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**Datasheet for the decision
of 14 January 2025**

Case Number: T 0056/23 - 3.2.01

Application Number: 18210706.0

Publication Number: 3494928

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.

Headword:

Relevant legal provisions:
EPC Art. 76(1), 56
RPBA 2020 Art. 13(1), 13(2), 11

Keyword:

Divisional application - subject-matter extends beyond content of earlier application (yes)

Inventive step - common general knowledge - obvious combination of known features

Amendment after notification of Art. 15(1) RPBA communication:

Auxiliary request 67 - exceptional circumstances (yes) - taken into account (yes) - Auxiliary request 73 - exceptional

circumstances (no) - taken into account (no)

Remittal - special reasons for remittal (no)

Decisions cited:

T 0247/20

Catchword:



Beschwerdekammern

Boards of Appeal

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Case Number: T 0056/23 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 14 January 2025

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
22 December 2022 concerning maintenance of the
European Patent No. 3494928 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The patent proprietor and the opponents 1 and 2 each filed an appeal, on 10 January 2023, 14 February 2023 and 19 January 2023, respectively, against the decision of the opposition division, posted on 22 December 2022, to maintain European patent No. 3494928 in amended form on the basis of auxiliary request 33 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 (D8). In its decision, the opposition division held among others that the main request (patent as granted) and auxiliary requests 1 to 32 contravened the requirement of Article 76(1) EPC. Regarding auxiliary request 33, the opposition division found that none of the objections raised under Articles 76(1), 83, 54 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:

D5: US 2006/0259137 A1
D8: WO 2012/048035 A2
D14: WO 2009/094188 A2
D19: WO 2009/149462 A2

III. With communication dated 27 October 2023 the Board informed the parties that the request to accelerate the appeal proceedings filed by the appellant (opponent 1) with the statement of grounds of appeal was granted

(Article 10(3) RPBA).

IV. In the communication pursuant to Article 15(1) RPBA dated 18 January 2024 the Board informed the parties, inter alia, of their preliminary view that claim 1 of the main request and of all other requests then on file (auxiliary requests 1 to 64 and 1' to 63') was not allowable for lack of compliance with the requirements of Article 76(1) EPC.

V. Oral proceedings were held before the Board on 14 January 2025.

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, auxiliary, that the patent be maintained on the basis of one of the auxiliary requests 1 to 3 filed with the statement of grounds of appeal, or on the basis of one of the auxiliary requests 4 to 64 or 1' to 63' filed with the reply to the opponents' statements of grounds of appeal, or on the basis of auxiliary requests 67 to 73 in the order 67, 73, 68 to 72 wherein auxiliary requests 68 and 69 were filed with letter dated 17 December 2024, auxiliary requests 67 and 70 to 72 were filed with letter dated 10 January 2025 and auxiliary request 73 was filed during oral proceedings.

The appellants (opponents 1 and 2) requested that the decision under appeal be set aside and that the patent be revoked.

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

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

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

1.2 a prosthetic aortic heart valve having a balloon-expandable frame (12) having a radially collapsed state and a radially expanded state, the frame (12) comprising:

1.2.1 an inflow row of openings (36) at an inflow end portion of the frame (12),

1.2.2 an outflow row of openings (40) at an outflow end portion of the frame (12); and

1.2.3 at least one intermediate row of openings (38) between the inflow row of openings (36) and outflow row of openings (40);

1.2.4 wherein the inflow row of openings (36) is formed by a circumferentially extending lower row of angled struts (22) arranged end-to-end and a circumferentially extending first intermediate row of angled struts (24) arranged end-to-end, the lower and first intermediate rows of angled struts (22, 24) interconnected by a plurality of substantially straight, axially extending struts (34),

1.2.5 wherein the outflow row of openings (40) is formed by a circumferentially extending upper row of angled struts (32) arranged end-to-end and a

circumferentially extending second intermediate row of angled struts (28) arranged end-to-end,

1.2.5.1 the upper and second intermediate rows of angled struts (28, 32) interconnected by a plurality of axially extending struts (31) and a plurality of angularly spaced, axially extending commissure window frame portions (30),

1.2.5.1.1 wherein each axially extending strut (31) and each commissure window frame portion (30) of the outflow row of openings (40) extends from a location defined by the convergence of the lower ends of two angled struts (32) of the upper row of angled struts (32) to another location defined by the convergence of the upper ends of two angled struts (28) of the second intermediate row of angled struts (28); and

1.2.6 wherein adjacent angled struts of the frame (12) form an angle of at least 120°, when the frame is in the radially expanded state;

1.3 the assembly further comprising a leaflet structure, wherein each commissure window frame portion is configured to mount a respective commissure of the leaflet structure.

In **auxiliary request 67**, two amendments A-II and A-X were implemented in claim 1. A-II was added after feature 1.2.3 and reads as follows:

A-II: wherein the openings of the inflow row of openings (36) are larger than the openings of the at least one intermediate row of openings (38);

A-X is a set of amendments wherein

- Feature 1.2.5 is amended as follows (amendments indicated by underlines):

wherein the outflow row of openings (40) is formed by a circumferentially extending upper row of angled struts (32) arranged end-to-end and connected at junctions (46, 64) and a circumferentially extending second intermediate row of angled struts (28) arranged end-to-end and connected at junctions (44, 64)

- the following is specified after feature 1.2.5.1.1:

wherein a lower end of each axially extending strut (31) is connected to two angled struts (28) of the second intermediate row of angled struts (28) at a junction (44), and wherein an upper end of each axially extending strut (31) is connected to two angled struts (32) of the first intermediate row of angled struts (32) at a junction (46)

- and the following is specified after feature 1.3:

wherein the junctions (44, 46, 64) prevent full closure of the openings (40) of the outflow row of openings, and wherein the geometry of the axially extending struts (31), and the junctions (44, 46, 64) assists in creating enough space in the openings (40) of the outflow row of openings in the radially collapsed state to allow portions of leaflets of the leaflet structure to protrude outwardly through the openings (40) of the outflow row of openings.

