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**Datasheet for the decision  
of 22 June 2023**

**Case Number:** T 0687/21 - 3.2.01

**Application Number:** 15727774.0

**Publication Number:** 3145449

**IPC:** A61F2/24

**Language of the proceedings:** EN

**Title of invention:**

SELF-EXPANDING HEART VALVES FOR CORONARY PERFUSION AND SEALING

**Patent Proprietor:**

St. Jude Medical, Cardiology Division, Inc.

**Opponent:**

Neovasc Tiara Inc.

**Headword:**

**Relevant legal provisions:**

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

**Keyword:**

Novelty - main request (no) - auxiliary request (yes)  
Inventive step - auxiliary request (yes) - non-obvious  
combination of known features  
Sufficiency of disclosure - undue burden (no) - enabling  
disclosure (yes)  
Amendments - extension beyond the content of the application  
as filed (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

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**Case Number: T 0687/21 - 3.2.01**

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.01**  
**of 22 June 2023**

**Appellant:** St. Jude Medical, Cardiology Division, Inc.  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
31 March 2021 concerning maintenance of the  
European Patent No. 3145449 in amended form.**

**Composition of the Board:**

**Chairman** G. Pricolo  
**Members:** A. Wagner  
O. Loizou

## **Summary of Facts and Submissions**

- I. The appeals by the patent proprietor (appellant I) and the opponent (appellant II) are directed against the decision of the opposition division to maintain European patent No. 3 145 449 in amended form on the basis of auxiliary request 1.
- II. In its decision, the Opposition Division held among others that the main request (patent as granted) met the requirements of Article 100 b) and c) EPC, but that the subject-matter of claim 1 was not novel over WO 2012/032187 A1 (D3).  
The objections raised by the opponent under Article 54 EPC and Article 56 EPC were considered not to be prejudicial to the maintenance of the patent on the basis of auxiliary request 1.
- III. In order to come to the latter conclusion the opposition division considered, among others, the following documents:
- D3: WO 2012/032187 A1  
D4: WO 2011/051043 A1  
D5: WO 2009/042196 A2  
D6: WO 2012/040643 A2  
D7: WO 2010/086460 A1  
D8: WO 2014/059064 A1
- IV. Oral proceedings by videoconference were held before the Board on 22 June 2023.
- V. Appellant I (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request), alternatively

that the patent be maintained in amended form on the basis of one of the auxiliary requests 1 to 11 filed with the statement of grounds of appeal or auxiliary request 12 filed with letter dated 21 April 2023.

Appellant II (opponent) requested that the decision under appeal be set aside and the patent be revoked.

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

**1.** A prosthetic heart valve, comprising:

**1.1** a collapsible and expandable stent including a plurality of commissure features and a plurality of struts forming cells, the stent having a proximal end, a distal end, an annulus section adjacent the proximal end, an aortic section adjacent the distal end, and a transition section disposed between the annulus section and the aortic section, the aortic section having a larger diameter than the annulus section;

**1.2** a valve assembly disposed entirely in the annulus section of the stent for controlling the flow of blood through the stent, the valve assembly including a plurality of leaflets, and a cuff,

**1.3** characterized in that the cuff is disposed on a surface of the stent and extends fully over at least two rows of cells of the stent and the at least two rows of cells include a first row and a second row,

**1.4** the second row having a plurality of primary cells and a plurality of undersized cells that are smaller than the primary cells,

**1.5** each of the primary cells being disposed directly below one of the commissure features of the stent.

Claim 1 of **auxiliary request 1** comprises additionally the feature of granted claim 3 as follows:

**1.6** wherein the cuff is disposed about an abluminal surface of the stent.

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

*Sufficiency of disclosure*

Figure 1 showed a prior art heart valve and provided the skilled person with a clear geometric arrangement of a heart valve on which the claimed heart valve is based. The fact that the patent did not comprise a figure showing an embodiment according to claim 1 did not form a ground for insufficiency.

*Added subject-matter*

- Deletions of figures

The opposition division was right in stating that deleting matter could not be regarded as added subject-matter. The originally filed drawings 3A to 13 were obviously wrong and therefore deleted during examination proceedings. To meet the requirements of Article 84 EPC, it was common practice during examination proceedings to delete figures not falling under the claims, unless these embodiments could reasonably be considered to be useful to highlight specific aspects of the subject-matter. The same had to be applied for obviously wrong figures.

- Claim 1 based on parts not forming part of the disclosure

According to Rule 56(4) EPC only the explicit references to the missing figures should be considered non-existing, not the entire paragraphs of the description in which these references were mentioned. The content of these paragraphs, from which feature 1.4 was partly extracted, was always part of the original application published as PCT-application WO 2015/179468 A1.

- Feature "undersized cells smaller than the primary cells"

The wording found a basis in original claim 5 and original paragraph [0031] of the PCT-publication WO 2015/179468 A1 wherein it was clearly defined that an undersized cell was smaller than a primary cell, i.e. a standard cell. Adding the definition that "undersized" meant "smaller than a primary cell" was just a clarification.

