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**Datasheet for the decision
of 22 March 2024**

Case Number: T 1928/22 - 3.2.01

Application Number: 19154572.2

Publication Number: 3498226

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
PROSTHETIC HEART VALVE

Patent Proprietor:
Edwards Lifesciences Corporation

Opponents:
1. Meril GmbH
2. Abbott Cardiovascular Systems Inc.
3. Meril Life Sciences Pvt Ltd.

Headword:

Relevant legal provisions:
RPBA 2020 Art. 12(4)
EPC Art. 76(1), 83, 84, 56

Keyword:

Amendment to case - amendment admitted (yes) - amendment
overcomes objection (yes)
Divisional application - subject-matter extends beyond content
of earlier application (no) - after amendment
Sufficiency of disclosure - (yes)
Claims - clarity after amendment (yes)
Inventive step - main request (yes) - non-obvious combination
of known features

Decisions cited:

Catchword:



Beschwerdekammern

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Case Number: T 1928/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 22 March 2024

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
14 June 2022 concerning maintenance of the
European Patent No. 3498226 in amended form.**

Composition of the Board:

Chairman G. Pricolo

Members: A. Wagner

A. Jimenez

Summary of Facts and Submissions

I. The appeals by the patent proprietor and the opponent 1 are directed against the decision of the opposition division to maintain European patent No. 3 498 226 in amended form on the basis of auxiliary request 2 filed during the oral proceedings.

II. The patent in suit was filed as a divisional application based on the international application published as WO 2012/048035 A2. In its decision, the opposition Division held among others that the main request (patent as granted) and auxiliary request 1 contravened the requirement of Article 76(1) EPC. Regarding auxiliary request 2, the opposition division found that none of the objections raised under Articles 76(1), 83, 84 and 56 EPC was prejudicial to the maintenance of the patent in amended form.

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

D1: WO 2012/048035 A2 (international publication of the parent application)

D7: WO 2009/042196 A2

D8: US 2006/0259136 A1

D15: US 2005/0283231 A1

D16: US 2006/0259137 A1

D17: WO 2009/149462 A2

D24: US 2010/0168844 A1

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

IV. Oral proceedings were held before the Board on 22 March 2024.

V. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request, filed as auxiliary request 88 with the reply to the opponent 1's statement of grounds of appeal.

The appellant (opponent 1) requested that the decision under appeal be set aside and the patent be revoked.

The party as of right (opponent 2) did not submit any comments or requests and informed the Board with letter dated 8 February 2024 that they will not attend the oral proceedings.

The intervention was withdrawn.

VI. Claim 1 of the main request on file reads as follows (feature numbering according to the impugned decision and complemented by the Board):

1. An assembly for implanting a balloon-expandable prosthetic aortic valve (10) in a patient's body, the assembly comprising:

1.1 a delivery apparatus comprising an elongated shaft (180) having an inflatable balloon (182), and

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

1.2.1 a balloon-expandable annular frame (12) having an inflow end portion and an outflow end portion;

1.2.2 a leaflet structure (14) positioned within the frame (12),

1.2.2.1 the leaflet structure (14) comprising a plurality of commissure portions; and

1.2.3 an annular inner skirt (16) positioned along an inner surface of the frame (12), the inner skirt (16) being secured by suturing to the inside of the frame (12);

1.2.4 characterized in that the frame (12) comprises a plurality of angularly spaced commissure windows (30) each comprising an enclosed opening (20) between first and second axially oriented side struts (31), wherein the plurality of commissure portions extend outwardly through respective commissure windows (30);

1.2.4.1 wherein the leaflet structure (14) comprises a plurality of leaflets (40) each comprising two opposing side tabs (366), each side tab (366) being paired with an adjacent side tab (366) of an adjacent leaflet (40) to form the commissure portions of the leaflet structure (14), wherein each commissure portion extends radially outwardly through a corresponding commissure window (30) of the frame (12) to a location outside of the frame (12) and is sutured to the side struts of the commissure window (30);

1.2.5 wherein the prosthetic aortic valve (10) further comprises an annular outer skirt (18) positioned around an outer surface of the frame (12),

1.2.5.1 the outer skirt (18) comprising an inflow edge (160) secured by suturing to an inflow edge of the inner skirt (16) at the inflow end portion of the frame (12),

1.2.5.2 an outflow edge (162) secured by suturing to the frame (12) at a second location, and

1.2.5.3 an intermediate portion between the inflow edge and the outflow edge;

1.2.6 wherein when the prosthetic aortic valve (10) is in the expanded configuration, the intermediate portion of the outer skirt (18) comprises slack in the axial direction between the inflow edge of the outer skirt (18) and the outflow edge of the outer skirt (18), and

1.2.7 when the prosthetic aortic valve (10) is collapsed to the collapsed configuration, the axial distance between the inflow edge (160) of the outer skirt (18) and the outflow edge (162) of the outer skirt (18) increases, reducing the slack in the outer skirt (18) in the axial direction,

1.2.8 wherein the outflow edge (162) of the outer skirt (18) comprises a plurality of alternating projections (164) and notches (166), the projections (164) being secured by suturing to the frame (12) at the second location, the outer skirt (18) being unsecured to the frame (12) at the notches (166).