Claim 1 of the subsequent **auxiliary request 73** is based on auxiliary request 67 and introduces the amendments A-IV and A-VI in this order after amendment A-X.

Amendments A-IV and A-VI read as follows:

A-IV: the prosthetic aortic heart valve further comprises an inner skirt (16) secured to the inside of the frame (12) via sutures (70), and

A-VI: wherein the commissure window frame portions (30) each comprise an enclosed opening between first and second axially oriented side struts, wherein the leaflet structure comprises a plurality of leaflets (40), wherein each of the plurality of leaflets (40) comprises 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 frame portion (30) of the frame (12) to a location outside of the frame (12) and is sutured to the side struts of the commissure window frame portion.

Furthermore, all dependent claims were deleted in auxiliary request 73.

VII. In the communication pursuant to Article 15(1) RPBA (see point IV above) the Board explained (see points 2.6.3 and 2.6.4 of the communication) the reasons for non-compliance with Article 76(1) EPC concerning feature 1.2.5 of claim 1. Although the Board agreed with the opposition division that an end-to-end arrangement included a situation where the ends of the struts were connected via a junction, it considered that the junctions 64, 46 at the upper row of angled struts and the junctions 44, 64 at the second intermediate row of angled struts - i.e. the end-to-end arrangements - were described as having a specific geometry which was inextricably linked to the object of

providing a small crimped diameter. Paragraph [057] with figures 18 and 53 disclosed that *"As can be seen, the geometry of the struts 31, and junctions 44, 46 and 64 assists in creating enough space in openings 40 in the crimped state to allow portions of the leaflets to protrude (i.e., bulge) outwardly through openings. This allows the valve to be crimped to a relatively smaller diameter than if all of the leaflet material is constrained within the crimped frame."* Thus the end-to-end arrangements of the upper and second intermediate row of angled struts were not disclosed as generally as claimed but as junctions 64, 44, 46 that prevented full closure of the outflow row of openings in the crimped state. None of the amendments made in the auxiliary requests was directed to this objection. Consequently none of the auxiliary requests seemed to meet the requirements of Article 76(1) EPC and the patent was likely to be revoked.

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

Added subject-matter - main request - claim 1

Feature 1.2.1 with feature 1.2.3

The opposition division erred in concluding that the inflow row of openings and the intermediate row of opening described in paragraph [012] of D8 were only disclosed in the context of the additional feature mentioned in the last sentence of paragraph [012] that *"The openings of the inflow row of openings are larger than the openings of the at least one intermediate row of openings."* (impugned decision, point 22.1). When comparing figures 5, 12 and 74, it became apparent that

said additional feature was not inextricably linked to the existence of an inflow row of openings and an intermediate row of opening. Also paragraph [0054], wherein the structure of the rows of openings was described, was silent about larger openings in the inflow row of openings.

Feature 1.2.5

With regard to the end-to-end arrangements defined in feature 1.2.5, the opposition division correctly stated that the phrase "arranged end-to-end" included the situation where the ends of struts were connected via a junction as shown in figures 5 to 10 (impugned decision, point 22.3). The end-to-end arrangement - as explicitly disclosed in paragraph [054] of D8 for the inflow row of angled struts and as shown in figure 5 - was to be understood as struts not being interrupted in its circumferential extension. This also applied for all other rows of angled struts of the frame shown in figure 5 and shown in more detail in figures 6 to 10.

Added subject-matter - dependent claims as granted

The opposition division was right in their findings with regard to the dependent claims. They all found sufficient support in D8. In particular:
Claim 3 was based on paragraph [012] with figure 5.
Claim 11 was based on paragraph [015].
Claim 15 was based on paragraph [053].

Auxiliary request 67 - admission

The Board's arguments provided with the communication under Article 15(1) RPBA on feature 1.2.5, concerning

the omission of the functional feature of the junctions in the outflow row of openings, were not previously submitted as such by the opponents. The filing of auxiliary request 67 was in reaction to this new situation. These circumstances were to be regarded as exceptional and justified the admissibility of auxiliary request 67.

Auxiliary request 67 - Inventive step: D5 with D14 or D19 in view of common general knowledge

Claim 1 of auxiliary request 67 differed from the embodiment of D5, figure 12, because in this embodiment no commissure window frame portions were provided. The opposition division was right in stating that paragraph [0134] of D5 even taught away from using the commissure windows shown in previous embodiments of D5 (impugned decision, point 25).

Additionally feature 1.2.6 was not disclosed.

Finally, the cited prior art was silent about feature A-X that the junctions in the upper row of openings were such that they created enough space in the radially collapsed state of the heart valve to allow portions of the leaflet structure to protrude outwardly through the openings.

The embodiment presented in D5, figure 12 was a reliably working concept that the skilled person would not arbitrarily modify without any pointer. All distinguishing features together had the synergetic effect of allowing a small crimped profile. Just picking from the prior art the features needed to complement the known assembly in order to arrive at the claimed subject-matter was based on hindsight.

Request for remittal

At the oral proceedings, the appellant (patent proprietor), after having heard the conclusions of the Board that, on the one hand, the main request was not allowable in view of features 1.2.1 with features 1.2.3 and 1.2.5 and, on the other hand, that claim 1 of auxiliary request 67 did not involve an inventive step starting from D5, and dependant claims 3, 11-13 and 15 of auxiliary request 67 did not comply with the requirement of Article 76(1) EPC, requested that the case be remitted to the opposition division for further prosecution. This was justified as auxiliary request 67 was particularly aimed to address the objection of the Board concerning feature 1.2.5 whilst auxiliary requests 1 to 64 and 1' to 63' were filed at an earlier stage in order to address the inventive step objections of the opponents. It would only be fair to the patent proprietor to be given the opportunity to combine the new amendment A-X with the amendments previously made. This could only be done properly before the department of first instance.

