the original applications as filed (no)

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

T 1247/22

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0447/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 February 2025

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
23 February 2023 concerning the maintenance of
European Patent No. 3501455 in amended form**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: D. Ceccarelli
N. Obrovski

Summary of Facts and Submissions

I. The patent proprietor and the opponent both appealed against the Opposition Division's decision that, account being taken of the amendments made by the patent proprietor during the opposition proceedings in accordance with auxiliary request 2 then on file, the patent and the invention to which it related met the requirements of the EPC.

II. Oral proceedings took place on 11 February 2025.

The appellant-patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on 28 January 2022, or on the basis of one of auxiliary requests 1 to 7, of which auxiliary request 4 was filed on 28 January 2022, auxiliary requests 2 and 3 were filed on 30 March 2022, and auxiliary requests 1, 5, 6 and 7 were filed on 5 July 2023.

III. The appellant-opponent ("the opponent") requested that the decision under appeal be set aside and that the patent be revoked.

IV. The following documents are mentioned in this decision:

D1: WO 03/047468 A1

D2: WO 2007/103229 A2

D3: WO 2008/011261 A2

D4: WO 2008/070244 A2

D5: WO 2008/079962 A1

D6: WO 2008/106531 A1

D7: WO 2009/052188 A1

D9: US 2003/0167089 A1

D13: US 2006/0265056 A1

V. **Independent claim 1 and dependent claims 2 to 7, 13 and 15 of the main request** read as follows:

"1. An assembly for implanting a prosthetic aortic valve (10) in a native aortic valve of a patient's body, the assembly comprising:

 a delivery catheter (100) comprising an inflatable balloon (110); and

 a prosthetic aortic valve (10) configured to be radially collapsible to a collapsed state for introduction into the body on the delivery catheter (100) and radially expandable using the balloon (110) of the delivery catheter (100) to an expanded state for implanting the prosthetic aortic valve (10) at the native aortic valve in the body, the prosthetic aortic valve (10) comprising:

 a radially collapsible and expandable annular frame (12), the frame having three angularly spaced commissure attachment posts and a plurality of angularly spaced, axial struts that are interconnected by at least three rows of circumferential struts including a first row of circumferential struts defining an inflow end of the frame (12), a second row of circumferential struts defining an outflow end of the frame (12), and a third row of circumferential struts positioned axially between the first and second rows of angled struts along the length of the frame (12) and adjacent the second row of circumferential struts, each row of circumferential struts including struts arranged in a zig-zag pattern extending around the circumference of the frame (12);

 an annular skirt member (16) positioned inside of and secured to the frame (12); and

a leaflet structure comprising three leaflets, the leaflet structure having a scalloped lower edge portion secured to an inner surface of the skirt member (16) and three commissures formed at adjacent sides of the leaflets, each commissure being attached to one of the commissure attachment posts, the skirt member (16) disposed between the frame (12) and the leaflet structure (14),

characterized in that an upper edge of the skirt member (16) has a zigzag shape that generally follows the zig-zag pattern of and is attached with sutures to the third row of struts (22)."

"2. The assembly of claim 1, wherein the rows of circumferential struts include pairs of circumferential struts extending between two axial struts (30), the struts of each pair having adjacent ends interconnected by a generally U-shaped crown portion (26) defining a gap (28) between the adjacent ends."

"3. The assembly of claim 2, wherein the U-shaped crown portions (26) each include a horizontal portion extending between and connecting the adjacent ends of the pair of struts so as to define the gap (28) between the adjacent ends, the U-shaped crown portion (23) connecting the adjacent ends at a location offset from a natural point of intersection of the pair of adjacent struts."

"4. The assembly of claim 2, wherein each strut of a pair of struts connected at a common U-shaped crown portion (26) has one end connected to a respective axial strut (30) at a node (32) and another end interconnected to an adjacent end of the other strut of the same pair by the U-shaped crown portion (26)."

"5. The assembly of claim 2, wherein each pair of struts (22) of the third row that is connected at a common U-shaped crown portion (26) forms a cell with a pair of struts (24) in the second row that is connected at a common U-shaped crown portion (26)."

"6. The assembly of claim 5, wherein each cell is connected to an adjacent cell at a node (32), each node (32) interconnected with the third row of struts (22) by a respective axial strut (30) that is connected to and extends between the node (32) and a location on the third row of struts (20) where two struts are connected at their ends opposite U-shaped crown portions (26)."

"7. The assembly of claim 1, wherein a lower edge of the skirt member (16) is attached with sutures to the first row of struts (20)."

"13. The assembly of claim 1, wherein the struts (20) of the first row are thicker than the struts (24) of the second row."

"15. The assembly of claim 1, wherein the frame (12) has exactly four row of circumferential struts."

Claims 8 to 12, 14 and 16 are further dependent claims.

VI. The opponent's arguments, where relevant to this decision, can be summarised as follows.

Admittance of the main request

The main request should not be admitted into the appeal proceedings for lack of substantiation. The proprietor had not explained why the numbering of the rows in

claim 1 differed from the numbering in the original application, which had been considered to add subject-matter by the Opposition Division in the impugned decision.

Extension of subject-matter

Claim 1 of the main request required that the rows of circumferential struts include a third row of circumferential struts positioned axially between the first and second rows of angled struts. Angled struts were not mentioned anywhere in the original application. The Opposition Division had taken the position that the expression "angled struts" was a linguistic error and that it was immediately apparent to a skilled reader that "circumferential struts" were meant. However, both "angled struts" and "circumferential struts" had a clear, credible technical meaning. According to case law, the word "angled" had to be given its clear, credible technical meaning and the description could not be used to give it a different one. Moreover, there was no indication in the patent that "angled" was intended to mean "circumferential". Figure 1 of the patent showed struts extending along a circumference of a prosthetic aortic valve at an angle with respect to the circumferential direction. A configuration with angled struts extending radially outwards from the frame of the prosthetic aortic valve, in addition to struts extending in the circumferential direction, was encompassed by the claim feature. In conclusion, the technical meaning of the term "angled struts" could not simply be ignored. The proprietor's argument that the term "angled struts" further qualified the first and second rows of circumferential struts constituted a change of its case and should not be admitted into the appeal proceedings.

The Opposition Division had identified an error in that "the first and second rows of angled struts" lacked an antecedent basis in the claim. However, if that had been the case, there would have been other possible ways of correcting the error. One possibility, other than interpreting the reference to angled struts as a reference to the circumferential struts, would have been to replace the definite article "the" with an indefinite article "a". Claim 1 of the main request required the presence of a first, a second and a third row of circumferential struts together with first and second rows of angled struts. There was no disclosure in the original application of an embodiment with these rows of struts.