VII. The appellant's (opponent 1's) arguments relevant to the present decision may be summarized as follows:

Admittance of the main request

The main request, filed as auxiliary request 88 with the patent proprietor's reply, should not be admitted under Article 12(6) RPBA. In appeal, there was no change in the opponent 1's pleading that could justify new auxiliary requests.

Furthermore, the primary object of the appeal proceedings was to review the impugned decision. However auxiliary request 88 was not part of that decision.

Added subject-matter

The subject-matter of claim 1 extended beyond the content of the parent application for several reasons:

a) Feature 1.2.3 allegedly was based on paragraph [064] of D1. However, paragraph [064] did not refer to an "annular" inner skirt. An "annular" inner skirt was defined in paragraph [019] or claim 22 of D1, but only in combination with a weave of non-parallel strands. Also in the context of paragraphs [064] to [067] or in claim 1 of D1 the inner skirt was always disclosed as being a fabric.

b) Features 1.2.5 to 1.2.8 allegedly found basis in original claims 13 and 14 of D1. Therein it was disclosed that the inflow edge of the outer skirt was secured "to" the frame at a first location. The word "to" required a direct attachment to the frame. However, the wording of feature 1.2.5.1 required no longer a direct attachment.

c) Feature 1.2.5.1 concerning the inflow edge of the outer skirt was taken from paragraph [083] of D1. This paragraph referred to a specific outer skirt shown in figures 41 to 43 disclosing the outer skirt only in

combination with a straight lower edge.

d) Also the amendment in feature 1.2.8 "by suturing" - concerning the outflow edge of the outer skirt - was taken from paragraph [083] according to which the projection 164 sutured to the second rung II of struts of the frame 12 and with the corners 162 of the projections 164 folded over respective struts of rung II. All these features were missing in claim 1.

e) Feature 1.2.1 - defining an inflow and an outflow end portion of the frame 12 - added subject-matter as the essential feature from paragraph [008] "*The outer diameter of the inflow end portion of the frame is smaller than the outer diameter of the outflow end portion of the frame.*" was missing.

f) New feature 1.2.4.1 concerning the tabs of the leaflet structure was not disclosed in combination with an outer skirt having slack. Basis for feature 1.2.4.1 was paragraph [074] of D1. At the one hand, this paragraph was not concerned with an outer skirt. At the other hand, feature 1.2.4.1 was taken out of the context and disclosed in paragraph [074] only in combination with other features which were missing in claim 1.

Sufficiency of disclosure

The invention was not sufficiently disclosed over the entire scope as claim 1 did not specify how the slack as defined in features 1.2.6 and 1.2.7 was achieved. Furthermore the application as a whole failed to disclose sufficient information regarding the material of the outer skirt.

Clarity

By adding the wording "*by suturing*" in feature 1.2.8, claim 1 was rendered unclear. Claim 1 lacked essential features to allow the projections to be sutured to the frame.

Inventive step

D24 and D7 disclosed all the features added by the amendments made to claim 1 of the main request. The discussion was thus the same as in the impugned decision, point 27. The conclusion of the opposition division that the subject-matter of claim 1 as granted involved an inventive step starting from D24 or from D7 was wrong. The features of claim 1 did not have a synergistic effect. Instead, claim 1 merely represented an aggregation of features which were all obvious.

D24 with common general knowledge or D7:

In a first line of attack, claim 1 differed from D24 (figures 5, 6, 7) only in feature 1.2.5.1 ("sutured"). The inner skirt was disclosed by the portion of the outer skirt that was wrapped around the inflow end of the frame as described in paragraph [070]. Feature 1.2.5.1 was well known from the skilled person's common general knowledge or from D7, figure 15B, and therefore an obvious alternative.

A second line of attack concerned the reinforcement structure 36 of the leaflet structure (figure 5) having the function of an inner skirt as described in paragraph [046], last sentence and paragraph [058] of D24. Alternatively or in addition to the reinforcement structure, an inner skirt, which was well known in the

prior art, could easily be provided and attached to the frame by the skilled person.