Admission of auxiliary request 73

Claim 1 was a combination of claim 1 of auxiliary request 67 with the additional amendments A-IV and A-VI made to claim 1 of auxiliary request 46. The latter request was already on file in the first instance proceedings. The amendments A-IV and A-VI with regard to the inner skirt and the commissure portions of the leaflets extending outwardly through the commissure windows addressed the inventive step objection. Amendment A-VI was substantiated with regard to inventive step on page 104, point 5.c) of the patent proprietor's reply to the opponents' statement of

grounds of appeal.

- IX. The appellants' (opponents') arguments relevant to the present decision may be summarised as follows:

Added subject-matter - main request - claim 1

Feature 1.2.1 with feature 1.2.3

The opposition division correctly held that without defining the openings of the inflow row of openings being larger than the openings of the at least one intermediate row of openings, claim 1 contravened Article 76(1) EPC.

Feature 1.2.5

The connection of the ends of the angled struts of the upper and second intermediate row of angled struts was not an end-to-end arrangement. Instead in paragraph [057], the ends of these angled struts were described as being arranged spaced apart by junctions or by the commissure window frame portion. This was also shown in figures 5, 7 and 10.

Added subject-matter - dependent claims as granted

The dependent claims also introduced added subject-matter, in particular claims 3, 11-13 and 15 extended beyond the content of the parent application.

Auxiliary request 67 - admission

An objection of intermediate generalisation concerning feature 1.2.5 was raised by the opponents from the beginning of the opposition proceedings. The argument

was always that the junctions connecting the angled struts of the outflow row of openings were missing. The Board only expanded on the existing objection. In T 247/20 (Case Law Book, 10. Edition, Chapter V.A. 4.2.2.m) it was held that further developing an already existing argument was not an amendment to a party's appeal case. There were thus no exceptional circumstances that could justify the late filing of auxiliary request 67 after the preliminary opinion of the Board was issued.

Auxiliary request 67 - Inventive step: D5 with D14 or D19 in view of common general knowledge

D5 was even novelty destroying for the subject-matter of claim 1 of auxiliary request 67. Figure 12 seen together with paragraph [0134] clearly disclosed commissure window frame portions as claimed. An angle of 120° was clearly shown in figure 12 and a hexagon shape was explicitly disclosed in paragraph [0134]. A regular hexagon had always sides at an angle of 120°. With regard to the junctions, it only depended the degree of how far the heart valve was collapsed. The functional feature of creating enough space was inherent.

Should the Board not follow this line of argumentation it was submitted that these features did not provide any synergetic effect. The problem to be solved was how to realize the heart valve of D5, figure 12.

The provision of commissure window frame portions was well known from the prior art, e.g. D14, figures 3 and 32, and even considered as an obvious alternative in D5 itself (paragraph [0134]).

Feature 1.2.6 was obvious in view of the disclosure of a hexagon shape in paragraph [0134] and figure 12 of

D5.

The feature A-X concerning the junctions and their special function was not presented by the appellant (patent proprietor) as involving an inventive step over the prior art but only to overcome an added subject-matter issue.

Junctions in the outflow row of openings with a similar shape as in the patent in suit (figure 5) were commonly known as became apparent from D5, figure 6C, or D19, paragraph [049] with figure 9. Their provision resulted automatically in the claimed function.

Request for remittal

The request was not to be admitted. Firstly, the proceedings were accelerated because of national infringement proceedings. Secondly, there were no special reasons to remit.

Admission of auxiliary request 73

The patent proprietor already had sufficient opportunities to file auxiliary requests. Auxiliary request 73 was clearly late filed. The amendments A-IV and A-VI added to claim 1 were introduced in the first instance to overcome objections of added-subject-matter but were never substantiated with regard to inventive step.

Reasons for the Decision

1. Article 100(c) EPC - main request - claim 1

1.1 The patent in suit is based on a divisional application of the international application published as WO

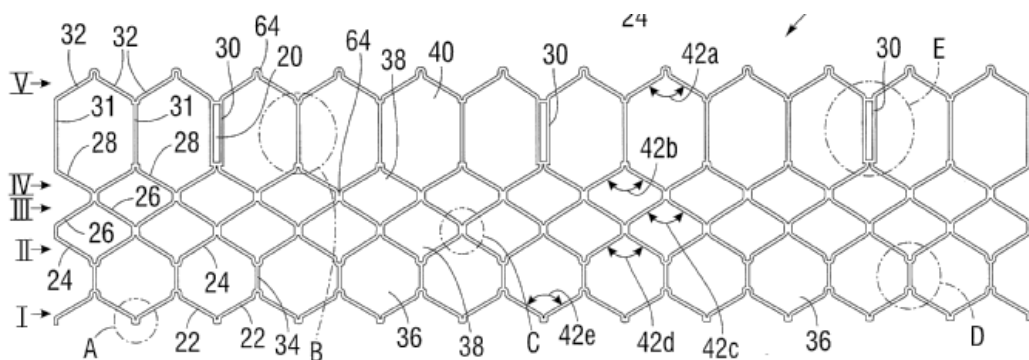
2012/048035 (D8). The description of the original application of the patent in suit is identical to the description of the parent application D8 with added paragraph [0115] incorporating the claims of the parent application.