Moreover, claim 1 of the main request specified a frame having axial struts interconnected by at least three rows of circumferential struts. Claim 5 and paragraph [009] of the original application disclosed a plurality of rows of circumferential struts. The introduction of the expression "at least three" into claim 1 constituted a selection that was not originally disclosed. Claim 1 excluded the possibility that the axial struts were interconnected by two rows of circumferential struts while the original disclosure did not provide any basis for such an exclusion.

As correctly concluded by the Opposition Division, the original application did not disclose that an upper edge of the skirt member was always attached to the penultimate row of struts. This was not necessarily the case with embodiments with four or more rows of struts, as encompassed by claim 1 of the main request.

The original application did not disclose an upper edge of the skirt member having a zig-zag shape as defined

in claim 1 of the main request. Paragraph [062] of the application disclosed that "the upper edge of skirt 16 desirably has an undulated shape that generally follows the shape of the second row of struts 22 of the frame". Such an undulated shape was shown in Figures 16 and 17 of the original application and was not the same as a zig-zag shape. In fact, the original application itself distinguished between these shapes. The Opposition Division's statement, with which the proprietor agreed, that suturing the skirt to the frame would result in an edge having a zig-zag shape was not substantiated by any facts and was even contradicted by the disclosure. Such a zig-zag shape of the upper edge of the skirt member in an assembled state was not disclosed in the description and was not derivable from the figures of the original application either. Figures 1 and 2, in particular, could not provide a basis for the claimed feature as they were schematic and the edge of the skirt was not visible at all in these figures. What was visible was a suture line along the struts. The original application was also silent as to an upper edge of the skirt member generally following the zig-zag pattern of the third row of struts. Paragraph [062] disclosed a skirt having an undulated shape that generally followed the shape of the second row of struts. An upper edge following a zig-zag pattern of a row of circumferential struts was not disclosed.

Claim 1 of the main request specified a first row of circumferential struts defining an inflow end of the frame and a second row of circumferential struts defining an outflow end of the frame. However, the original application did not disclose that a row of circumferential struts defined any end at all.

A number of features had been impermissibly omitted

from claim 1 of the main request. One example was the annular skirt comprising slits intended to be aligned with crown structures at the circumferential struts of the frame. Moreover, claim 1 of the original application required a plurality of leaflets and two side flaps extending between respective ends of the upper edge and the lower edge. It also included the feature of a reinforcing bar being positioned against each side flap for reinforcing the attachments between the commissures and the commissure attachment posts. There was no hint in the original application that these features could be omitted, as in the case of claim 1 of the main request.

The first row of circumferential struts adjacent to the inflow end of the frame and the second row of struts adjacent to the outflow end of the frame as defined in claim 1 of the main request had been introduced on the basis of original claim 14. However, this claim comprised other features that were inextricably linked with the claimed ones, e.g. that the struts of the first row were thicker than the struts of the second row. Omitting the feature regarding the relative thickness of the first and second rows of struts from claim 1 and claiming this feature alone in claim 13 constituted inadmissible extensions of subject-matter. Moreover, the features of original claim 5, i.e. the circumferential struts extending between and not just interconnecting the axial struts, should have been introduced into claim 1 of the main request due to the dependencies of claim 14 on claim 5 and of claim 5 on claim 1 in the original application.

As the feature combination of claim 1 of the main request was not disclosed in the original application, the combination of the features of the dependent claims

with the features of claim 1 was not disclosed in the original application either.

U-shaped crown portions having the features defined in dependent claims 2 to 6 of the main request were only disclosed in connection with embodiments having exactly three or four rows of circumferential struts. However, the claims were not restricted to such embodiments. Moreover, paragraph [049] disclosed the features of the crown structures in combination. Separating these features in dependent claims 2 to 6 constituted an extension of subject-matter. The original application did not disclose that the lower edge of the skirt member was attached with sutures to the first row of struts. The figures showed a lower edge of the skirt extending downwardly beyond the first row of struts. As a consequence, claim 7 of the main request comprised added subject-matter. Claim 15 of the main request restricted the number of rows of circumferential struts to exactly four. However, in the original application, frames with four rows of circumferential struts were disclosed in combination with valves that were more than 29 mm in diameter and with four columns of struts for each 120-degree frame segment. The omission of these features in claim 15 constituted an extension of subject-matter.

Sufficiency of disclosure

According to claim 1 of the main request, a third row of circumferential struts was positioned between two rows of angled struts and, at the same time, was adjacent to a second row of circumferential struts.

The opposed patent did not disclose how a third row of struts might be arranged next to a second row at an

end, and might also be positioned between two other rows of struts.

The opposed patent did not provide sufficient information as to how a zig-zag shaped upper edge of a skirt might be sutured to a row of circumferential struts having a zig-zag pattern. Top portions of the upper edge could not be wrapped around the circumferential struts due to the presence of axial struts extending from the zig-zag of the circumferential struts.

Novelty

The subject matter of claim 1 of the main request was not novel in view of D7.

D7 disclosed an assembly for implanting a prosthetic aortic valve including a balloon catheter and a prosthetic aortic valve being collapsible and expandable. The prosthetic aortic valve (Figure 2) comprised an annular frame with three rows of circumferential struts arranged in a zig-zag pattern and a leaflet structure in the form of a three-leaflet membrane. According to paragraph [0044] of D7, a membrane support with a skirt could be affixed to the frame. Figure 2 showed lines of the leaflet structure covered by a skirt member in the area below a third row of circumferential struts. This meant that the skirt member terminated at the third row of circumferential struts, where it was attached to the frame with sutures (paragraph [0044]). The pattern on the circumferential struts was different from the pattern on the barbed axial struts in Figure 2 and indicated sutures. It followed that the upper edge of the skirt member had a zig-zag shape that followed the zig-zag pattern of the

third row of struts. Moreover, the leaflet structure inherently had a scalloped lower edge portion since native aortic valves had this shape. This was due to the presence of the leaflets and commissures and was supported by paragraph [0052], last sentence.

Inventive step

The subject-matter of claim 1 of the main request was not inventive when starting from D1.