*Main request - novelty over D3*

Features 1.3 and 1.4 were not disclosed in D3.

Feature 1.3 required a full extension of the cuff over at least two rows of cells. In figure 1 or figure 5e of D3 it could be seen that the cells of the upper anchoring crown 23 were bent outwards. Neither the skirt nor the leaflets extended fully over the at least two rows of cells as they did not follow the bent portion of the cells of the second row. Additionally, D3 only disclosed the assembled heart valve in the expanded state. Therefore no unambiguous

conclusion was possible whether feature 1.3 was disclosed for a heart valve in a collapsed state. Thus feature 1.3 was not directly derivable, neither for the expanded nor for the collapsed state.

With regard to feature 1.4 the opposition division was wrong in concluding from the schematic drawings (figures 1 or 6) of D3 that the second row (upper crown 23) had a plurality of primary cells (between legs 32, 33) and a plurality of undersized cells that were smaller than the primary cells (outward bent cells in figure 1). A schematic drawing could not be used to derive a ratio between two dimensions. D3 was absolutely silent about the sizes of the cells.

*Auxiliary request 1 - novelty over D3 to D7*

Claim 1 now clearly required that the cuff covered two rows of cells at the abluminal surface of the stent. Claim 1 was novel over D3 as therein it was the cuff at the luminal side that was considered as covering two rows of cells.

D4 (figure 1) did not go beyond the disclosure of D3 and did not unambiguously disclose any cuff extending over two rows of cells of the stent.

D5 (figures 1A and 3B) disclosed an outer cuff 80 fully extending over all cells, thus over all sections of the stent 10, including the aortic section. However, according to feature 1.2 the valve assembly had to be disposed entirely in the annulus section. The same was valid for D6 (figure 1A) and D7 (figure 16f), both disclosing a cuff covering the complete stent.

*Auxiliary request 1 - inventive step*

Starting from D3

Claim 1 differed at least in feature 1.6. Contrary to the appellant's (opponent's) opinion feature 1.6 was not an arbitrary choice. D3, page 19, fourth paragraph, introduced the compromise about adding skirts to obstruct leakage and the thickness relevant for compressing the stent-valve. D3 taught a specific arrangement with regard to this compromise by reducing the overlap of skirts and leaflets to minimize the overall thickness (D3, page 24, fifth paragraph). In contrast, the technical problem in the patent in suit was directed to the balance between an improved paravalvular leakage while guaranteeing coronary perfusion as described in paragraph [0025] of the patent in suit. D3 did not hint to feature 1.6 to solve the problem posed. Changing the cuff arrangement of D3 according to claim 1 would be based on hindsight.

Starting from D8

D8 was not the most promising starting point as the disclosed heart valve had less features in common with the claimed subject-matter than the heart valve shown in D3. D8 at least did not disclose features 1.4 and 1.5. These features had to be seen together with features 1.3 and 1.6. This feature combination had the technical effect of reducing paravalvular leakage due to less-than-perfect placement while maximizing coronary perfusion as described in paragraphs [0001], [0025] and [0026] of the patent in suit. Neither from the common general knowledge nor from one of the documents D3 to D7 the provided solution achieved by the claimed feature combination was rendered obvious.

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

*Sufficiency of disclosure*

The features of claim 1 as well as the description itself were so generic and ambiguous about their actual technical sense that a skilled person had insufficient information on how to put the invention into practice. Without any figures of an actual embodiment of the claimed prosthetic heart valve, the overall structure of the heart valve of claim 1 was so undefined that rework without requiring an inventive step was not possible.

*Added subject-matter*

- Deletions of figures:

As the description explicitly referred to figures 2A to 4B, the patent proprietor deleted means for interpretation for the claimed subject-matter. Cancelling these means of interpretation broadened the overall disclosure beyond the subject-matter as originally disclosed. The opposition division failed to provide any reasons for determining figures 3A to 13 as being wrong. The deletion of these figures added matter to the application as filed.

- Claim 1 based on parts not forming part of the disclosure:

The part of the original description (paragraph [0031] of WO 2015/179468 A1) from which the wording "*smaller than the primary cell*" in feature 1.4 was extracted, did not form part of the original disclosure. The

original paragraphs [0010] to [0015] and [0026] to [0044] of the WO-application all referred to figures not filed. According to Article 14(2) PCT these paragraphs were also to be considered non-existent and thus did not form part of the original disclosure. Claim 1 therefore contravened Article 123(2) EPC.

- Feature "undersized cells smaller than the primary cells":

The amendment taken from the description resulted in an unallowable intermediate generalisation. The feature was taken from a specific embodiment described in original paragraphs [0031, 0032] of the WO-application. In paragraph [0032] the specific configuration was only described with axial struts parallel to a central axis of the heart valve in a transition row between commissure features. Further features described in paragraph [0032] also were inextricably linked to the described embodiment (e.g. group of three cells including a single hexagonal cell and a pair of mirror-image asymmetric cells, diamond shape, etc.).