D7 with common general knowledge or D24, D8, D15, D16 or D17:

Starting from figure 15A of D7, the only distinguishing features of claim 1 were features 1.2.5.2 and 1.2.8 requiring projections and notches at the outflow edge of the outer skirt with the projections being sutured to the frame. Feature 1.2.8 implied feature 1.2.5.2. Feature 1.2.8 solved the problem of providing an alternative design for the outer skirt. However, the claimed design for the outer skirt was known from D24 (figures 7 or 10), D8 (figure 3B), D15 (figures 39G), D16 (figure 6A) or D17 (figure 16).

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

Admittance of the main request

The main request filed as auxiliary request 88 in appeal was not entirely new. The individual amendments, which all addressed different objections of the opponent, were already introduced in the first instance proceedings with letter dated 2 March 2022. Therein (page 20, last paragraph) it was already stated that for procedural efficiency no explicit claim sets for all possible combinations were submitted.

Added subject-matter

ad a) The wording of feature 1.2.3 was based on paragraph [064] of D1. That the inner skirt was

"*annular*" was taught throughout the whole application. The materials proposed for the inner skirt were all presented as "*desirable*" (paragraph [063]).

ad b) Features 1.2.5 to 1.2.8 were based on claims 13 and 14 and paragraph [083] of D1. The subject-matter of claims 13 and 14 and paragraphs [083] was shown in the embodiment of figures 42 to 43. Therefrom it became clear that the wording "*secured to the frame*" of claim 13 included the meaning of an indirect attachment of the inflow edge of the outer skirt according to feature 1.2.5.1.

ad c) The fact that the wording of claim 13 "*secured to the frame*" was replaced by the more restricted wording of feature 1.2.5.1 did not create a functional or structural link to the feature "*straight lower edge*" of the outer skirt.

ad d) The only amendment to the original wording of claim 14 was to specify in feature 1.2.8 that the projections of the outer skirt were secured "*by suturing*". However the sutures were neither linked to the specific frame design nor to the specific location at the frame (second rung II of struts) nor to the specific way of folding the corners of the projections over respective struts. All these features were presented as being optional in paragraph [083] ("*can*").

ad e) Feature 1.2.1 was already part of original claim 1 without further details concerning the diameters as specified in paragraph [008]. The opponent 1's objection was a clarity objection.

ad f) Feature 1.2.4.1 was based on original claim 4 of D1. The combination of feature 1.2.4.1 and an outer

skirt having slack was directly derivable from the embodiment shown in figures 42 and 43.

Sufficiency of disclosure

By providing a prosthetic heart valve as described in the patent in suit the skilled person would immediately arrive at a prosthetic heart valve with all the features required by granted claim 1. How the slack was realized was described in paragraph [0060] of the patent in suit. With regard to the material reference was made to paragraph [0059].

Clarity

The objection raised by the appellant (opponent) was not caused by the amendment "*by suturing*" in feature 1.2.8.

Inventive step

D24 with common general knowledge or D7:

Features 1.2.3, 1.2.4.1 and 1.2.6 to 1.2.8 were not disclosed in D24. In particular, D24 did not disclose an inner skirt at all. There was no hint for the skilled person - neither from common general knowledge nor from D7 - to provide an inner skirt to the specific prosthetic heart valve of D24.

D7 with common general knowledge or D24, D8, D15, D16 or D17:

The embodiment of figure 15A was not an appropriate starting point as it did not show a balloon-expandable annular frame. Furthermore, the combination of features

1.2.5.1 with 1.2.5.2 and of features 1.2.3 with 1.2.5 as well as features 1.2.6 to 1.2.8 were not disclosed. In particular feature 1.2.8 could not just be seen in isolation, cherry-picked out of a specific disclosure and implemented in any heart valve without affecting other features of this heart valve.

Reasons for the Decision

1. Admittance of the main request

1.1 The main request was filed for the first time as auxiliary request 88 with the reply to the opponent 1's statement of grounds of appeal. The Board exercised its discretion under Article 12(4) and (6) RPBA and admitted the main request into the proceedings.

1.2 In the present case, even though the specific combination of the individual amendments was not submitted before, numerous objections of added subject-matter were raised by the opponents in opposition proceedings, and for each of these objections individual amendments, representing individual fall back positions, were submitted by the patent proprietor.