D1 disclosed an assembly for implanting a prosthetic aortic valve in a native aortic valve of a patient's body with a delivery catheter and a prosthetic aortic valve (Figures 1, 23d and 23e) with a radially collapsible and expandable annular frame, an annular skirt member and a leaflet structure as defined in the preamble of claim 1 of the main request.

D1 did not disclose an upper edge of the skirt member with a zig-zag shape that generally followed the zig-zag pattern of, and was attached with sutures to, the third row of struts of the annular frame. According to Figure 23e of D2, the skirt member was punctually joined with sutures at different circumferential rows of struts, following the line at which the skirt member was joined to the leaflet structure.

The distinguishing feature of claim 1 of the main request had the technical effect that the skirt member was more tightly secured to the annular frame. This solved the technical problem of providing a more stable coupling. Alternatively, the technical effect could be seen as less material having to be required for the skirt member. This solved the technical problem of reducing the amount of fabric required to provide the

skirt member.

Since the leaflet structure and the skirt member were different elements, there was no need for the sutures for joining the skirt member to the annular frame to follow the contour of the leaflet structure. D1 provided a hint at the claimed solution in that it disclosed that the shape of the skirt member could be varied in some cases (page 33, third paragraph, tenth sentence) and that the skirt was joined along a zig-zag pattern to a first row of circumferential struts at the inflow end of the frame. The person skilled in the art would have provided a similar attachment to the third row of circumferential struts to obtain a more stable coupling which better avoided potential leakage and back flow between the annular frame and the leaflet structure (as taught in D1, page 33, third paragraph, sixth sentence). There was no technical difficulty in providing such an attachment following a zig-zag pattern, which would have to be spaced from the third row of circumferential struts only in the proximity of the commissure attachment posts.

Moreover, D2 (Figure 5A), D3 (Figure 1B), D4 (Figure 6) and D5 (Figure 7) disclosed zig-zag shapes, and these would have been considered by the person skilled in the art for reducing the amount of fabric required to provide the skirt member.

Even if the Board concluded that D7 was not detrimental to novelty, the subject-matter of claim 1 of the main request would not involve an inventive step when starting from D7. D1 to D6 disclosed frames and skirt structures for supporting a three-leaflet valve as defined in claim 1 of the main request.

The subject-matter of claim 1 of the main request was not inventive when starting from any of D3, D4 and D5, either.

D3 disclosed an assembly for implanting a prosthetic aortic valve in a native aortic valve of a patient's body, comprising a delivery catheter and a prosthetic aortic valve, the aortic valve having a leaflet structure having a scalloped lower edge portion secured to an inner surface of a skirt member (paragraph [0026] and Figures 1A and 1B). D3 also disclosed an upper suture line (Figure 1B) with a zig-zag shape connecting a skirt member to a row of circumferential struts (paragraph [0025]). The person skilled in the art would have omitted the uppermost row of circumferential struts in the prosthetic aortic valve of Figure 1B in order to reduce the crimping profile of the prosthesis. It followed that the subject-matter of claim 1 of the main request was obvious in the light of a combination of D3 with common general knowledge.

D4 also disclosed an assembly for implanting a prosthetic aortic valve in a native aortic valve of a patient's body, comprising a delivery catheter and a prosthetic aortic valve (Figures 6 and 7), the aortic valve having a leaflet structure having a scalloped lower edge portion secured to an inner surface of a skirt member. Paragraph [0033] disclosed a bioprosthetic leaflet. Any bioprosthetic or biological leaflet had a shape conforming to the native leaflets and therefore had a scalloped lower edge portion. D4 also disclosed an upper suture line (Figure 6) with a zig-zag shape connecting a skirt member to a row of circumferential struts. The person skilled in the art would have omitted the uppermost row of circumferential struts in the prosthetic aortic valve of Figure 6 in

order to reduce the crimping profile of the prosthesis. It followed that the subject-matter of claim 1 of the main request was obvious in the light of a combination of D4 with common general knowledge.

D5 also disclosed an assembly for implanting a prosthetic aortic valve in a native aortic valve of a patient's body, comprising a delivery catheter and a prosthetic aortic valve (Figures 1 and 2 and paragraphs [040] and [041]), the aortic valve having a leaflet structure having a scalloped lower edge portion secured to an inner surface of a skirt member (paragraph [041] disclosed a harvested natural valve as the leaflet structure, which inherently had a scalloped lower edge portion). D5 also disclosed an upper suture line (Figure 2) with a zig-zag shape connecting a skirt member to a row of circumferential struts. The person skilled in the art would have omitted the uppermost row of circumferential struts in the prosthetic aortic valve of Figure 1 in order to reduce the crimping profile of the prosthesis. It followed that the subject-matter of claim 1 of the main request was obvious in the light of a combination of D5 with common general knowledge.

Even if the Board concluded that D3, D4 or D5 did not disclose leaflets having a scalloped lower edge portion, this feature was in any case disclosed in D9 (Figure 2) and D13 (Figure 1a). Thus, under no circumstances could this feature provide an inventive step.

VII. The proprietor's arguments, where relevant to this decision, can be summarised as follows.

Admittance of the main request

The main request was a request on which the decision under appeal was based. Hence, it formed part of the appeal proceedings. Reasons why the main request did not comprise added subject-matter had been provided in the statement setting out the grounds of appeal (section 2.1).

Extension of subject-matter

In claim 1 of the main request, the wording "a third row of circumferential struts positioned axially between the first and second rows of angled struts along the length of the frame (12) and adjacent the second row of circumferential struts" contained an obvious error. The word "the" showed that reference was being made to a previously introduced feature, and yet the claim had not previously made any mention of rows of angled struts. Instead, the claim had previously referred to "a first row of circumferential struts" and "a second row of circumferential struts". The person skilled in the art, reading the claim on its own and with a mind willing to understand, would interpret the wording "rows of angled struts" to mean "rows of circumferential struts". The correction would have been read into the claim, and for this reason a formal correction was not necessary. If the wording "angled struts" were to be given a technical meaning, the circumferential struts as described and as shown in the figures were in fact "angled struts". This wording explained that the circumferential struts were angled struts. A basis for the angle formed by the struts was provided in paragraph [048] and the figures of the original application. This argument had been made on page 9 of the reply to the opponent's statement of

grounds of appeal and therefore did not amount to a change of the proprietor's appeal case. The opponent's argument that there was no disclosure in the original application of three rows of circumferential struts in addition to two rows of angled struts failed to take account of the fact that the first and second rows of angled struts were the first and second rows of circumferential struts.