The opposition division erred in concluding that "undersized" implied "smaller than the primary cell". In original claim 5, incorporated in granted claim 1, no reference was given to which entity "undersized" referred. In original claim 7, the undersized cells of the second row "*are smaller than cells of the first row*". "Undersized" could e.g. refer to any other cells besides the standard cells or to an extension of a row.

*Main request - novelty over D3*

The claim wording of feature 1.3 "*extending fully over at least two rows of cells*" did not require the cuff (skirt) to occlude any of the cells or to follow any bending of cells. Feature 1.3 was disclosed when applying method claim 38 of D3 (see figures 5a and 5b). Additionally it was not defined in which state the cuff had to fully extend over two rows. At least in the collapsed state, in which the cells of the second row were not bent outwards, the inner skirt 35 also occluded the two rows of cells of the stent.

With regard to feature 1.4 reference was made to figure 1 or 6 of D3, wherein it was clearly and unambiguously shown that the cells axially directly below the commissure features 22a had axial and circumferential extensions larger than the neighboring cells. Thus, the second row of cells comprised primary and undersized cells as required by feature 1.4.

*Auxiliary request 1 - novelty over D3 to D7*

D3:

The opposition division was wrong to limit the claim wording "*extending fully over at least two rows of cells*" to an extension in the axial direction. The wording also covered an extension in a circumferential direction. In D3, the outer skirt 34 in figure 6 extended in circumferential direction fully over at least two rows of cells, one row being defined in an axial direction.

Furthermore the claim wording did not exclude an embodiment in which the cuff comprised several layers - as also described in the patent, column 8, lines 51 to 54. The cuff then comprised one layer (inner layer)

disposed according to feature 1.3 and another layer disposed about an abluminal surface. Such an embodiment was disclosed in D3 with the inner skirt 35 extending fully over two rows of cells and the skirt 34 disposed about the abluminal surface of the stent.

D4:

Contrary to the opposition division's opinion features 1.3 to 1.5 were disclosed in D4. The upper anchoring crown comprised primary cells, disposed below the commissure features, and undersized cell, visible in figure 2I. In paragraph [0098], D4 disclosed a cuff 102, 103 fully extending over a lower anchoring crown 4 and an upper anchoring crown 3.

D5:

The opposition division erred in that features 1.1, 1.4 and 1.5 were not disclosed in D5. As could be seen in figure 1A, the second row of cells - being the row positioned in the aortic section 30 - comprised primary cells, disposed below the commissure features 20, and undersized cell. Contrary to the opposition division's opinion, the primary cells were not "above" because by simply turning figure 1A upside down, "above" became "below". In paragraphs [0110, 0111, 0112] an outer cuff 80 fully extending over all cells of the stent 10 was disclosed.

D6:

Contrary to the statement under point 6.4 of the impugned decision, features 1.3 to 1.5 were not lacking in D6. In figure 1A with page 11, third paragraph, D6 disclosed a valve assembly 108 comprising leaflets 128a-c and a cuff, the cuff being disposed over the complete abluminal surface of the stent 104 (see figure 1A "*leaflet membrane entirely*

*exterior/abluminal to frame at all points of attachment*"). A stent structure as claimed was shown in figures 1G and 1H.

D7:

Contrary to the opposition division's opinion features 1.1, 1.2, 1.4 and 1.6 were disclosed.

As regards feature 1.1, D7 disclosed on page 11, lines 32 to 38, that the upper end section (aortic section) spread out further than the lower end section (annulus section).

Figure 7b disclosed primary cells directly below the commissure feature 24 being larger than the undersized cells formed by struts 18a, 16c, 19c and the collar 40.

In figure 16f, the arrangement of the leaflets 102 and the cuff 105 at the abluminal surface was shown. On page 88, lines 27ff, it was described that the cuff may be arranged at the outside to cover the complete exterior of the stent.

*Auxiliary request 1 - inventive step*

Starting from D3

The conclusion of the opposition division that the subject-matter of claim 1 as maintained by the opposition division involved an inventive step starting from D3 was wrong. The cuff per se solved the problem of reducing paravalvular leakage. The effect was reached regardless of the luminal or abluminal placement. The feature added to claim 1 as granted - being the sole distinguishing feature - was an arbitrary design choice without any technical effect and could not justify an inventive step.

Furthermore, D3 itself, page 19, last paragraph taught

to provide an outer skirt to obstruct leakage at the interface with the surrounding tissue. The placement of a cuff at the abluminal surface of the stent was a well known feature.

Alternatively each of the documents D4 to D7 taught the disposal of a cuff on the abluminal surface of the stent to reduce paravalvular leakage.