Under these circumstances the Board considered that the patent proprietor was justified in not filing auxiliary requests for all possible combinations of individual amendments already in opposition proceedings, and in filing the main request including a specific combination of individual amendments with the reply to the opponent 1's statement of grounds of appeal. This was the earliest point in time at which the patent proprietor was made aware of what objections of added subject-matter, among all that were previously raised,

were maintained in appeal by the opponents. Furthermore, the main request complies with needs of procedural economy, by rendering unnecessary the discussion of several issues of added subject-matter in connection with the patent as granted. It also does not add complexity to the case as claim 1 is based on claim 1 of auxiliary request 2 as maintained by the opposition division, further restricted by feature 1.2.4.1 which was recited in granted claim 5. Also, it allows the Board to take the positive assessment of inventive step in respect of claim 1 of auxiliary request 2 by the Opposition Division as a suitable basis for reviewing the decision under appeal in that context.

2. Added subject-matter

- 2.1 The main request meets the requirements of Article 76(1) EPC.
- 2.2 The appellant (opponent 1) raised objections regarding
 - a) feature 1.2.3 defining an annular inner skirt;
 - b) features 1.2.5 to 1.2.8 compared to original claims 13 and 14 of D1;
 - c) feature 1.2.5.1 compared to paragraph [083] of D1;
 - d) feature 1.2.8 with regard to paragraph [083] of D1,
 - e) feature 1.2.1 compared to paragraph [008] of D1, and
 - f) feature 1.2.4.1 compared to paragraph [074] and original claim 4 of D1.
- 2.3 ad a)
 - 2.3.1 Feature 1.2.3 finds a basis in paragraph [064] of D1, first sentence, reciting "*The [inner] skirt 16 can be secured to the inside of frame 12 via sutures 70*".

2.3.2 The appellant (opponent 1) was of the opinion that in paragraphs [063] to [067], the inner skirt was only disclosed in combination with a fabric material. Additionally, an "annular" inner skirt was only disclosed in paragraph [019] with a non-parallel weave.

2.3.3 The Board is not convinced. That the inner skirt is "annular" is not linked to any specific skirt material but taught throughout the application for all embodiments of the inner skirt (see e.g. figures 2, 19A, 19B, 20, 32, 37, 39, 42). In paragraph [063] it is generally disclosed that "*the inner skirt 16 desirably comprises a tough, tear resistant material such as polyethylene terephthalate (PET), although various other synthetic or natural materials can be used.*" The original disclosure therefore provides a basis for an annular inner skirt without the restriction to a specific material. The fabric material is mentioned with regard to inner skirts of the prior art (paragraph [065]). D1 further teaches that in case the skilled person wants to use a fabric as known from the prior art, it is "*desirable*" to use a non-parallel weave (paragraph [067]). None of these materials is presented as being inextricable linked to an annular inner skirt sutured to the inside of the frame.

2.4 ad b)

2.4.1 Features 1.2.5 to 1.2.8 find literal basis in claims 13 and 14 together with paragraph [083] of D1 for feature 1.2.5.1.

2.4.2 Contrary to the appellant's (opponent 1's) opinion the wording of original claim 13 "*secured to the frame at a first location*" does not necessarily imply a direct

attachment of the inflow edge of the outer skirt to the frame.

Claims 13 and 14 refer to the outer skirt with projections and notches at the outflow edge. This embodiment is undoubtedly described in paragraphs [083] and [084] and shown in figures 41 to 43 of D1.

For the inflow edge of the outer skirt, paragraph [083] describes with reference to figure 42, that the lower edges of the inner and outer skirts are sutured to each other as defined in feature 1.2.5.1. The inflow edge of the inner skirt is secured to the frame (sutures 70 in figure 40). Therefrom the skilled person understands that feature 1.2.5.1 describes a more specific, i. e. limiting, embodiment of the more general, original claim wording "*secured to the frame at a first location*".

2.4.3 Consequently, the indirect securing by suturing the inflow edge of the outer skirt to an inflow edge of the inner skirt (feature 1.2.5.1) - which in turn is fixed to the frame - falls under the original wording of claim 13.

2.5 ad c)

2.5.1 The specific embodiment defined in feature 1.2.5.1 finds basis in paragraph [083].

2.5.2 Contrary to the appellant's (opponent 1's) opinion, paragraph [083] does not present the embodiment in which the inflow edge of the outer skirt is "*secured by suturing to an inflow edge of the inner skirt (16) at the inflow end portion of the frame (12)*" as being inextricably linked to the straight lower edge of the outer skirt. The paragraph rather lists several

possible design options for the outer skirt, one of them being a straight lower edge.

2.6 ad d)

2.6.1 The amendment "by suturing" in feature 1.2.8 also finds basis in paragraph [083].

2.6.2 Feature 1.2.8 corresponds to the original wording of claim 14 with the wording "*by suturing*" added. Contrary to the appellant (opponent 1's) opinion, this amendment does not create an inextricable link to the specific way of attachment of the projections of the outflow edge to the frame.