1.2 The claims of the original patent application were all newly drafted with the filing thereof. Claim 1 as granted is based on claims 1 and 10 of this original application. Article 123(2) EPC is thus met.

1.3 The objections of the appellants (opponents) under Article 100(c) EPC refer to the newly drafted set of claims of the application as originally filed compared to the disclosure of the parent application D8 and thus concern Article 76(1) EPC.

1.4 The ground for opposition under Article 100(c) EPC having regard to Article 76(1) EPC is prejudicial to the maintenance of the patent as granted.

1.5 As basis for the claims as granted, reference is made to D8, paragraph [012], paragraphs [054] to [061] and figure 5 (reproduced below).



1.6 **Feature 1.2.1 with feature 1.2.3**

- 1.6.1 The Board confirms the findings of the opposition division (impugned decision, point 22.1), that a frame with axially extending struts 34 in the inflow row of openings is only disclosed with the additional limitation that the openings 36 of the inflow row of openings are larger than the openings 38 of the at least one intermediate row of openings.
- 1.6.2 The axially extending struts 34 for forming the inflow row of openings are disclosed in paragraph [054] describing the embodiment shown in figure 5. For this embodiment, it is shown and also described in paragraph [061] that "*the lowermost row of openings on the frame is relatively larger than the openings of the two intermediate rows of openings*".
- 1.6.3 Paragraph [061] also discloses the inextricable link between the size of the openings of the inflow row of openings relative to the size of the openings of the at least one intermediate row of openings for the embodiment of figure 5.
- 1.6.4 To outline the inextricable link it is firstly noted that one of the core teachings of D8 is to provide a prosthetic heart valve with a small crimped profile. In this regard, paragraph [006] discloses that the diameter of the crimped profile is an important design parameter. The specific frame design shown in figure 5 of D8 has this in mind as becomes apparent from the description, paragraphs [053, 055, 056, 057, 060, 061] on which the set of claims of the patent in suit is based.
- In this context, paragraph [061] discloses that in the embodiment of figure 5, due to the larger openings, the diameter of the inflow region "*is reduced compared to the diameter of the upper portion of the frame (which*

is not covered by the outer skirt) such that the outer skirt 18 does not increase the overall crimp profile of the valve." As held by the opposition division, the larger openings at the inflow row of openings contribute to the overall task of D8 and is inextricably linked to the structural design of the frame to achieve this task.

1.6.5 Paragraph [061] does not mention the relative size of openings as being optional. Therefore also the argument of the appellant (patent proprietor) that the claim already included the features of the commissure window frame portions as defined in feature 1.2.5.1.1 and the angle of 120° between adjacent angled struts (feature 1.2.6) which according to paragraph [055] and [058] both contributed to a small crimped profile such that no further specification of the frame structure was required, can not convince. All these features are disclosed as a set of features for the specific embodiment of figure 5.

1.6.6 Figures 5 and 12 seen together with paragraph [012] of D8 - to which the appellant (patent proprietor) referred to - might be seen as a basis for a frame with an inflow row of openings, an outflow row of openings and at least one intermediate row of openings with or without larger openings in the inflow row. However, as soon as the frame is further specified as having axially extending struts for forming the inflow row of openings as it is done in feature 1.2.4, the frame is only disclosed as also having openings in the inflow row that are larger than those in the at least intermediate row of opening as explained above.

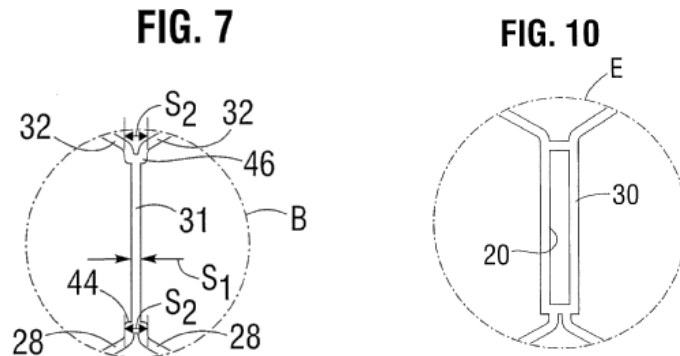
1.6.7 Hence, the omission of the further limitation that the openings in the inflow row of openings are larger than

the openings in the at least one intermediate row of openings results in an unallowable intermediate generalisation.

1.7 Feature 1.2.5 - end-to-end arrangement at the outflow row of openings

1.7.1 The end-to-end arrangements of the upper row of angled struts and of the second intermediate row of angled struts which form the outflow row of openings are not disclosed as generally as claimed.

1.7.2 The opponents argued that the junctions 44, 46, 64 and the commissure window frame portions 30 arranged in between the angled struts of the outflow row of openings (figures 5, 7 and 10, the last two of them being reproduced below) resulted in an arrangement in which the angle struts were spaced apart at their ends and thus not end-to-end.



1.7.3 However, the Board agrees with the opposition division's conclusion that an end-to-end arrangement includes a situation where the ends of the angled struts are connected via junctions as shown in figures 5, 7 or 10 and described in paragraph [057]. It is in particular noted that the arrangement at the ends of the inflow row of angled struts 22 shown in detail A of

figure 5 (see also figure 6 of D8) which according to paragraph [054] explicitly is an end-to-end arrangement, is very similar to the arrangement shown in figure 7 wherein the connection of the upper and second intermediate row of angled struts 32, 28 of the outflow row of openings is shown. According to paragraph [057], these angled struts are connected via junctions 44, 46. This in turn means that also the ends of the angled struts in the inflow row are connected end-to-end via junctions.

Thus even if paragraph [054] only provides a verbatim disclosure for an end-to-end arrangement at the inflow row of opening, D8 also provides a basis for an end-to-end arrangement at the outflow row of opening.