To avoid the overlap the skilled person would simply provide the inner cuff of D3 at the abluminal surface. The skilled person was able to adapt the shape of the cuff to the shape of the struts.

Starting from D8

D8 could be considered as closest prior art as it required less amount of structural modifications to arrive at the claimed subject-matter. With reference to figure 1 of D8, claim 1 only differed from the heart valve of D8 in features 1.4 and 1.5 (primary cells directly below the commissure features and undersized cells). These features had no technical effect but were an arbitrary design choice. Therefore claim 1 was rendered obvious by common general knowledge. The features were also known from D3 to D7.

## **Reasons for the Decision**

### **1. Sufficiency of disclosure**

- 1.1 The Board confirms the opposition division's view that the patent in suit fulfils the requirements of Article 83 EPC. The objection raised concerns both requests dealt with in this decision.

- 1.2 The appellant's (opponent's) arguments that a skilled person did not know how to put the invention into practice
  - because the features of claim 1 as well as the description itself were so ambiguous about their actual technical sense and
  - because the patent in suit did not show an embodiment according to the claims,are not convincing.
  
- 1.3 The appellant (opponent) pointed to the terms "below", "directly below", "adjacent" and "row". "Below" depended on the orientation of the device, the difference between "adjacent" and "directly below" was not clear, a "row" could extend in a circumferential direction and/or an axial direction and it remained open if the features had to be present in the collapsed or expanded state.
  
- 1.4 The Board does not agree. From the application as a whole the skilled person can retrieve sufficient information about how the heart valve according to claim 1 can be put in practice.
  - 1.4.1 The geometric relationship of the claimed heart valve becomes clear from figure 1, wherein a prior art heart valve - on which the claimed heart valve is based - is shown. Seen together with paragraph [0014] of the patent in suit and the skilled person's knowledge of the anatomy of the heart, the alleged ambiguous wording "below one of the commissure features" clearly refers to the orientation as shown in figure 1, i.e. the in-situ-orientation. Also an annulus section 140 "adjacent" the proximal end 130 and an aortic section 142 "adjacent" the distal end 132 are clear from figure

1.

1.4.2 Furthermore, in the description the term "row" is only described as being an "annular row" (e.g. paragraphs [0017, 0026, 0028]). The skilled person understands from the application as a whole that a row extends circumferentially and that a cuff extending over two rows extends in an axial direction - as found by the opposition division (decision, page 10, last paragraph).

1.4.3 The patent in suit does not include a figure showing an example for the claimed heart valve. However, starting from a prior art heart valve as shown in figure 1, paragraph [0027] describes how an annular row with primary cells and undersized cells can be obtained. According to paragraph [0027] the axial struts between the commissure features - in circumferential direction left/right from the commissure features - have a length that is greater than that of an adjacent commissure feature. As a consequence shortened struts form the upper struts of undersized cells while the standard or primary cells are kept as they are.

1.5 Consequently, the invention is sufficiently disclosed.

## **2. Article 123(2) EPC**

2.1 The Board confirms the opposition division's conclusion that the requirements of Article 123(2) EPC are met. The objection raised concerns both requests dealt with in this decision.

2.2 Contrary to the appellant's (opponent's) argumentation the skilled person would not have considered deleted

figures 3A to 13 as means of interpretation for the claimed subject-matter.

- 2.2.1 It is obvious for the skilled person that the figures 3A to 4B do not belong to the originally filed description published as PCT-application WO 2015/179468 A1. As mentioned by the appellant (patent proprietor), the reference numerals used in original paragraphs [0023] to [0033] were not in accordance with the filed drawings and vice versa. Paragraph [0031] e.g. referred to figure 3B with reference signs 340, 341, 342, 366, 376, 380, 384, 386 while none of these numbers appears in figure 3B of the original application. Furthermore the skilled person recognizes that the described features are not shown in figure 3B, e.g. commissure features 366, cuff 376, standard cells 382a, undersized cells 382b. The same is valid for figures 3A, 4A and 4B which are explicitly mentioned in the originally filed description.
- 2.2.2 As far as figures 3C to 13 are concerned it is noted that none of them are mentioned in the original description and thus could not be used to limit the scope of the claims.
- 2.2.3 Also the argument that the deleted figures were means of interpretation at least in the sense that the skilled person would exclude the shown embodiments from falling within the claimed subject-matter, can not be followed. As mentioned by the appellant (patent proprietor) it is established case law (see Case Law of the Boards of Appeal of the EPO, 10th Edition, Chapter II.A.5.3, third paragraph) that in order to meet the requirements of Article 84 EPC, in particular under the aspect that the claims have to be supported by the

description, drawings inconsistent with amended subject-matter should normally be deleted.