Claim 1 is directed to one aspect of the invention concerning the skirt arrangement with an outer skirt comprising slack (paragraphs [015], [083], [084]). The disclosure of D1 includes also another aspect of the invention directed to a specific frame design (paragraphs [054] to [062]). These aspects are independent from each other.

Figures 42, 43 show an embodiment in which both aspects of the invention are realized. However, the specific frame is not linked to the effect of the slack provided by the outer skirt. Thus, the skilled person understands from paragraph [083] that also the specific way of attachment is optional ("*can be sutured to the second rung II of struts*", "*can be folded*").

2.7 ad e)

2.7.1 Feature 1.2.1 finds basis in original claim 1 of D1.

2.7.2 Feature 1.2.1 defines an annular frame with an inflow end portion and an outflow end portion. In original claim 1 of D1, no further details concerning the

diameters as specified in paragraph [008] "*The outer diameter of the inflow end portion of the frame is smaller than the outer diameter of the outflow end portion of the frame.*" were included. The diameters originally were defined in dependent claim 2.

Consequently the inflow end portion and the outflow end portion of the frame and the feature concerning the diameters are not presented as being inextricably linked.

2.7.3 Hence, the objection that allegedly essential features from paragraph [008] were missing is rather related to an issue of clarity rather than added-subject matter.

2.8 ad f)

2.8.1 Feature 1.2.4.1 finds literal basis in original claim 4 of D1. The Board sees no reason to refer to paragraph [074] mentioned by the appellant (opponent 1).

2.8.2 While original claim 4 defined three angularly commissure windows, paragraph [011] of D1 provides basis for the more general wording of feature 1.2.4 "*a plurality of angularly commissure windows*". This is not disputed by the appellant (opponent 1).

2.8.3 The appellant's (opponent 1's) objection that feature 1.2.4.1 was originally not disclosed in combination with the outer skirt comprising slack is not convincing. The embodiment shown in figures 42 and 43 of D1 shows all features of the prosthetic heart valve defined in claim 1 in combination.

2.9 Consequently, the subject-matter of claim 1 of the main request does not extend beyond the content of D1.

3. Sufficiency of disclosure

- 3.1 The main request meets the requirements of Article 83 EPC. The patent as a whole provides sufficient information to the skilled person to put the claimed assembly into practice.
- 3.2 The appellant (opponent) argued that without further defining the attachment of the outer skirt in claim 1 and without giving more information about the material of the outer skirt, the skilled person was not able to provide a prosthetic heart valve with the slack defined in features 1.2.6 and 1.2.7.
- 3.3 The Board is not convinced. As acknowledged by the appellant (opponent 1), outer skirts are commonly used for heart valves to prevent paravalvular leakage. Therefore also materials for these skirts are generally known by the skilled person and even mentioned in paragraph [0059] of the patent in suit. Providing a slack is a question of size and geometry of the outer skirt as shown e.g. in figure 41 to 43 and described in paragraph [0059, 0060] of the patent in suit and not a question of material.
- 3.4 Concerning the attachment, the patent teaches to suture the projections of the outflow edge 162 of the outer skirt to the frame as shown e.g. in figures 1 to 3, 42 or 43 and to suture the inflow edge 160 of the outer skirt to the inflow edge of the inner skirt at the inflow portion of the frame as shown in figure 42. The skilled person is able to dimension the outer skirt such that there is excess material between the outer skirt's lower and upper edges 160, 162 without undue burden.

4. **Clarity**

4.1 The main request meets the requirements of Article 84 EPC.

4.2 The objection concerns feature 1.2.8 which was already included in claim 1 as granted - except that it is now specified that the projections are secured "*by suturing*" to the frame. This amendment is taken from the description (paragraph [083]) and was also included in auxiliary request 2 as maintained by the opposition division.

4.3 The appellant (opponent 1) argued that claim 1 lacked essential features to suture the projections to the frame. The frame had to have a specific design at the second location which allowed for implementation of feature 1.2.8.

4.4 However, the Board confirms the findings of the opposition division (impugned decision, point 26) that this potential lack of clarity is not a consequence of the amendment "*by suturing*" but was already inherent in the wording as granted ("*projections secured to the frame*").

5. **Article 56 EPC**

5.1 The Board confirms the opposition division's findings that the subject-matter of claim 1 - even without feature 1.2.4.1 which was added to claim 1 as maintained by the opposition division - involves an inventive step.