- 1.7.4 The Board however does not agree with the patent proprietor that the further specification of the junctions in paragraph [057] can be omitted when defining the end-to-end arrangements of the upper row of angled struts and of the second intermediate row of angled struts. In this regard, paragraph [057] with figure 18 discloses that *"As can be seen, the geometry of the struts 31, and junctions 44, 46 and 64 assists in creating enough space in openings 40 in the crimped state to allow portions of the leaflets to protrude (i.e., bulge) outwardly through openings. This allows the valve to be crimped to a relatively smaller diameter than if all of the leaflet material is constrained within the crimped frame."*

Paragraph [057] is the only passage at all in D8 that addresses the connections at the ends of the angled struts in the outflow row of openings. While no specific geometry for the junctions of the end-to-end arrangement is defined in paragraph [0057], the functional feature - that the junctions are designed to

prevent full closing of the upper openings to allow the leaflet material to protrude therein in the crimped state to achieve one of the main tasks of D8 of a small crimped diameter - is presented as being inextricably linked with the junctions in the outflow row of openings.

- 1.7.5 Consequently, the omission of the functional feature of the junctions in the outflow row of openings results in an unallowable intermediate generalisation.

2. Auxiliary requests 1 to 64 and 1' to 63'

As claim 1 of each of the auxiliary requests 1 to 64 and 1' to 63' suffers from at least one of the deficiencies mentioned in points 1.6 and 1.7 above, these requests are likewise not allowable under Article 76(1) EPC. This was not contested by the appellant (patent proprietor), who, at the oral proceedings wished to proceed further with auxiliary request 67 after the conclusion of the Board on the two above issues of added subject-matter was announced.

3. Auxiliary request 67 - admission

- 3.1 Auxiliary request 67 was filed in writing after notification of the above-mentioned communication under Article 15(1) RPBA and falls under the provision of Article 13(2) RPBA. The Board admitted auxiliary request 67 into the proceedings.

- 3.1.1 Essentially, the reason for the Board to admit auxiliary request 67 was that the reasoning on added subject-matter with regard to feature 1.2.5 provided in the communication under Article 15(1) RPBA gave rise to exceptional circumstances, whereby amendment A-X made

to claim 1 directly addressed said reasoning. Moreover, amendment A-II made to claim 1 solved the problem of added subject-matter concerning feature 1.2.1 with feature 1.2.3.

3.1.2 Contrary to the appellants' (opponents') view, although the reasoning of the board builds on the opponents' objection with regard to feature 1.2.5, namely that the angled struts of the outflow row of opening were not at all arranged end-to-end, but connected spaced apart via junctions, the Board's reasoning is that the end-to-end arrangement at the outflow row of opening is not disclosed **in such a general manner** as claimed in claim 1 as granted (see point 1.7 above).

3.1.3 The appellants (opponents) raised further objections concerning the admissibility of auxiliary request 67 but it is not necessary to deal with them in detail here as this request fails for lack of inventive step, as explained below.

4. Auxiliary request 67 - Inventive step

4.1 The subject-matter of claim 1 of auxiliary request 67 does not involve an inventive step starting from D5 in view of common general knowledge, as exemplified in D14 and D19.

4.2 Auxiliary request 67 includes the amendments A-II and A-X. Amendment A-II addresses the objection with regard to the openings of the inflow row of openings by specifying them as being larger than the openings of the at least one intermediate row of openings (see point 1.6 above). Amendment A-X addresses the objection with regard to the functional feature of the junctions

in the outflow row of opening (see point 1.7 above).

4.3 D5, figure 12, can be seen as an appropriate starting point as the embodiment shows a frame for a heart valve having a similar structure as defined in the claim.

4.4 Contrary to the appellants' (opponents') opinion, D5 does not directly disclose all features of claim 1 in combination.

4.4.1 The Board agrees with the patent proprietor that the embodiment of figure 12 (reproduced below) does not directly and unambiguously disclose

- features 1.2.5.1 and 1.2.5.1.1 concerning the commissure window frame portions in the upper row of opening,
- features 1.2.6. about the angle of 120° formed by adjacent angled struts of the frame and
- feature A-X with regard to the junctions connecting two angled struts in the upper row of opening to prevented full closing of the opening.

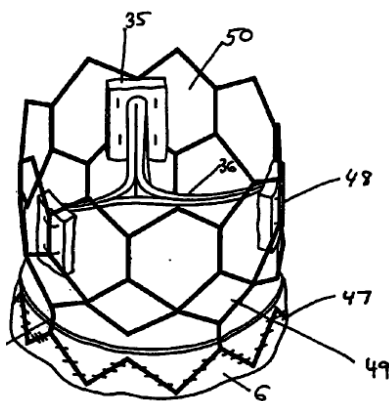


FIG. 12

4.4.2 Features 1.2.5.1, 1.2.5.1.1 (commissure window frame portions)

The appellants (opponents) argued that not figure 12

but the variant of figure 12 as described in paragraph [0134] had to be considered as the starting point. Paragraph [0134] disclosed that "*The commissural tabs (35) of the valve (32) can be stitched directly to the hexagon shaped elements (50) of the outflow ring, rather than being secured via slots.*" In the opponents' view the embodiment of figure 12 was thus disclosed with both the one or the other way of attachment.

However, while in other embodiments of D5, e.g. figures 5, 6C or 10, commissure windows are disclosed, D5 presents in figure 12 an embodiment without commissure windows or slots - as described in paragraph [0134]. Paragraph [0134] is understood as describing an alternative way of attachment instead of the previously used slots. The embodiment of figure 12 is thus not directly disclosed in combination with commissure window frame portions - as also found by the opposition division (impugned decision, page 19, fourth paragraph).