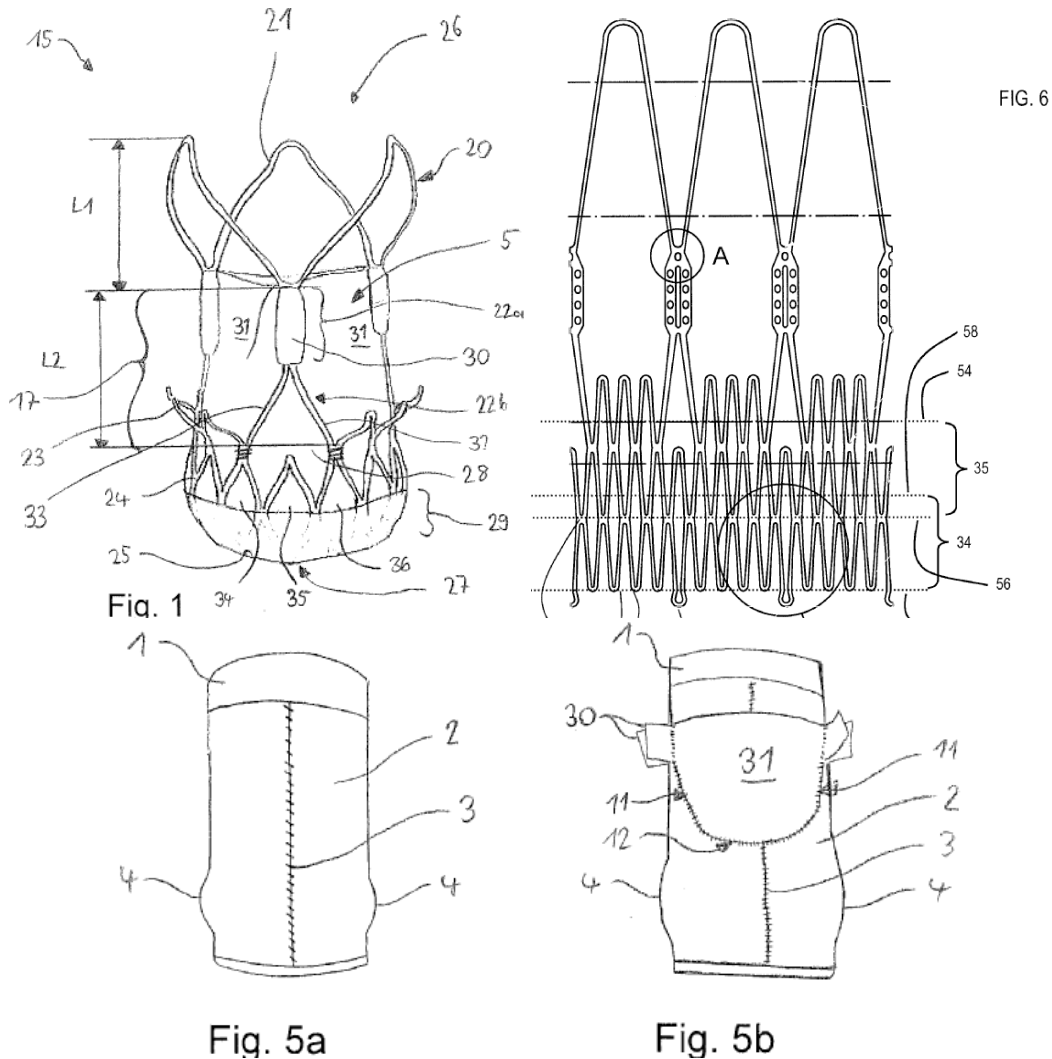
- 2.3 The appellant (opponent) further argued that claim 1 was based on parts of the application not forming part of the disclosure. The Board does not agree.
- 2.3.1 Rule 56 EPC refers - inter alia - to missing drawings. According to Rule 56(4) EPC, the consequence of not having the correct drawings on file is that these drawings were deemed not to have been filed and the references to the drawings in the description were deemed to be deleted.
- 2.3.2 Rule 56(4) EPC is to be understood that only the direct references to the figures are deemed to be deleted - which was actually done during examination. The passages of the detailed description referring to an exemplary embodiment were included in the original application (paragraphs [0010] to [0015] and [0026] to [0044]) and are still part of the disclosure.
- 2.3.3 The same applies mutandis mutatis to the application of Article 14(2) PCT, which relates to missing drawings in international applications and is cited by the appellant (opponent) with regard to the A1-publication WO 2015/179468 of the patent in suit.
- 2.4 The amendment "smaller than the primary cells" in feature 1.4 does not constitute an unallowable intermediate generalisation. Claim 1 as granted combines original claims 1 and 5 and original page 10, last two lines, wherein it is disclosed that the undersized cells may have an area that is "*smaller than that of standard cells*".