Paragraph [009] and claim 5 of the original application provided a basis for frames with a plurality of rows of struts. Paragraph [048] and Figure 7 disclosed an embodiment with three rows of struts. This provided a basis for a frame having at least three rows of circumferential struts.

The original application disclosed specific embodiments of prosthetic valves with frames having three rows of circumferential struts (Figures 1-4, 7, 9, 19 and 23) and frames having four rows of circumferential struts (Figures 8, 10 and 24). Paragraph [053] stated that Figures 8 and 10 showed an alternative frame that was similar to the frame of Figures 7 and 9 except that it had four rows of struts. The person skilled in the art would understand that the features of the three-row frame were directly transferable to the four-row frame, unless explicitly stated otherwise. In the embodiment with three rows of circumferential struts, there were sutures on two of the rows, with the upper edge of the skirt being attached via sutures to the row adjacent to the uppermost row (Figures 1, 4, 19 and 23). In the embodiment with four rows of circumferential struts, there were sutures on three of the rows, with the upper edge of the skirt being attached via sutures to the row adjacent to the uppermost row (Figure 24). Moreover, Figures 3, 4, 7 and 9 showed vertically extending

posts 18 having a group of upper holes in line with the upper two rows of circumferential struts, and a separate lower hole in line with the lower row of circumferential struts. Figures 8 and 10 showed vertically extending posts 18 each having a group of upper holes in line with the upper two rows of circumferential struts, and two additional separate holes each in line with a respective one of the other rows of circumferential struts. Figure 13 showed a scalloped lower edge portion of a leaflet extending up to bars 62 having a group of holes that corresponded to the group of holes on the vertically extending posts. Paragraph [058] of the original application stated that "the point of attachment of the leaflets to posts 18 can be reinforced with bars 62". As the scalloped lower edge portion of the leaflet structure was secured to an inner surface of the skirt member, the skirt member had to extend up to the region of the group of holes in post 18, i.e. to extend and be attached to the row adjacent to the uppermost row. The person skilled in the art was therefore taught by the original application that the upper edge of the skirt was attached to the row of struts adjacent to the outflow row, irrespective of whether the frame had three, four or more rows of circumferential struts.

Paragraph [062] of the original application disclosed that the upper edge of the skirt member had an undulated shape that generally followed the shape of the second row of struts of the frame depicted in Figures 1 and 2. It also disclosed that the upper edge was wrapped around the upper surfaces of the struts and secured in place with sutures. Paragraph [009] and Figures 1 and 2 of the original application disclosed that the struts were arranged in a zig-zag pattern. It followed that the upper edge of the skirt, when

attached to the struts of the frame, had to have a zig-zag shape that generally followed the zig-zag pattern of the third row of struts within the meaning of claim 1 of the main request. The claim defined the shape of the upper edge of the skirt when assembled.

Paragraph [046] and claim 14 of the original application provided a basis for the first row of circumferential struts defining an inflow end of the frame and a second row of circumferential struts defining an outflow end of the frame.

The features recited in the summary section of the original application were listed as part of various representative embodiments. Independent claim 15 of the original application did not include many of these features. The features not present in claim 1 of the main request were merely optional features.

Paragraph [050] of the original application presented the feature that the struts of the first row were thicker than the struts of the second row as optional. Paragraphs [009] and [048] described axial struts interconnected by at least three rows of circumferential struts, without stating that the circumferential struts extended between the axial struts.

Dependent claims 2 to 6 were based on paragraphs [010] and [049] and claim 6 of the original application. Dependent claim 7 was based on paragraphs [056] and [062] and Figures 1, 2, 4, 5 and 29 of the original application. Claim 15 was based on paragraphs [052] and [053] and Figures 8, 10, and 25 to 29 of the original application.

Sufficiency of disclosure

In claim 1 of the main request, the wording "a third row of circumferential struts positioned axially between the first and second rows of angled struts along the length of the frame (12) and adjacent the second row of circumferential struts" contained an obvious error and the person skilled in the art would interpret the rows of angled struts to mean the rows of circumferential struts. The person skilled in the art would have no difficulty in providing a frame with a third row of circumferential struts positioned axially between the first and second rows of circumferential struts. Such an arrangement was shown in Figures 1 to 4, 7 and 9, and was described in paragraphs [0019], [0020] and [0022] of the patent as granted.

A zig-zag shaped upper edge of a skirt sutured to a row of circumferential struts having a zig-zag pattern was shown in Figures 1, 2 and 4 and described in paragraphs [0010], [0019], [0027] and [0033] of the patent as granted. The person skilled in the art would have no difficulty in implementing this teaching.

Novelty

D7 did not disclose an upper edge of a skirt member having a zig-zag shape that generally followed the zig-zag pattern of, and was attached with sutures to, a third row of struts of an annular frame of a prosthetic aortic valve. Figure 2, which was schematic, showed some lines of a leaflet structure which did not extend below a third row of circumferential struts and some other lines which did. It could not be inferred from this figure that the skirt member terminated at the third row of circumferential struts. The pattern on the

circumferential struts was not described in D7, and it could not be inferred what it indicated. Moreover, D7 did not disclose a leaflet structure having a scalloped lower edge portion secured to an inner surface of a skirt member. Rather, a circumferential line in Figure 2 of D7 hinted to the fact that the lower edge of the skirt member in that figure was flat. The opponent's statement that the leaflet structure had to have a scalloped lower edge portion since native aortic valves had this shape, was not supported by any evidence.

Inventive step

D1 did not disclose an upper edge of a skirt member with a zig-zag shape that generally followed the zig-zag pattern of, and was attached with sutures to, a third row of struts of an annular frame of a prosthetic aortic valve.

This distinguishing feature created a more durable prosthetic aortic valve, because the zig-zag shape of the upper edge of the skirt attached with sutures to the struts allowed for a tight attachment. Hence, the distinguishing feature solved the problem of how to increase the reliability of the prosthetic heart valve of D1.

The person skilled in the art would not have modified the attachment of the skirt member of D1 in the claimed way. The skirt member in Figures 23d and 23e of D1 extended to, and was attached to, posts which ended at an uppermost row of circumferential struts. This attachment had to be kept to ensure that the valve according to D1 worked correctly. Moreover, the person skilled in the art would have had no motivation from D1

to apply a zig-zag cut, as D1 taught the attachment of the skirt member to three upper rows of struts of the annular frame, which provided a working device.