4.4.3 Feature 1.2.6 (angle of at least 120°)

The opponents argued that a regular hexagon was the first to come in mind when the general term "hexagon" was mentioned in paragraph [0134]. Because the regular hexagon was so much more prominent than any other variant of hexagon, it justified a direct and immediate disclosure by the term in the light of the skilled person's understanding.

The Board however agrees with the opposition division (impugned decision, page 20, second paragraph) that even if paragraph [0134] indeed mentions "*hexagon shaped openings*", a direct disclosure of 120° between the angled struts is not unambiguously derivable.

Paragraph [0134] is silent about a "regular" hexagon. Furthermore, the figure is schematic, shows a perspective view and can not be used as proof that the angled struts form at least an angle of 120° - as argued by the patent proprietor. It also could be 110° or 115°.

4.4.4 Feature A-X (junctions to create space in the collapsed state)

The Board does not agree with the appellants' (opponents') argument that feature A-X is inherent to the frame of D5, figure 12. The schematic figure does not allow any conclusions to be drawn about the junctions connecting the angled struts and their specific function as defined in claim 1.

4.5 Consequently, the claimed subject-matter is new over D5 and differs in the provision of commissure window frame portions, in feature 1.2.6 and in feature A-X.

4.6 The Board agrees with the appellants (opponents) that, when starting from D5, figure 12, the problem can be seen in how to put the shown heart valve into practice.

4.7 The solution to this problem is rendered obvious by the common general knowledge of the skilled person as exemplified by e.g. D14 and D19. The missing features merely fill gaps in the disclosure of the schematic figure 12 of D5.

4.7.1 With regard to the commissure window frame portions the Board does not agree with the appellant's (patent proprietor's) argument that paragraph [0134] of D5 teaches against the provision of slots to attach the leaflets to the frame. Paragraph [0134] mentions the

stitching as an equivalent alternative to the slots. The skilled person knows that a frame as shown in figure 12 can easily be provided with commissure windows as e.g. shown in D14, figure 3 (reproduced below, left hand side) or figure 32. As pointed out by the appellants (opponents), this is also acknowledged in the patent in suit in paragraph [062] with regard to figure 44 (reproduced below, right hand side). While figure 44 only shows struts but no commissure windows, paragraph [062] states that the frame "*can be adapted to include commissure frame portions*" - without any further explanations.

There is thus no technical hindrance to provide commissure windows at the very same position where the leaflets are attached in D5, figure 12 - thereby arriving at commissure window frame portions as claimed.

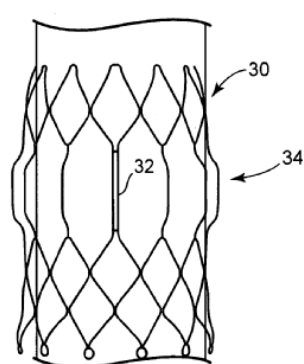
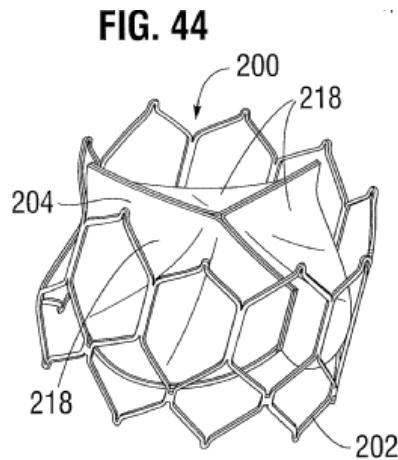


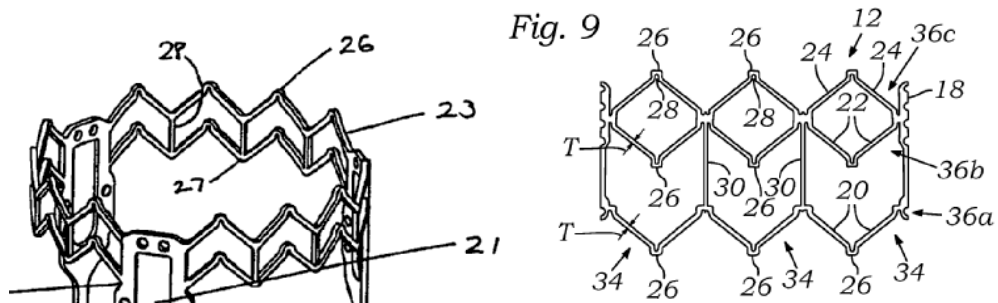
Fig. 3



4.7.2 The Board further agrees with the appellants (opponents) that the selection of an angle of at least 120° is merely one of several straightforward possibilities. A skilled person that wants to put the shown heart valve into practice has to select an appropriate shape for the hexagon. One obvious possibility with regard to the embodiment shown is a regular hexagon having per definition an angle of 120°

between adjacent struts. Feature 1.2.6 is thus obvious over D5 alone.

4.7.3 Feature A-X concerning the junctions in the outflow row of openings is rendered obvious by D5 itself in view of the common general knowledge as e.g. described in D19, figure 9 with paragraph [049]. When the skilled person tries to realize the schematic frame of D5, figure 12, they have to take a decision on how the junctions are put into practice. D5, figure 6C (a cut-out of which is reproduced below, left hand side), shows - in more detail - junctions at the ends of the angled struts that are very similar to the junctions 64, 44, 46 shown in figures 5 and 7 of the patent in suit. The skilled person knows - as also explicitly described in D19, paragraph [049] (see also figure 9 reproduced below) - that these types of junctions which create a gap 28 between the adjacent ends of the angled struts reduce residual strains on the frame during crimping.