5.2 D24 with common general knowledge or D7

- 5.2.1 The argumentation of the appellant (opponent 1) is based on the embodiment shown in figures 5, 6, 7 and 10 of D24. This embodiment discloses a prosthetic aortic heart valve with a leaflet structure (*"replacement valve 30"*) comprising a commissural tab region 35 and a reinforcement structure 36 (paragraph [0046]). The frame (*"valve support structure 24"*) is shown in figure 6 with commissure windows (*"axially extending slots 44"*, paragraph [0050]). An outer skirt (*"valve cuff 26"*) is shown in figure 7 and includes a skirt 60 and a flange 62. Paragraph [0070] further describes that the *"skirt 60 of valve cuff 26, which is positioned circumferentially around inflow rim 41 of valve support structure 24, may then be wrapped around the proximal inflow end 31 of replacement valve 22 and attached to the valve with, for example, sutures."*
- 5.2.2 Claim 1 differs from D24 at least in features 1.2.3 and 1.2.5.1, both referring to the inner skirt which is not disclosed in D24. An inner skirt is not rendered obvious when starting from D24, figures 5 to 7 and 10.
- 5.2.3 An inner skirt has, inter alia, the function to avoid contact between the valve leaflets and the frame and to avoid perivalvular leakage. In D24, the function of the inner skirt is integrated in the valve body 30 reaching from the commissure windows 44 down to the inflow rim 41 of the frame. The reinforcement structure 36 at the inflow end 31 of the valve body (figure 5) is attached to the inflow rim 41 of the frame (paragraph [0050]). Such an arrangement without an inner skirt is made possible because of the frame design (figure 6) not having any lattice structure between the outflow rim 43 and the inflow rim 41.

The prosthetic heart valve of D24 has thus a specific design that makes an inner skirt redundant. The function of the inner skirt to block the flow of blood through the open cells of the frame below the lower edge of the leaflets (perivalvular sealing, see also paragraph [0038] of the patent in suit) is taken over by the leaflet structure ("*replacement valve 30*") itself and by suturing the outer skirt 60 to the inflow end 31 of the valve body.

In the absence of any recognizable advantage, the skilled person would have no motivation to add an inner skirt.

5.2.4 In a first line of attack, the appellant (opponent 1) acknowledged feature 1.2.5.1 ("*sutured*") as not being disclosed in D24, but argued that the inner skirt was disclosed by the portion of the skirt 60 that was wrapped around the inflow end of the frame according to paragraph [0070].

The underlying problem was to provide an alternative skirt.

However, it was just an equivalent and obvious change for a skilled person to provide two parts for the inner and outer skirt which were sutured together at their inflow edges to provide an alternative skirt, e.g. to allow the use of two different materials or thicknesses for the two skirts.

Feature 1.2.5.1 was also rendered obvious by D7, figure 15A with paragraphs [0112, 0125], showing an inner and outer skirt sutured together at their inflow edges as a mere design choice. The skilled person got from D7 an inspiration to slice the skirt into two pieces as this allowed the adaptation of the sections for their specific purpose of avoiding peri- and paravalvular

leakage.

5.2.5 The Board is not convinced. First, the wrapping around of skirt 60 in D24 serves to attach the outer skirt at the inflow edge to the valve and to seal the inflow of the valve prosthesis. This does not change the teaching of D24 that no inner skirt is provided. The skilled person would not provide a skirt 60 and an additional part that is sutured to the inflow edge of skirt 60 simply to attach the outer skirt to the valve.

Second, in D24, paravalvular leakage is explicitly addressed in paragraph [0062] and avoided by flange 62. Perivalvular leakage (at the inside, between leaflets and frame) is avoided by the replacement valve 22 (figure 5) and by attaching the outer skirt to the valve body 30.

Should the skilled person wish to use different materials at the inside and the outside to avoid leakage, D24 would allow that by selecting different materials for the flange 62, the skirt 30 and the reinforcement structure 36. There is no need to cut the skirt 60 in two pieces.

Third, even if the wrapped around part of skirt 60 was considered as an inner skirt, it was still not obvious to modify the "made in one piece"-solution of D24. Such a modification would make the manufacturing of the prosthesis more time-consuming and more costly. The Board agrees with the appellant (patent proprietor) that when for a prosthetic heart valve, a given concept is designed and reliably works, the skilled person would not simply play around like cutting pieces in parts and suturing together without any pointer, or motivation, for doing so.

Also D7 can not render obvious the provision of an inner skirt that is sutured at its inflow edge to an inflow edge of the outer skirt. Even if D7, figure 15A, shows an inner and outer skirt 70/80 sutured together at their inflow edges, the skirt arrangement is not compatible with the skirt arrangement of D24, providing a specific design with harmonised components. Furthermore figure 15A teaches a one-piece buffer/cuff arrangement 70/80 (see also point 5.3.4 below).