None of D2, D3, D4 and D5 disclosed the distinguishing feature. They disclosed sutures arranged along a row of struts that did not correspond to the third row of struts according to claim 1 of the main request.

The distinguishing features of claim 1 of the main request over each of D3, D4, D5 and D7 were the leaflet structure having a scalloped lower edge portion secured to an inner surface of the skirt member and an upper edge of the skirt member having a zig-zag shape that generally followed the zig-zag pattern of, and was attached with sutures to, the third row of struts. Figures 1A and 1B and paragraph [0026] of D3 disclosed an arcuate line of a leaflet structure at the outflow end, but did not teach the use of a scalloped lower edge portion of the skirt member as defined in claim 1 of the main request. With respect to D4 and D5, the opponent had not provided any evidence that a bioprosthesis leaflet or a harvested natural valve necessarily had a scalloped lower edge portion.

The distinguishing features solved the problem of how to increase the reliability of the prosthetic heart valve of each of D3, D4, D5 and D7.

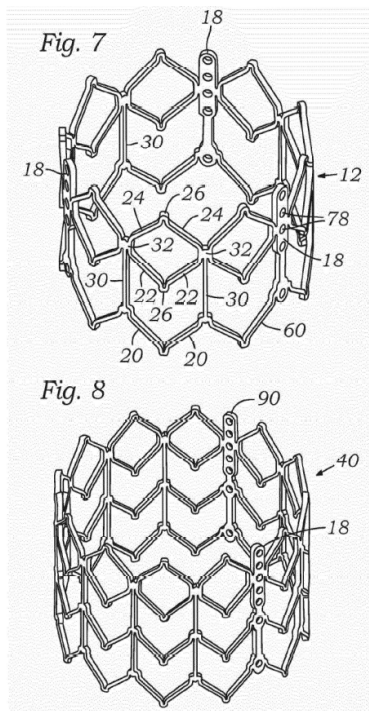
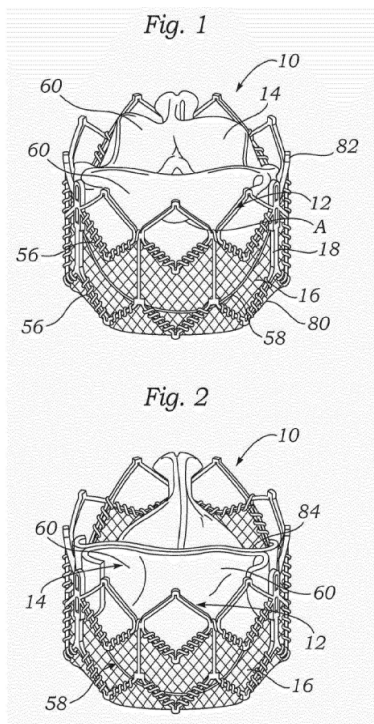
None of these documents or the common general knowledge suggested these distinguishing features for solving this problem. D1, D2 and D6, which were mentioned by the opponent, did not suggest them either. It followed that the subject-matter of claim 1 of the main request was inventive when starting from D3, D4, D5 or D7.

Reasons for the Decision

1. Subject-matter of the patent

The patent relates to an assembly for implanting a prosthetic aortic valve in a native aortic valve of a patient's body. The implantation of a prosthetic aortic valve may be required as a consequence of a vascular disease causing malfunction of the native valve and the heart. The prosthetic valve is intended to assume the function of the native valve.

The assembly comprises a delivery catheter with an inflatable balloon and the prosthetic aortic valve. An embodiment of the prosthetic aortic valve is depicted in Figures 1 and 2 of the patent. Alternative annular frames of the prosthetic aortic valve are depicted in Figures 7 and 8 of the patent. These figures are reproduced below.



The prosthetic aortic valve (10) is configured to be radially collapsible to a collapsed state for introduction into the body on the delivery catheter and radially expandable using the balloon of the delivery catheter to an expanded state for implantation at the native aortic valve in the body.

The prosthetic aortic valve comprises a radially collapsible and expandable annular frame (12), an annular skirt member (16) positioned inside of and secured to the frame and a leaflet structure (14) comprising three leaflets.

The annular frame has three angularly spaced commissure attachment posts (18) and a plurality of angularly spaced axial struts (30). The axial struts are interconnected by at least three rows of circumferential struts, including a first row of circumferential struts (20) defining an inflow end of the frame, a second row of circumferential struts (24) defining an outflow end of the frame, and a third row of circumferential struts (22) positioned axially between the first and second rows of angled (circumferential) struts along the length of the frame and adjacent to the second row of circumferential struts (24).

Each row of circumferential struts includes struts arranged in a zig-zag pattern extending around the circumference of the frame.

The leaflet structure has a scalloped lower edge portion secured to an inner surface of the skirt member and three commissures (84 - where the leaflets meet with one another) formed at adjacent sides of the leaflets. Each commissure is attached to one of the

commissure attachment posts of the annular frame.

The skirt member is disposed between the annular frame and the leaflet structure, and has an upper edge with a zig-zag shape that generally follows the zig-zag pattern of, and is attached with sutures to, the third row of struts (22).

The upper edge of the skirt member following the zig-zag shape of the strut elements to which it is sutured facilitates a tighter securement to the annular frame (paragraph [0033] of the patent).

2. Admittance of the main request

The opponent submitted that the main request should not be admitted into the appeal proceedings for lack of substantiation.

The main request was considered by the Opposition Division, which concluded, in the impugned decision, that claim 1 comprised added subject-matter.

Contrary to the opponent's allegation, the proprietor provided extensive arguments in section 2.1 of its statement setting out the grounds of appeal as to why in its view the main request did not comprise added subject-matter. There is thus no reason not to admit the main request under Article 12(3) and (5) RPBA.

The Board further notes that the decision under appeal is based on the main request. Accordingly, the Board does not have any discretion not to admit the main request under Article 12(2) and (4) RPBA.

3. Extension of subject-matter

3.1 The patent in suit is derived from European application EP 19154368.5, which is a divisional of European application EP 17180494.1, which is itself a divisional of European application EP 09759620.9 ("the original application"). The description, the drawings and the claims of the original application are comprised in the subsequent divisional applications (the claims are listed as "embodiments" at the end of the description of the divisional applications). For the assessment of added subject-matter under Articles 76(1) and 123(2) EPC, it is therefore sufficient to consider the disclosure of the original application.

3.2 The opponent argued that claim 1 of the main request contained added subject-matter because it referred to first and second rows of angled struts.