- 2.4.1 The original application discloses nothing else than an undersized cell as being smaller than a primary cell. The amendment is thus a clarification of the feature "undersized cell" defined in original claim 5.
- 2.4.2 First of all the skilled person understands from original claim 5 together with paragraph [0031] of the original description that the terms "standard cell" and "primary cell" are used as synonyms.
- 2.4.3 According to paragraph [0031], the "*second annular row includes two types of cells, standard cells and undersized cells*". No other cells are mentioned in this context. Further on it is disclosed that "*Undersized cells 382b, on the other hand, may each have an area that is smaller than that of standard cells 382a*". The teaching of the original application has no basis for any other understanding than that the undersized cell is compared to the standard cell.
- 2.4.4 Also original claim 7, referred to by the appellant (opponent), wherein it is defined that "*the second row having a plurality of undersized cells that are smaller than cells of the first row*" only discloses undersized cells smaller than the standard cells. In the original description, paragraph [0035], it is described that "*in contrast to [the previously described] heart valve 300 in which second annular row 382 has two types of cells (e.g. standard cells 382a and undersized cells 382b), second annular row 482 of heart valve 400 includes only undersized cells 482b.*" Also in this context, nothing else is originally disclosed than undersized cells being smaller than primary cells.

**3. Main request - Article 54 EPC (D3)**

3.1 The Board confirms the opposition division's opinion that claim 1 as granted is not novel over D3.

3.2 Disputed are the features 1.3 and 1.4. For an easier understanding of the following explanations, figures 1, 5a, 5b and 6 of D3 are reproduced below.



3.3 Feature 1.3

3.3.1 D3 discloses with method claim 38, that the leaflets 31 are attached to the tubular skirt 4, the skirt 4 is everted and the obtained valve component 5 is attached

to the stent component 5 (D3, figures 1, 5a, 5b). While with reference to figures 5a to 5e, D3 describes (page 31, last paragraph, to page 32, line 16) that a portion of the pericardium tissue 4 located on the exterior of the leaflets 31 (after eversion) is removed such that the valve component 5 consists of a single layer of pericardium tissue, claim 38 does not require this step. D3 thus discloses embodiments in which the inner skirt 28 extends to the axial height of the commissure feature 22a (figure 1) and therewith fully over two rows of cells. The first embodiment of D3 (figure 1) thus anticipates feature 1.3.

3.3.2 Also the second embodiment (figure 6) discloses feature 1.3. Although figure 6 indicates an extension of the inner skirt 35 between lines 54 and 56 (not fully extending over two rows of cells), page 33, first sentence of the third paragraph, describes in an alternative that the "*inner skirt 35 extends from the commissural posts towards the inflow extremity*".

3.3.3 Contrary to the argument of the appellant (patent proprietor) the wording of feature 1.3 "*extends fully over at least two rows of cells*" does not require occulting or covering the bent-out cells of the second row of cells (D3, figure 1). It is enough that the cuff stretches to the same height as the second row of cells in a non-bent state.

3.3.4 Even if a full coverage was claimed, it is noted that claim 1 does not define in which state the cuff has to fully extend over two rows of cells. D3, figure 6 shows the stent component in a collapsed state (page 37, lines 3, 4). This state corresponds to the state in which the fully assembled heart valve - including the cuff arranged according to page 33, third paragraph -

is implanted. Thus, contrary to the appellant's (patent proprietor's) opinion, D3 discloses also for the collapsed state an inner cuff that fully covers the two rows of cells.

3.4 Feature 1.4

3.4.1 The Board does not follow the appellant's (patent proprietor's) argument that because of the schematic nature of the drawings, feature 1.4 was not disclosed in figure 3 or 6. Instead the Board agrees with the opposition division that the dimensional relationship of cells with respect to each other is derivable from figures 1, 3 and 6 of D3. As pointed out by the appellant (opponent) the present case does not relate to size ratio but rather to relative sizes.

3.5 Consequently, the first embodiment (figure 1) produced according to claim 38 and the second embodiment (figure 6) in the alternative according to page 33, first sentence of the third paragraph, take away novelty of the subject-matter of claim 1 as granted.

**4. Auxiliary request 1 - Article 54 EPC**

4.1 The Board confirms the opposition division's finding that claim 1 as granted is novel over D3 to D7.

4.2 Claim 1 of auxiliary request 1 additionally requires that "*the cuff is disposed about an abluminal surface*" (feature 1.6).

4.3 The Board understands claim 1 in the same way as the opposition division did (impugned decision, point 6.1). Claim 1 defines a cuff at the abluminal surface extending in an axial direction over two rows of cells.