The skilled person being aware of this advantage would be motivated to use such junctions. As the geometry of the junctions is the same as in the patent in suit, they inherently must assist in creating enough space in the openings of the outflow row of openings in the radially collapsed state to allow portions of leaflets of the leaflet structure to protrude outwardly through the openings of the outflow row of openings as required by feature A-X.

4.8 The appellant (patent proprietor) was of the opinion that the skilled person would not simply play around and arbitrarily modify a heart valve from the prior art that was found to work reliably. The appellants' (opponents') approach of picking out single features out of different pieces of prior art was based on hindsight. Instead all features in combination resulted in a reliable and long-lasting heart valve. Providing the commissure windows as claimed, angles of at least 120° and junctions with the specific functions allowed that the leaflets did not protrude beyond the outflow end of the frame but through the openings of the outflow row of openings in the crimped state.

4.8.1 The Board is not convinced. First of all no synergistic effect has been made plausible for the combination of the distinguishing features. As explained above the missing features in the embodiment of D5, figure 12, are rather obvious design choices or equivalent alternatives for filling gaps in the disclosure of D5.

4.8.2 Furthermore, it is noted that feature A-X was introduced with the submissions dated 17 December 2024, wherein it was only shortly explained (point III.3, page 15) with regard to the contribution to inventive step, that the entire prior art was silent about a specific geometry of the axial struts and junctions which assisted in creating enough space in the openings of the outflow row of openings in the crimped state.

However, even if the function of assisting in creating enough space in the openings of the outflow row of openings in the crimped state is indeed not explicitly mentioned in the prior art, the frame in D5, figure 12, seen together with the obvious modification of providing commissure windows and kind of U-shaped

junctions at the ends of the angled struts, comprises all structural features of the claims. It is thus not apparent why the geometry being the same as claimed should not result in the same function as defined in feature A-X.

4.9 Consequently, the subject-matter of claim 1 of auxiliary request 67 does not involve an inventive step over D5 with common general knowledge.

5. Added subject-matter with regard to the dependent claims

5.1 The dependent claims 2 to 15 of auxiliary request 67 are identical to the dependent claims as granted. The Board agrees with the appellants (opponents) that dependent claims 3, 11 - and therewith claims 12 and 13 because of their dependency - as well as claim 15 contravene Article 76(1) EPC.

5.2 Claim 3

5.2.1 Claim 3 defines a coupling between the first intermediate row of angled struts (being row II in figure 5 in the patent in suit) and the second intermediate row of openings (being row IV in figure 5) at a location defined by the convergence of the upper ends of two angled struts of the first intermediate row of openings and at a location defined by the convergence of the lower ends of two angled struts of the second intermediate row of openings.

5.2.2 According to the appellant (patent proprietor) basis could be found in paragraph [012] and figure 5. Figure 5 clearly disclosed a coupling according to claim 3 for an example of two intermediate rows of openings. While

from paragraph [012] the skilled person was taught that the number of intermediate rows was not essential ("*at least one intermediate row of openings*"), the skilled person readily understood that the exact design of the coupling between the locations of converging ends may depend on the number of intermediate rows of openings.

- 5.2.3 The Board is not convinced. First of all it is noted that the wording of claim 3 is mainly based on figure 5. Paragraph [012] only defines in general the inflow row of openings, at least one intermediate row of openings and an outflow row of openings. Paragraph [012] is silent about any coupling features between these rows.

Even if the Board can agree that paragraph [012] provides a basis for frames with two, three, etc., intermediate rows of openings, the wording of granted claim 3 is broader than originally disclosed. In particular for two rows of intermediate openings, figure 5 only provides basis for a coupling with a further row of angled struts. Claim 3 would also allow a coupling with axially extending struts between the two convergences. However, such an embodiment is not originally disclosed.

- 5.2.4 Claim 3 thus introduces subject-matter that goes beyond the original disclosure of D8.

5.3 Claim 11

- 5.3.1 Claim 11 defines an outer skirt with an inflow edge and an outflow edge.

- 5.3.2 According to the appellant (patent proprietor) basis could be found in paragraph [015]. The opposition

division was right in finding that the intermediate portion of the outer skirt defined therein was implicit.

5.3.3 The Board does not agree. According to paragraph [015] (bold added by the Board) "*The outer skirt can comprise an inflow edge secured to the frame at a first location, an outflow edge secured to the frame at a second location, **and** an intermediate portion between the inflow edge and the outflow edge. When the valve is in the expanded configuration, the intermediate portion of the outer skirt **comprises slack** in the axial direction between the inflow edge of the outer skirt and the outflow edge of the outer skirt*".

5.3.4 As argued by the appellants (opponents), paragraph [015] only provides basis for an outer skirt having an intermediate portion such that when the valve is in the expanded configuration there is a slack.

5.3.5 Thus even if an intermediate portion in general might be implicit for an outer skirt with an inflow edge and an outflow edge, the intermediate portion disclosed in paragraph [015] has to be dimensioned such that slack is provided as described.

5.4 Claim 15

5.4.1 Claim 15 defines that the frame comprises a material selected from a group comprising stainless steel and a cobalt-chromium alloy.

5.4.2 According to the appellant (patent proprietor) basis could be found in paragraph [053]: "*Suitable plastically-expandable materials that can be used to form the frame 12 include, without limitation,*

stainless steel, a nickel based alloy (e.g., a cobalt-chromium or a nickel-cobalt-chromium alloy), polymers, or combinations thereof."). According to the patent proprietor the terms in brackets obviously referred to "plastically-expandable materials".

5.4.3 The Board is not convinced and agrees with the appellants (opponents) that claim 15 is broader than the original disclosure because the cobalt-chromium alloy only is disclosed as a variant of a nickel based alloy.

6. Request to remit the case to the department of first instance

6.1 During oral proceedings, the appellant (patent proprietor) submitted a request for remittal. The request was rejected as there were no special reasons for a remittal (Article 11 RPBA).

6.2 At the time of the request for remittal the main request and all auxiliary requests 1 to 64, 1' to 63' and 67 were found not to be allowable under Article 76(1) EPC and/or Article 56 EPC. There was thus no request in the proceedings and consequently no issue on the table on which the opposition division did not have decided yet but which would justify a remittal for further prosecution.

6.3 The appellant (patent proprietor) argued that special reasons were to be seen in the exceptional circumstances under Article 13(2) RPBA that justified an amendment of the patent proprietor's case. In fact, only at the day of oral proceedings, feature A-X was confirmed as overcoming the added subject-matter argument raised by the Board in their

preliminary opinion with respect of feature 1.2.5. A proper filing of an auxiliary request that combined the amendment A-X with amendments made earlier in the proceedings to overcome the remaining issues, in particular inventive step, could only be made in appropriate manner before the department of first instance.

- 6.4 The Board is not convinced for the following reasons.
- 6.4.1 The objection of lack of inventive step starting from D5 as the closest prior art was discussed before the opposition division and maintained in the appeal proceedings by the appellants (opponents). It was also mentioned in the communication pursuant to Article 15(1) RPBA by the Board as the only relevant attack on inventive step among the other attacks submitted by the opponents. The distinguishing features of claim 1 of auxiliary request 67 with regard to D5 are the same as identified by the opposition division for claim 1 as maintained (impugned decision, point 25).
- 6.4.2 Considering that the proprietor was given the opportunity to react to the objection of added subject-matter concerning feature 1.2.5 (as explained above) and further considering that the proprietor had several opportunities for preparing contingency positions in reaction to the objection of inventive step starting from D5, both in opposition and appeal proceedings, it is not apparent what reasons would have justified a remittal as requested by the proprietor.
- 6.4.3 In fact, a remittal would unduly lengthen the proceedings, and this would run contrary to the decision of the Board to accelerate the present appeal proceedings.

7. Auxiliary request 73 - Admission

- 7.1 Auxiliary request 73 was filed during oral proceedings before the Board and falls under the provision of Article 13(1) and (2) RPBA.
- 7.2 Claim 1 of auxiliary request 73 is a combination of auxiliary requests 67 and auxiliary request 46. Claim 1 is complemented by the amendments A-IV and A-VI known from first instance proceedings. Furthermore, all dependent claims are deleted.
- 7.3 Amendment A-IV introduces the feature of an inner skirt secured at the inside of the frame. Amendment A-VI defines leaflets with opposing side tabs wherein the side tabs of adjacent leaflets are paired to form a commissure portion that extends radially outwardly through a corresponding commissure window frame portion.
- 7.4 These amendments can not be considered as being prima facie suitable to overcome the lack of inventive step of the subject-matter of claim 1 of auxiliary request 67.
- 7.4.1 As pointed out by the appellants (opponents), the written submissions of the patent proprietor lack any substantiation as regards the reasons why the amendments A-IV and/or A-VI may contribute to an inventive step, in particular over D5. According to the patent proprietor's reply to the opponents' statement of grounds of appeal, the amendments A-IV and A-VI only address issues of added subject-matter (page 94, last two lines, and page 96, fourth paragraph).

- 7.4.2 Even if on page 104 of the patent proprietor's reply (last paragraph), it is stated that D5 failed to disclose commissure windows and leaflets forming commissures as required according to amendment A-VI in the context of the valve shown in the figure 12 embodiment, a reasoning why these features would support an inventive step is still missing.
- 7.4.3 Furthermore, figures 9 and 12 of D5 show a leaflet with the features added by amendment A-VI (i.e. two opposing side tabs, each side tab being paired with an adjacent side tab of an adjacent leaflet to form commissure portions). Additionally, with the preliminary opinion, the Board already indicated that the provision of commissure window frame portions does not involve an inventive step but only has to be regarded as an alternative.
- 7.4.4 In oral proceedings, the appellant (patent proprietor) argued that even if commissure window frame portions were provided in the frame of D5, figure 12, the skilled person would not attach the commissure portions of the leaflets to a location outside of the frame as required by amendment A-VI.

The Board is not convinced. As D5, paragraph [0134], discloses slots, i.e. commissure windows, as an alternative to the direct stitching to the struts (see point 4.7.1 above), the skilled person would also draw the commissure portions of the leaflets radially outward through the commissure windows to a location outside the frame. That's how leaflets are attached to commissure windows as e.g. described in D5, paragraph [0104], or D14, paragraph [00057] (page 10, lines 20 to 29).

- 7.4.5 Consequently the appellant (patent proprietor) has not demonstrated that auxiliary request 73 would prima facie overcome the lack of inventive step in view of D5, contrary to the provisions of Article 13(1) RPBA.
- 7.4.6 Furthermore, also the provisions of Article 13(2) RPBA speak against the admissibility of auxiliary request 73. Though exceptional circumstances might (and were) recognised in connection with the issue of added subject-matter concerning feature 1.2.5, as explained above, the Board cannot see what exceptional circumstances would justify admitting the amendment to the patent proprietor's case at the oral proceedings before the Board, consisting in relying on features A-IV and A-VI for supporting inventive step when this was never done before.

8. Auxiliary requests 68 to 72

Each of the auxiliary requests 68 to 72 suffers from at least one of the deficiencies mentioned above. In particular, they all include dependent claims 3, 11 to 13 and 15 as granted in claim 1 and thus fall at least for non compliance with the requirements of Article 76(1) EPC (see point 5 above), irrespective of the objections of admissibility raised by the appellants (opponents).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked

The Registrar:

The Chairman:



H. Jenney

G. Pricolo

Decision electronically authenticated