However, as correctly concluded by the Opposition Division in the impugned decision, and as explained in T 1247/22, points 2.2.1 to 2.2.4 of the Reasons, which relates to a family member of the patent in suit, the person skilled in the art would understand, without having to resort to the description and drawings, that the first and second rows of "angled struts" recited in the claim are simply the first and second rows of circumferential struts that had previously been defined and were subsequently referred to again in the claim. The description and the drawings of the patent in suit fully support this understanding, as whenever they refer to rows of struts, these are circumferential struts.

The Board accepts the opponent's argument that the term "angled struts" has a technical meaning which,

according to established case law, should not be ignored. However, as the proprietor pointed out, this means that, according to claim 1 of the main request, the first and second rows of circumferential struts are angled. In this respect, the Board notes that the proprietor made this argument, which relates to a feature disputed in the impugned decision, on page 9 of its reply to the opponent's statement of grounds, and the Board sees no reasons for not admitting it under Article 12(4) RPBA.

A basis for the first and second rows of angled circumferential struts is provided in Figures 1, 2, 7 and 8 and paragraph [048] of the original application, which disclose struts extending along a circumference of a prosthetic aortic valve at an angle with respect to the circumferential direction. The opponent's argument that angled struts extending radially outwards from the frame of the prosthetic aortic valve were encompassed by the expression "angled struts" is not convincing. Such angled struts would not extend in the circumferential direction and would not interconnect with the axial struts, as required by claim 1 of the main request.

In conclusion, the reference to angled struts in claim 1 of the main request does not add subject-matter.

- 3.3 The opponent argued that claiming "at least three rows of circumferential struts" added subject-matter. However, as explained in T 1247/22, points 2.1.1 to 2.1.2 of the Reasons, a basis in the original application is provided by paragraph [0009], which discloses "a plurality of rows of circumferential struts", and Figures 1, 4 and 7 to 10, which disclose

embodiments with exactly three or four rows of circumferential struts.

- 3.4 The Opposition Division did not allow the main request because it considered that the original application did not disclose that the skirt had to be attached to the penultimate row of circumferential struts at the outflow end of the frame in a configuration comprising more than three circumferential struts, as defined in claim 1. The opponent shared the Opposition Division's view and raised a corresponding objection on appeal.

The Board does not share the Opposition Division's view on this claimed feature.

Claim 1 of the main request defines the "second row of circumferential struts defining an outflow end of the frame" and the "third row of circumferential struts positioned axially between the first and second rows of angled struts along the length of the frame and adjacent the second row of circumferential struts". Furthermore, the claim specifies that "an upper edge of the skirt member [...] is attached with sutures to the third row of struts". It follows that, as correctly concluded by the Opposition Division, according to the claim, the skirt member is attached to the penultimate row of circumferential struts at the outflow end, irrespective of the number of rows of circumferential struts of the annular frame.

Figures 1 and 2, together with paragraph [056] of the original application, disclose such an attachment for an embodiment having an annular frame with three rows of circumferential struts. As remarked by the proprietor, the original application as filed discloses a further embodiment having an annular frame with four

rows of circumferential struts, depicted in Figures 8 and 10. Paragraph [053] of the original application states: "FIGS. 8 and 10 show an alternative frame 40 that is similar to frame 12 except that frame 40 has four rows of struts". This indicates to the person skilled in the art that also in this embodiment the skirt is attached to the penultimate row of circumferential struts. If this had not been the case, the description and/or the drawings would have disclosed this (as in the case of the minimal differences in the openings in support posts 18, as noted by the Opposition Division in the impugned decision).

Moreover, Figures 8 and 10 show upper openings in support posts 18, corresponding to openings 78 in Figure 7, to which bars 62 on leaflets 60 (Figure 13) are attached. In this respect the Opposition Division, commenting on Figure 13, stated: "according to the description in §28, it is the leaflet for the embodiment of figure 1, which has exactly 3 circumferential rows". However, in view of paragraph [053] and the fact that the leaflet structure of Figure 13 fits the embodiment of Figures 8 and 10, there is no reason why this leaflet structure should be different in the embodiment according to Figures 8 and 10. The scalloped lower edge portion of the leaflet structure approximately reaches bars 62 (Figure 13) and thus has to extend above the second row from below of circumferential struts in the embodiment of Figure 8. Since the skirt member has to extend to the scalloped lower edge portion of the leaflet structure (paragraphs [008], [060] and [063] of the original application), which is fixed to the skirt, it has to reach the third row from below of circumferential struts.

It follows that the description and drawings of the original application as filed disclose an attachment of the skirt member to the penultimate row of circumferential struts at the outflow end also for an embodiment with four rows of circumferential struts. Figure 24 clearly supports this conclusion, although the structure of the annular frame may differ from that of Figures 8 and 10.

No embodiments with more than four rows of circumferential struts are specifically described. On this basis, it is directly and unambiguously derivable from the description and drawings of the original application as filed that configurations comprising more than four rows of circumferential struts should only differ from the specifically disclosed embodiments in the number of rows of circumferential struts, and not in other features such as the relative place of attachment of the skirt. If this had not been the case, there would have been a specific disclosure in this respect.

In conclusion, the claimed skirt member being attached to the penultimate row of circumferential struts at the outflow end does not add subject-matter.

- 3.5 The opponent argued that claiming an upper edge of the skirt member having a zig-zag shape added subject-matter. It considered that paragraph [062] together with Figure 16 of the original application as filed disclosed an undulated shape instead. However, claim 1 also recites that the annular skirt member is positioned inside of, and secured to, the frame and that the zig-zag shape of the upper edge of the skirt member generally follows the zig-zag pattern of the

third row of struts. As held in the impugned decision and also explained in case T 1247/22, points 2.3.2 and 2.6.1 of the Reasons, the disputed claim feature relates, contrary to Figure 16, to an assembled state and finds a basis in Figure 1 in combination with paragraphs [009] and [048], as well as in paragraph [062], of the original application.

Paragraph [009] of the original application generally discloses struts arranged in a zig-zag pattern. Paragraph [062] of the original application discloses that the upper edge of the skirt member, having an undulated shape that generally follows the shape of the second row of struts of the frame depicted in Figures 1 and 2, is wrapped around the upper surfaces of the struts and secured in place with sutures. The struts depicted in Figures 1 and 2, in accordance with paragraph [009] and also paragraph [048], are arranged in a zig-zag pattern. Hence, the upper edge of the skirt, when attached to the struts of the frame, has a zig-zag shape that generally follows the zig-zag pattern of the third row of struts as defined in claim 1 of the main request.