- 4.3.1 The Board does not follow the appellant's (opponent's) claim interpretation that the cuff may extend in a circumferential direction over two rows of cells. A prosthetic heart valve typically comprises a circular, lattice-like stent component as defined in feature 1.1. It is common for these prosthetic heart valves that a cuff surrounds the stent component and extends in an axial direction. The skilled person would exclude the appellant's (opponent's) claim interpretation as being inappropriate.
- 4.3.2 The Board also does not follow the appellant's (opponent's) argument that the claim included a cuff comprising a first layer according to feature 1.3 and a second layer according to feature 1.6. The appellant (opponent) based their argument on the use of the indefinite article "*disposed about **an** abluminal surface*" in feature 1.6, on claim 2 according to which the cuff could also be supposed on a luminal surface and on paragraph [0038] wherein the cuff may include two layers disposed at the the two different surfaces.
- 4.3.3 As argued by the appellant (patent proprietor) feature 1.2 of claim 1 requires a cuff, which is further defined in features 1.3 and 1.6 by referring back to "the cuff". Consequently the cuff at the abluminal surface is the one that fully extends over two rows of cells.
- 4.3.4 The indefinite article used for the abluminal surface is used because no abluminal surface is introduced before in the claim.
- 4.3.5 Claim 2 of auxiliary request 1 unambiguously defines a "further" disposal of the cuff on a luminal surface - additionally to the cuff as defined in claim 1. In the

same sense, paragraph [0038] of auxiliary request 1 was adapted during opposition proceedings by clarifying that the cuff at the luminal surface might be disposed "additionally" to the cuff at the abluminal surface. Thus, also in the light of the description, the skilled person understands that it is the cuff at the abluminal surface that has to extend over two rows of cells.

#### **4.4 D3**

4.4.1 D3 discloses an inner cuff ("inner skirt 35") disposed at the luminal surface extending over two rows of cell and an outer cuff ("outer skirt 34") disposed at the abluminal surface not extending over two rows of cell (figures 1, 6). These findings are not disputed by the parties. In accordance with the understanding of claim 1 explained under point 4.3, feature 1.6 is not disclosed in D3.

4.4.2 The claimed subject-matter is thus novel over D3.

#### **4.5 D4 to D7**

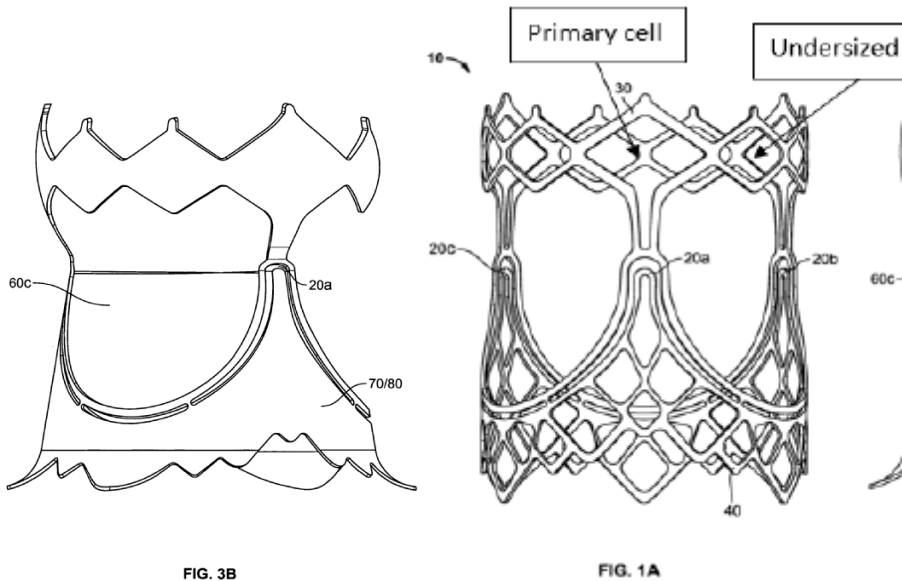
4.5.1 With regard to novelty over D4 to D7, the parties referred to the written submissions during oral proceedings. Therefore the Board sees no reason to deviate from its preliminary opinion as set out in the communication pursuant to Article 15(1) RPBA, which is hereby confirmed and reads as follows:

4.5.2 D4 at least does not directly and unambiguously disclose feature 1.3. The claimed subject-matter is thus novel over D3.

As pointed out by the appellant (patent proprietor) by referring to D4, figures 1 and 2A (reproduced below),



section and the aortic section.



4.5.4 As regards D6, reference is made to figure 1A (reproduced below), wherein it is explicitly stated that the cuff ("leaflet membrane") covers entirely the abluminal surface of the stent.