- 5.2.6 In a second line of attack, the appellant (opponent 1) argued that feature 1.2.5.1 was disclosed by suturing the skirt 60 to the reinforcement structure 35 of the replacement valve. The reinforcement structure provided the same function as an inner skirt and was simply an equivalent to the inner skirt. There was no technical hindrance to implement an inner skirt.

The Board does not agree as there is no motivation for the skilled person to do so. Possible contact between the frame and the valve leaflets is minimized by the minimalist frame design. Therefore there is no need to add an inner skirt to which the leaflets are secured. The reinforcement structure fits perfectly the needs of the specific prosthetic heart valve of D24.

An additional inner skirt would even be against the teaching of D24 to allow easy valve collapsibility as the additional tissue would increase the diameter of the crimped valve and complicate the collapsing.

- 5.2.7 The appellant (opponent 1) was further of the opinion that claim 1 merely represented an aggregation of features which were all obvious and well known from the common general knowledge. Alone for this reason claim 1 could not involve an inventive step.

The Board does not agree. Even if an inner skirt per se and/or the suturing of inflow edges of inner and outer skirts is known, it is not the question whether or not a specific feature is known from general knowledge or any prior art document. The relevant question is whether or not the skilled person would have considered and combined the respective disclosures. In the present case, the skilled person would not include features 1.2.3 and 1.2.5.1 in the device of D24.

5.2.8 The appellant (patent proprietor) further disputed the disclosure of features 1.2.4.1 and 1.2.6. to 1.2.8 in D24. As features 1.2.3 and 1.2.5.1 already support inventive step over D24, these issues can remain undecided.

5.3 D7 with common general knowledge or with D24, D8, D15, D16 or D17

5.3.1 The argumentation of the appellant (opponent 1) is based on the embodiment shown in figure 15A. This embodiment shows a prosthetic heart valve with a leaflet structure ("*leaflet design 60*", paragraph [0120] and figure 10) and an inner and outer skirt ("*cuff and buffer section 70/80*", paragraph [0125]).

5.3.2 Claim 1 differs from D7 at least in feature 1.2.8 - which is undisputed - and in the combination of features 1.2.5.1 with 1.2.5.2. These features all refer to the outer skirt and involve an inventive step.

5.3.3 The technical effect of the design of the outflow edge of the outer skirt with projections sutured to the frame and notches unsecured to the frame is that the outer skirt fills gaps between the frame and the

surrounding native annulus. The problem to be solved is thus seen in improving paravalvular sealing.

- 5.3.4 Contrary to the appellant's (opponent 1's) opinion, the combination of features 1.2.5.1 and 1.2.5.2 is neither disclosed nor rendered obvious from D7 itself.

It might be true that figure 15A discloses feature 1.2.5.1 (inflow edges of the inner and outer skirts are sutured to each other) and that figure 15B discloses feature 1.2.5.2 (outflow edge of the outer skirt sutured to the frame), however the embodiments of figure 15A and figure 15B are clearly alternatives (paragraph [0125]: "*Figs. 15a-b show two different valve variations that have a few key differences.*"). The skilled person understands that either the one or the other arrangement is applicable.

The statement in the last sentence of paragraph [0125] that "*Any or all of these features can be combined.*" referred to by the appellant (opponent 1) can not be understood as a pointer to combine features 1.2.5.1 and 1.2.5.2.

In figure 15A the buffer 70/80 covers all of the expanding cells of stent portion 40 - shown in figures 5A, 5B. Therefore the buffer 70/80 is wrapped over the expanding cells 40. In figure 15B however, the buffer 70/80 goes half of the way up the stent cells 40 to approximately the bend line 52. Here the buffer is secured to the frame at the outflow edge but wrapped around the frame's inflow end. The teaching of both embodiments described in paragraph [0125] is to provide a one-piece buffer. Nothing in these embodiments teaches to provide an inner skirt separate to the outer skirt which would require the combination of features 1.2.5.1 and 1.2.5.2.

5.3.5 According to the appellant (opponent 1), feature 1.2.8 (projections and notches at the outflow edge of the outer skirt) solved the problem of providing an alternative attachment of the outer skirt. The skilled person would be motivated to modify the cuff of D7 as feature 1.2.8 was generally known and D7 itself disclosed in paragraph [0165] that the "*buffer and cuff material can also be shaped to outline the contour of the expandable stent portion.*" Providing secured projections and unsecured notches at an outflow end of a skirt was generally known e.g. from D24 (figures 7 and 10), D8 (figure 3B), D15 (figure 39G), D16 (figure 6B) or D17 (figure 16). Feature 1.2.8 was therefore obvious or from the general common knowledge or from any one of D24, D8, D15, D16 or D17.