- 3.6 The opponent argued that claiming struts defining an inflow end and an outflow end added subject-matter. This objection is not convincing either. As explained in T 1247/22, point 2.5.1 of the Reasons, Figures 1 and 2 of the original application show a first row and a second row of circumferential struts at two ends of the annular frame. Calling these ends an "inflow" end and an "outflow" end merely explains the intended location after implantation, which is disclosed in paragraph [046] and claim 14 of the original application.

3.7 The opponent also argued that the omission of several features in claim 1 of the main request was not allowable. This objection amounts to an allegation that the claim, the individual features of which find a basis in the summary of the invention together with the description of specific embodiments, comprised an unallowable intermediate generalisation.

The Board does not consider that the description and drawings of the original application as filed link any further features to the claimed ones in an inextricable way. The opponent presented no arguments in this respect. It is noted that no further feature is indispensable for the function of facilitating a tighter securement of the leaflet structure to the annular frame and protecting against tearing of the leaflets, which is what the claimed invention aims to achieve (paragraphs [0027], [0033] and [0034] of the patent).

As regards the two side flaps, the reinforcing bar and the struts from the first row being thicker than struts of the second row (as disclosed in claim 14 of the original application), the Board agrees with the analysis made in T 1247/22, points 2.7.1 and 2.7.2 of the Reasons, which concluded that these features were presented as optional in the original application. It also follows that claiming that the struts from the first row are thicker than the struts of the second row in dependent claim 13 does not introduce any added subject-matter.

As regards the omission of mentioning circumferential struts extending between axial struts, claim 1 of the main request defines that the axial struts are interconnected by at least three rows of

circumferential struts. This implies that the circumferential struts also extend between the axial struts as disclosed in claim 5 of the original application.

- 3.8 The opponent also raised objections against several of the dependent claims.

A basis for the U-shaped crown together with the other features defined in claims 2 to 6 of the main request is provided by paragraphs [009], [010] and [049] of the original application, which are not limited to embodiments having exactly three or four rows of circumferential struts (as also explained in T 1247/22, point 2.8.2 of the Reasons). A basis for a lower edge of the skirt member being attached with sutures to the first row of struts as defined in claim 7 of the main request is provided by Figures 1 and 2 of the original application as filed (as also explained in T 1247/22, point 2.8.3 of the Reasons).

As regards the omission of the frame diameter and the number of columns in claim 15, this does not amount to an unallowable intermediate generalisation, because the omitted features are not inextricably linked to the number of rows of circumferential struts.

Paragraph [052] of the original application, which relates to valves being more than 29 mm in diameter and having four columns of struts for each 120-degree frame segment, discloses an optional configuration, as also explained in T 1247/22, points 2.8.4 and 2.8.5 of the Reasons.

- 3.9 It follows that the main request does not include added subject-matter. Hence, it complies with Articles 76(1)

and 123(2) EPC.

4. Sufficiency of disclosure

4.1 The opponent based a first objection of a lack of sufficiency on the understanding that "the first and second rows of angled struts" were different from the first and second rows of circumferential struts. As this is not the case, the objection is moot.

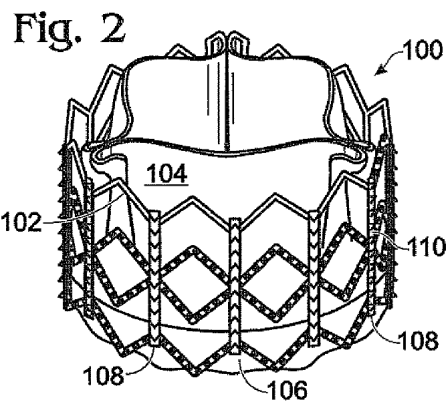
4.2 The opponent also argued that the patent did not provide a sufficient disclosure on how to suture a zig-zag shaped upper edge of a skirt to the third row of circumferential struts, in essence because of the presence of axial struts which would be in the way.

However, Figures 1, 2 and 4 provide such a disclosure, with the sutures passing around the axial struts.

4.3 It follows that the objections of insufficient disclosure raised by the opponent do not prejudice the maintenance of the patent on the basis of the main request (Article 83 EPC).

5. Novelty

The opponent submitted that D7 deprived the subject-matter of claim 1 of the main request of novelty. As regards the claimed prosthetic aortic valve, it made reference to Figure 2 of this document, which is reproduced below.



D7 discloses a membrane support (106) with a skirt on the exterior and a thinner ribbon on the interior, for sandwiching a flexible membrane (paragraph [0044]). It also discloses that the membrane support can be affixed to an annular frame (102).

However, there is no direct and unambiguous disclosure of an upper edge of a skirt member having a zig-zag pattern. Contrary to the opponent's arguments, it is not derivable from Figure 2, in part due to the schematic nature thereof, how the skirt member is attached to the annular frame and where the skirt member ends in the axial direction of the annular frame. The opponent's argument that the figure showed lines of the leaflet structure covered by a skirt member in the area below a third row of circumferential struts is not convincing. While on the left of the figure such lines appear not to extend below the third row of struts, on the right of the figure they do appear to do so. What the pattern on the circumferential struts indicates is not directly and unambiguously derivable either, in the absence of any further disclosure in the description.

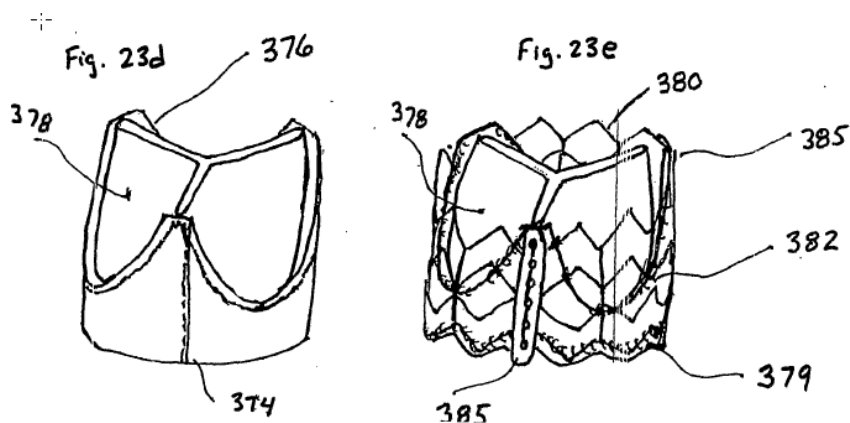
Moreover, D7 does not disclose a leaflet structure with a scalloped lower edge portion. This is not derivable

from Figure 2 or its disclosure of flexible membrane 104 (a leaflet structure within the meaning of the claim). The opponent's submission that the leaflet structure inherently had a scalloped lower edge portion since native aortic valves had this shape, is an unsubstantiated statement. The last sentence of paragraph [0052] of D7, referred to by the opponent and mentioning leaflets and commissures, describes the upper edge portion of the leaflet structure.