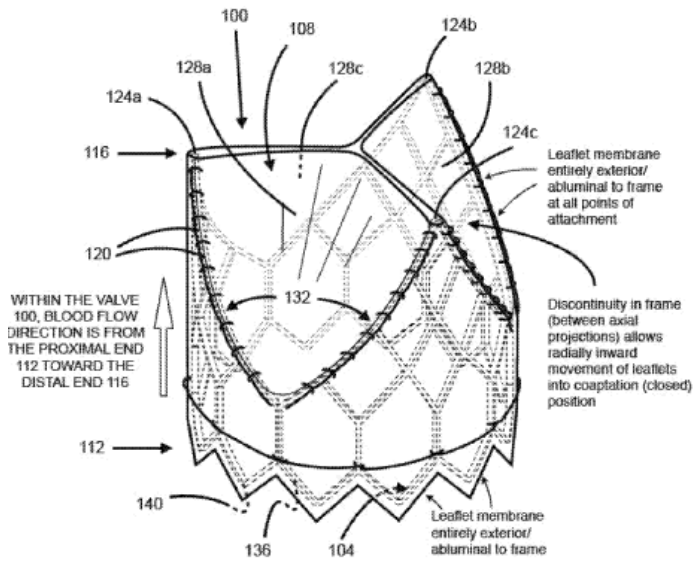


Figure 1A

4.5.5 D7 discloses on page 88, lines 27ff, that a cuff may be arranged at the outside of the stent "extending from a location near the lower end section of the stent to a location near the upper end section of the stent" to

cover the all or most of the abluminal surface of the stent.

4.5.6 The prosthetic heart valve according to claim 1 of auxiliary request 1 is thus novel over D4 to D7.

## **5. Auxiliary request 1 - Article 56 EPC**

5.1 The Board confirms the opposition division's finding that claim 1 as granted involves an inventive step.

### **5.2 D3 as closest prior art**

5.2.1 Claim 1 differs from D3 in feature 1.6. Contrary to the appellant's (opponent's) opinion the placement of the cuff at the abluminal surface as claimed is not an arbitrary design choice when starting from D3.

5.2.2 The appellant (opponent) argued that the disposal of the cuff per se solved the problem of reducing paravalvular leakage. The effect was reached regardless of the luminal or abluminal placement.

5.2.3 The Board agrees that the arrangement of the cuffs in D3 already solves the problem of reducing paravalvular leakage, see page 19, last paragraph: "*Providing both skirts may be beneficial in terms of obstructing leakage overall.*". Therefore the problem might be seen in providing an alternative cuff arrangement.

5.2.4 However there is no hint for the skilled person to modify the heart valve of D3 according to claim 1, be it from common general knowledge or in combination with one of the documents D4 to D7.

5.2.5 The same passage on page 19 of D3 (last paragraph) teaches against an outer skirt fully extending over two rows of cells in addition to the inner skirt to avoid a too thick heart valve: *"However, the presence of both skirts can add significantly to the thickness of material carried by the stent, and thereby increase the difficulty of compressing the stent-valve to a desirably small size. By providing both skirts, with only partial overlap in an axial direction, the benefits of both skirts can be obtained, but with a reduced thickness profile in the regions where only one skirt extends. Overlapping the skirts can provide better sealing between the skirts than were the skirts to be arranged edge to edge on the interior and exterior respectively of the stent component"*.

5.2.6 Furthermore - and contrary to the appellant's (opponent's) opinion - the skilled person would also not provide the inner skirt at the abluminal surface as the inner skirt essentially serves to fix the leaflets at the valve assembly, see figure 5b and page 31, second paragraph to page 32, line 4.

5.2.7 The claimed subject matter is thus not obvious starting from D3 combined with common general knowledge or with one of the documents D4 to D7.

### 5.3 **D8 as closest prior art**

5.3.1 Figure 1 in D8 is similar to figure 1 of the patent in suit. Thus, in accordance with the disclosure of the patent in suit, a prosthetic heart valve according to D8 is a suitable closest prior art. As described in D8, paragraph [0033], a cuff 106 may be disposed on the abluminal surface and may cover all or part of the

abluminal surface of the annulus section.

- 5.3.2 It is undisputed that claim 1 at least differs from D8 in features 1.4 and 1.5 (primary cells directly below the commissure features and undersized cells).
- 5.3.3 Even if features 1.4 and 1.5 might be known from e.g. D3, the appellant's (opponent's) argument that these features had no technical effect but were an arbitrary design choice is not convincing.
- 5.3.4 According to paragraph [0028] of the patent in suit, features 1.4 and 1.5 solve the technical problem to increase coronary perfusion. By providing undersized cells in the second row, the *"transition row now includes a plurality of larger cells (i.e. hexagonal cells 384b and asymmetric cells 384a) through which blood may flow. These larger cells allow blood to flow unimpeded to the coronary arteries"* (paragraph [0028] of the patent in suit). This object is also mentioned in paragraph [0001] of the patent in suit.
- 5.3.5 The appellant (opponent) did not present a problem-solution approach explaining how a skilled person would arrive at the claimed subject-matter, when starting from D8 and being confronted with the technical problem of increasing coronary perfusion.
- 5.3.6 None of the cited documents describes that due to undersized cells smaller than primary cell in a second row of cells, the coronary perfusion could be improved.
- 5.3.7 Consequently, claim 1 of auxiliary request 1 involves an inventive step starting from D8 combined with common general knowledge or one of the documents D3 to D7.

**Order**

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

The appeals are dismissed.

The Registrar:

The Chairman:



A. Voyé

G. Pricolo

Decision electronically authenticated