5.3.6 None of these attacks is convincing. D7, paragraph [0165], refers to figure 60 showing a one-piece buffer and cuff material as in figures 15A and 15B. Even if the skilled person may think about an alternative design when reading the last sentence of paragraph [0165] and try to shape the buffer and cuff material to outline the contour of the stent, D7 still does not include any teaching to provide the inner and outer skirt as separate pieces as required by the claim wording.

Feature 1.2.8 might be disclosed in D24, D15 and D16 but as a specific solution in a specific prosthetic valve.

Assuming that in D24, the embodiment shown in figure 10, discloses feature 1.2.8 (which is disputed by the appellant (patent proprietor)), and the skilled person would consider the teaching of D24 to improve paravalvular sealing, the skilled person would add flanges 62, 72 to the already available outer skirt as

D24 discloses that the improvement in sealing is achieved by these flanges (see D24, paragraphs [0015] to [0019]).

D24 may show an outer skirt 70 (figure 10) with a scalloped shape at its outflow edge. However this shape is described as being optional (paragraph [0015]) and is not directly applicable to the embodiment of figure 15A in D7 as the cuff and buffer section 70/80 is made in one piece, provided with through-holes at the common outflow edge for the frame struts. There is no reason why the skilled person would change the design of buffer 80 of D7.

D16 (figure 5) discloses a similar heart valve as D24. Assuming that in D16, the embodiment shown in figure 6A discloses feature 1.2.8, and the skilled person considers the teaching of D16 to improve paravalvular sealing of the device of D7, the skilled person has no motivation to implement the shape of the outflow edge of the outer skirt ("*cuff 37*") of D16 to the device of D7. As in D24, also D16 discloses a second cuff ring 38 additionally to the outer skirt 37 to create a tight seal (paragraph [0105]). To improve e.g. paravalvular sealing, the skilled person would thus only add the cuff ring 38 to the buffer 80 of D7. Furthermore, as in D24, the outer skirt is wrapped around the inflow end of the frame and secured to the valve (paragraph [0105]) and not to an inner skirt.

In D16 as in D24, the outer skirt, the specific frame design (figure 6C) and the valve structure (figure 2) are all adapted to each other to provide a reliable prosthetic heart valve. The appellant 's (opponent 1's) argumentation consists in picking out one single feature from one of the specific elements and apply it to the teaching of D7 and as such is based on hindsight.

Even if the skilled person would consider D16 or D24 and would implement an outflow edge of the outer skirt with projections and notches, neither D7, nor D24 or D16 propose to combine feature 1.2.8 (and thus feature 1.2.5.2) with feature 1.2.5.1 (see also point 5.2.2 above which also applies for D16).

D15, figures 39C-G, shows a specific apparatus wherein the replacement valve 520 is not connected to the expandable portion of the anchor but wrapped about an end of the anchor. Such wrapping may be achieved by everting the valve during endovascular deployment (paragraph 0126]). The alleged outer skirt 528 is an everting segment and an integral part of the valve structure (see figure 39C). There is no reason why the skilled person should pick out a feature of an everting replacement valve and implement it into the device of D7, figures 15A, which already has a cuff to provide a seal.

D8 (figure 3B) and D17 (figure 16) only refer to an inner skirt. D7 itself comprises a similar disclosure for the inner skirt, e.g. in figure 6. Combining D7 with D8 or D17 would not result in adding any feature to the design of the outer skirt.

- 5.3.7 The appellant (patent proprietor) further disputed the disclosure of features 1.1, 1.2.1, 1.2.6 and 1.2.7 as well as the combination of features 1.2.3 with 1.2.5. Since feature 1.2.8 and the combination of features 1.2.5.1 and 1.2.5.2 already involve an inventive step, these issues can remain undecided.

6. Admission of late-filed documents

The appellant (opponent 1) submitted several late-filed documents at different stages of the proceedings. The

appellant (patent proprietor) requested to not admit any of the documents. As all these documents were not relied upon against the main request, there is no need to decide on their admissibility.

7. Description

The appellant (patent proprietor) filed amended paragraphs 11 and 12 of the description. All parties agreed that no further amendments are necessary to the description as maintained by the opposition division.

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:

Description:

- Paragraphs 1-10, 13-39, 41-89 of the patent specification ,
- paragraphs 11 and 12 as filed during the oral proceedings before the Board on 22 March 2024 and
- paragraph 40 as filed during the oral proceedings before the opposition division on 2 May 2022.

Claims:

- No. 1 - 11 according to the main request filed as auxiliary request 88 with the reply to the statement of grounds of appeal on 7 March 2023.

Drawings:

- Sheets 1-26 of the patent specification

The Registrar:

The Chairman:



M. Schalow

G. Pricolo

Decision electronically authenticated