It follows that the subject-matter of claim 1 of the main request is novel over D7 (Article 54(1) and (2) EPC).

6. Inventive step

6.1 The opponent raised an objection of a lack of inventive step of the subject-matter of claim 1 of the main request starting from D1. It referred to Figures 23d and 23e of D1, which are reproduced below.



It is common ground that D1 discloses an assembly for implanting a prosthetic aortic valve in a native aortic valve of a patient's body (Figure 4 and page 24, third paragraph), comprising a delivery catheter with an inflatable balloon and the prosthetic aortic valve

(page 20, last paragraph). The prosthetic aortic valve is configured to be radially collapsible and expandable (page 23, first sentence).

As the opponent argued, according to the embodiment depicted in Figures 23d and 23e, the prosthetic aortic valve comprises an annular frame (support construction 380) with commissure attachment posts (385), axial struts and rows of circumferential struts with struts arranged in a zig-zag pattern; a leaflet structure (378) with a scalloped lower edge portion, three leaflets and three commissures attached to the commissure attachment posts (385); and an annular skirt member (374) between the annular frame and the leaflet structure and to which the scalloped lower edge portion of the leaflet structure is attached.

The subject-matter of claim 1 of the main request differs from the disclosure of D1 in that an upper edge of the skirt member has a zig-zag shape that generally follows the zig-zag pattern of, and is attached with sutures to, the third row of struts. According to D1, as can be seen in Figure 23e, the skirt member is punctually joined with sutures at different circumferential rows of struts, following the line at which the skirt member is joined to the leaflet structure.

As the proprietor submitted, this distinguishing feature has the technical effect that the skirt member can be more tightly secured to the annular frame (because the upper edge of the skirt member generally follows the path of the elements to which it is sutured - paragraph [0033] of the patent).

This solves the objective technical problem of providing a more durable assembly. The problems of providing a more stable coupling or reducing the amount of fabric required to provide the skirt member, as submitted by the opponent, are not acceptable as they do not follow from the technical effect of the distinguishing feature. The more stable coupling is the technical effect of the distinguishing feature, while the amount of fabric required to provide the skirt member depends on its total surface, not on its particular shape.

D1 does not address the objective technical problem. Whether it discloses that the shape of the skirt member could be varied in some cases or that the skirt is joined along a zig-zag pattern to a first row of circumferential struts at the inflow end of the frame is of no relevance in this respect.

D2 (Figure 5A), D3 (Figure 1B), D4 (Figure 6) and D5 (Figure 7), which were referred to by the opponent, all disclose a skirt member with an upper edge having a zig-zag shape. However, none of these documents provide any incentive to implement such a skirt member in the assembly of D1 in order to solve the objective technical problem.

In this respect, it is of little relevance whether the person skilled in the art would have had technical difficulty in modifying the attachment between the skirt member and the frame of D1 in the way defined in claim 1 of the main request, in the absence of any hint to do so. Nevertheless, the Board notes that, as the proprietor observed, the skirt member in Figures 23d and 23e of D1 extends to and is attached to the commissure attachment posts at an uppermost row of

circumferential struts. Keeping the attachment to the uppermost row of circumferential struts at the commissure attachment posts, which seems to be necessary to ensure that the valve according to D1 works correctly, would not result in an upper edge of the skirt member having a shape that generally follows the zig-zag pattern of the third row of struts (as defined in present claim 1). The deviation from the pattern of the third row of struts at the commissure attachment posts would be too great for the person skilled in the art to consider that the shape of the skirt member would still generally follow the zig-zag pattern of the third row of struts within the meaning of claim 1 of the main request.

It follows that the subject-matter of claim 1 of the main request is inventive when starting from D1 (Article 56 EPC).

6.2 The opponent also argued that the subject-matter of claim 1 of the main request was not inventive when starting from D3, D4, D5 or D7.

None of these documents discloses an upper edge of the skirt member attached with sutures to a third row of circumferential struts within the meaning of claim 1.

As observed by the proprietor, the figures of D3, D4 and D5 referred to by the opponent disclose an attachment to a row which is not adjacent to the second row of circumferential struts as in the case of the third row defined in claim 1 of the main request.

Moreover, none of D3, D4, D5 and D7 disclose a leaflet structure having a scalloped lower edge portion secured to an inner surface of a skirt member.

None of paragraph [0026] of D3, the disclosure of "bioprosthetic" leaflets of D4 and the disclosure of a "harvested natural valve" in D5, referred to by the opponent, imply a leaflet structure for a prosthetic aortic valve having a scalloped lower edge portion. The opponent's argument in this respect is an unsubstantiated statement.

These distinguishing features have the technical effects that the skirt member can be more tightly secured to the annular frame (because the upper edge of the skirt member has an upper edge that generally follows the path of the elements to which it is sutured, proximate the outflow end of the frame) and stresses on the leaflets are reduced (because of the scalloped geometry - paragraph [0028] of the patent).

This solves the objective technical problem of providing a more durable assembly. The problem of reducing the crimping profile of the prosthesis, as submitted by the opponent, is not acceptable as it does not follow from the technical effects of the distinguishing features.

D3, D4, D5 and D7 do not address the objective technical problem. Hence, the person skilled in the art would not have found any incentive in these documents to implement the distinguishing features in their prosthetic aortic valves in an obvious way. D1, D6, D9 and D13, which were cited by the opponent, do not address the objective technical problem either, and it is not apparent why the person skilled in the art would have considered them at all when starting from D3, D4, D5 or D7.

It follows that the subject-matter of claim 1 of the main request is inventive when starting from D3, D4, D5 or D7 (Article 56 EPC).

7. In conclusion, none of the opponent's objections prejudices the maintenance of the patent on the basis of the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division with the order to maintain the patent as amended in the following version:
 - claims 1 to 16 of the main request ("Claim set B") as filed on 28 January 2022
 - description and drawings of the patent specification.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated