Internal distribution code:

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

Datasheet for the decision of 21 January 2026

Case Number: T 2492/22 - 3.2.02

Application Number: 19154544.1

Publication Number: 3498225

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
PROSTHETIC HEART VALVE

Patent Proprietor:
Edwards Lifesciences Corporation

Opponents:
Abbott Cardiovascular Systems, Inc.
Meril GmbH

Relevant legal provisions:
EPC Art. 54, 56, 76(1), 83, 123(2)
RPBA 2020 Art. 13(2)

Keyword:
Amendment after summons - exceptional circumstances (yes) - taken into account (yes)
Amendments - added subject-matter - main request (yes) - auxiliary request (no)
Sufficiency of disclosure - auxiliary request (yes)
Novelty - auxiliary request (yes)
Inventive step - auxiliary request (yes)

Decisions cited:
G 0002/10, T 1762/21, T 1888/22, T 0056/23, T 0824/23, T 1011/23

UPC_CoA_464/2024

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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

Case Number: T 2492/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 January 2026

Appellant: (Patent Proprietor)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
Representative:	Thum, Bernhard Thum & Partner Thum Mötsch Weickert Patentanwälte PartG mbB Ismaninger Straße 57 81675 München (DE)
Appellant: (Opponent 1)	Abbott Cardiovascular Systems, Inc. 3200 Lakeside Drive Santa Clara, CA 95054 (US)
Representative:	Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
Appellant: (Opponent 2)	Meril GmbH Bornheimer Straße 135-137 53119 Bonn (DE)
Representative:	Marks & Clerk LLP 15 Fetter Lane London EC4A 1BW (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 22 September 2022 concerning maintenance of the European Patent No. 3498225 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The patent proprietor, opponent 1 and opponent 2 each filed an appeal against the interlocutory decision of the opposition division to maintain the contested patent as amended on the basis of the request then on file as auxiliary request 1.

II. The patent was granted from a divisional patent application ("the divisional application") derived from an earlier European patent application ("the parent application"), which was published as the following document:

D6 WO 2012/048035 A2

III. In its decision, the opposition division found that the patent could not be maintained as granted because independent claim 1 and several dependent claims, including claim 12, contained added subject-matter. On the other hand, the opposition division found auxiliary request 1 to be allowable since it did not contain added subject-matter, was sufficiently disclosed, and the subject-matter of claim 1 of that request was novel and involved an inventive step.

In order to come to these conclusions, the opposition division considered, *inter alia*, the following documents:

D1 P. W. Serruys *et al.*, "Transcatheter Aortic Valve Implantation: Tips and Tricks to Avoid Failure", 2009, pages 18-39 and 102-114
D5 US 2006/0259137 A1
D19 WO 2009/094188 A2

D20 WO 2009/149462 A2
D23 US 2008/0154355 A1
D25 US 2009/0157175 A1

IV. In its communication under Article 15(1) RPBA, the Board expressed the preliminary opinion, *inter alia*, that claim 12 as granted contained added subject-matter, whereas claim 1 as granted did not. In addition, the invention claimed in the patent as granted was sufficiently disclosed and the subject-matter of claim 1 as granted was novel and involved an inventive step.

V. With its submission of 15 January 2026 in response to the Board's communication, the patent proprietor filed a new auxiliary request 1a comprising only claim 1 as granted and no dependent claims.

VI. Oral proceedings were held before the Board on 21 January 2026 in the absence of opponent 1, who, although duly summoned, had announced in its submission of 13 November 2025 that it would not attend. At the end of the oral proceedings, the present decision was announced.

VII. The appellants' final requests were as follows.

The patent proprietor requested that the decision be set aside and that the patent be maintained as granted (main request) or, alternatively, as amended on the basis of one of the following auxiliary requests, ranked in this order: auxiliary request 1a filed with the patent proprietor's submission of 15 January 2026, auxiliary requests 1 to 3 filed with the patent proprietor's statement of grounds of appeal, auxiliary requests 4 to 111 filed with the patent proprietor's

reply to the opponents' statements of grounds of appeal, and auxiliary requests 112 to 137 filed with the patent proprietor's submission of 10 February 2025.

The opponents both requested that the decision be set aside and that the patent be revoked.

VIII. Claim 1 of the main request corresponds to claim 1 as granted and reads as follows (with the feature numbering used in the decision under appeal):

1 "*An assembly for implanting a balloon-expandable prosthetic aortic heart valve in a patient, comprising:*

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

1.2 *a prosthetic aortic heart valve (10) comprising a balloon-expandable frame (12) having a radially collapsed 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 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 intermediate row of angled struts (28) arranged end-to-end,*

1.2.4.1 *the upper and 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),*

1.2.4.1.1 *wherein an upper end of each axially extending strut (31) and an upper end of each commissure window frame portion (30) is connected to a junction (46) defined by the convergence of the lower ends of two angled struts (32) of the upper row of angled struts (32), and*

1.2.4.1.2 *a lower end of each axially extending strut (31) and a lower end of each commissure window frame portion (30) is connected to a junction (44) defined by the convergence of the upper ends of two angled struts (28) of the intermediate row of angled struts (28); and*

1.2.4.1.3 *wherein the plurality of commissure window frame portions (30) each comprise an enclosed opening (20) between first and second axially oriented side struts,*

1.3 *the prosthetic aortic heart valve (10) further comprising:*

1.3.1 *an annular inner skirt (16) positioned within the frame (12), the inner skirt (16) being secured to the inside of the frame (12), and*

1.3.2 *a leaflet structure (14) positioned within the frame (12), the leaflet structure (14) comprising a plurality of leaflets (40) and a plurality of commissure portions that extend outwardly through a respective commissure window frame portion (30),*

1.3.2.1 *wherein each of the plurality of leaflets (40) comprises a lower edge having a scalloped shape which is sutured to the inner skirt (16) between respective commissures of the leaflet structure (14).*"

Claim 12 of the main request corresponds to claim 12 as granted and reads as follows:

"*The assembly of any one of the preceding claims, wherein the frame (12) comprises a material selected from a group comprising stainless steel and a cobalt-chromium alloy.*"

IX. Auxiliary request 1a differs from the main request only in that all dependent claims have been deleted.

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

Main request - added subject-matter

Claim 12 as granted did not contain added subject-matter. A cobalt-chromium alloy as generally defined in that claim was explicitly disclosed in paragraph [053]

of the parent application as filed as an alternative to a nickel-cobalt-chromium alloy.

Auxiliary request 1a

Admittance

Auxiliary request 1a should be admitted into the appeal proceedings. It was limited to claim 1 as granted, the allowability of which could be inferred from the Board's communication under Article 15(1) RPBA. The deletion of the dependent claims overcame all objections considered convincing by the Board, thereby enhancing procedural economy without giving rise to any new issues.

Added subject-matter

Claim 1 as granted did not contain added subject-matter. The subject-matter of claim 1 as granted was based on an allowable intermediate generalisation of the original disclosure. The omitted features were not inextricably linked to the features retained in the claim.

The submissions made in this regard by opponent 1 in its statement of grounds of appeal should be disregarded. They did not properly substantiate why the decision under appeal was incorrect in this regard.

Sufficiency of disclosure

The claimed invention was sufficiently disclosed. The person skilled in the art would have no difficulty in carrying out the claimed invention using common general knowledge and the information contained in the patent.

In doing so, they would disregard any non-working configurations.

Novelty and inventive step

The subject-matter of claim 1 as granted was novel and inventive over the prior art referred to by the opponents.

D5

Paragraph [0134] of D5 neither disclosed nor suggested an alternative embodiment combining the anchoring structure shown in Figure 12 with slots for attaching the commissural tabs, as disclosed for the earlier embodiments of D5.

The person skilled in the art starting from the embodiment of Figure 12 would not replace the stitching of the commissural tabs with slot-based attachment without hindsight, even when taking D19 into account. This would run counter to the explicit teaching of paragraph [0134]. In any event, the combination of D5 with D19 would not lead to the subject-matter of claim 1 as granted.

D19

The crowns provided at the outflow end of the frames disclosed in D19 together formed an outflow row of openings. The longitudinal posts identified by the opponents as commissure window frame portions were therefore not positioned in an outflow row of openings, as required by features 1.2.4 to 1.2.4.1.2, but in an intermediate row.

Starting from D19, the person skilled in the art would neither remove the crowns from the outflow end portion of the frame nor relocate the longitudinal posts into the outflow row formed by the crowns without hindsight. They would therefore not arrive at the subject-matter of claim 1 as granted without exercising an inventive step.

D25

Opponent 2's novelty objection in view of D25 should not be admitted in the appeal proceedings, since it had been raised in the opposition proceedings only after expiry of the opposition period and had not been sufficiently substantiated.

In any event, the subject-matter of claim 1 as granted was novel over D25. The frame illustrated in the "triplicate illustration" did at least not disclose feature 1.2.4.1.2.

D20 and SAPIEN valve (D1)

Even if the person skilled in the art were to implement commissure window frame portions in the valve disclosed in D20 or in the SAPIEN valve, this would not lead to a configuration in which such frame portions were integrated into the frame as required by claim 1 as granted. In particular, opponent 2's reasoning relied on artificial and unconvincing interpretations of the frame shown in Figure 8 of D20.

XI. The opponents' arguments relevant to the present decision can be summarised as follows.

Main request - added subject-matter

Claim 12 as granted contained added subject-matter. There was no basis in the original disclosure for cobalt-chromium alloys in general, i.e. without any limitation that the alloys also contained nickel. The reference to a cobalt-chromium alloy in paragraph [053] appeared only in the context of examples of nickel-based alloys.

Auxiliary request 1a

Admittance

The opponents did not object to the admittance of auxiliary request 1a into the appeal proceedings.

Added subject-matter

Claim 1 as granted contained added subject-matter.

Claim 1 as granted resulted from an unallowable combination of features "cherry-picked" from different embodiments of the original disclosure, without a direct and unambiguous basis for such a combination. Furthermore, the "end-to-end" arrangement of the angled struts forming the outflow row of openings and the existence of "junctions" defined by these struts were not disclosed in the parent application as filed.

In any event, the features of claim 1 as granted were inextricably linked to a number of further features, the omission of which from claim 1 as granted constituted an unallowable intermediate generalisation of the original disclosure. In particular, the original disclosure was entirely directed to providing prosthetic heart valves having a reduced crimped

profile, as apparent from paragraph [006], which presented this reduction as the single overarching objective of the disclosure. Accordingly, the features of claim 1 as granted could not be allowably isolated from the further features of the originally disclosed valves contributing to that objective. This had been confirmed in T 56/23 (see Reasons 1.7.4 and 1.7.5), which concerned a prosthetic heart valve derived from the same original disclosure, in particular in relation to the design and functions of the junctions disclosed in paragraph [057].

Sufficiency of disclosure

The invention as defined in claim 1 as granted was not sufficiently disclosed. The claim encompassed various embodiments for which the patent provided no guidance, such as embodiments without commissural tabs or having an unspecified and potentially very large number of intermediate rows. Furthermore, the patent did not disclose how the various rows of openings were connected, which could be problematic for certain designs of the outflow row falling within the scope of the claim.

Novelty and inventive step

The subject-matter of claim 1 as granted was not novel in view of D5 and D25 and did not involve an inventive step starting from any of these documents, or from D19, D20 or the SAPIEN valve shown, for example, in D1.

D5

The wording "rather than being secured via slots" in paragraph [0134] of D5 implicitly disclosed, in

addition to the embodiment shown in Figure 12, a further alternative embodiment combining the hexagon-based anchoring structure with slot-based attachment of the commissural tabs. This alternative embodiment was novelty-destroying for claim 1 as granted.

In any event, this wording at least suggested implementing such a slot-based attachment mechanism in the embodiment shown in Figure 12. D19 provided a similar incentive. The person skilled in the art starting from Figure 12 of D5 would therefore arrive at the subject-matter of claim 1 as granted without exercising an inventive step.

D19

The person skilled in the art starting from one of the valves disclosed in D19, for example a valve based on the frame shown in Figure 32, would arrive at the subject-matter of claim 1 as granted without exercising an inventive step.

In particular, the row from which the crowns extended, marked "row I" in the annotated figure provided on page 9 of opponent 2's submission of 5 December 2023, constituted an outflow row of openings which comprised all features 1.2.4 to 1.2.4.1.2. This conclusion held notwithstanding the presence of the crowns, since feature 1.2.2 did not exclude further structural elements extending from the outflow row.

The crowns, which were not connected to each other, did not themselves form a row of openings. In any event, feature 1.2.2 did not exclude the presence of more than one outflow row. Accordingly, row I constituted an

outflow row of openings even if the crowns were regarded as defining a further outflow row.

D25

As illustrated in the coloured "triplicate illustration" provided on page 53 of opponent 2's statement of grounds of appeal, a frame obtained by repeating three times the frame pattern shown in Figure 13 of D25 comprised all features of claim 1 as granted, including feature 1.2.4.1.2. In the context of the contested patent, and as apparent from Figures 9 and 10, the formation of a "junction" did not require that the angled struts merge with each other when reaching the end of the corresponding axial strut. It was sufficient that the struts merge with an end of an axial strut, such as one forming part of a commissure window frame portion. Therefore, although the upper ends of the angled struts of the intermediate row of struts were not in direct contact with each other, their convergence still defined a junction according to feature 1.2.4.1.2.

This novelty objection could not be disregarded, since it had been admitted by the opposition division (see point 5.6 of the minutes of the oral proceedings) and formed part of the decision under appeal.

Concerning inventive step starting from D25, opponent 2 referred to section D.III of one of its earlier submissions filed in the opposition proceedings, Annex HL1, attached to its reply to the patent proprietor's statement of grounds of appeal. It was stated therein that any distinguishing features would be obvious in view of D25 alone or in combination with D1 or D5.

D20 and SAPIEN valve (D1)

Additional inventive-step objections were raised starting from the valve of Figure 8 of D20 or from the SAPIEN valve, considered to form part of the common general knowledge. Opponent 2 referred in this respect to passages of its earlier submissions, the aforementioned Annex HL1 and Annex C, attached to opponent 2's statement of grounds of appeal.

Starting from either valve, the person skilled in the art would consider implementing commissure window frame portions in the frame, thereby arriving at the subject-matter of claim 1 as granted, without exercising an inventive step.

Reasons for the Decision

Subject-matter of the contested patent

1. The contested patent relates to an assembly comprising a balloon-expandable prosthetic aortic heart valve and a delivery apparatus having an elongated shaft with an inflatable balloon for minimally invasive implantation of the valve in a patient, as defined in claim 1 as granted.

1.1 As illustrated, for example, in Figures 2, 4 and 5, reproduced below, the prosthetic aortic valve (10) comprises a balloon-expandable frame (12) including a plurality of angularly spaced, axially extending commissure window frame portions (30) (features 1.2 and 1.2.4.1), each comprising an opening (20) enclosed between first and second axially oriented side struts (feature 1.2.4.1.3). A leaflet structure (14)

comprising a plurality of leaflets (40) and a plurality of commissure portions that extend outwardly through a respective commissure window frame portion is positioned within the frame (feature 1.3.2).

FIG. 2

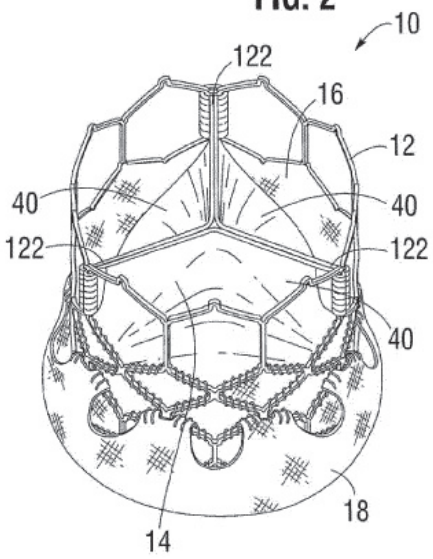


FIG. 4

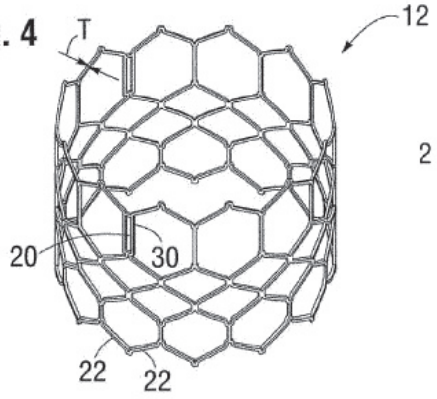
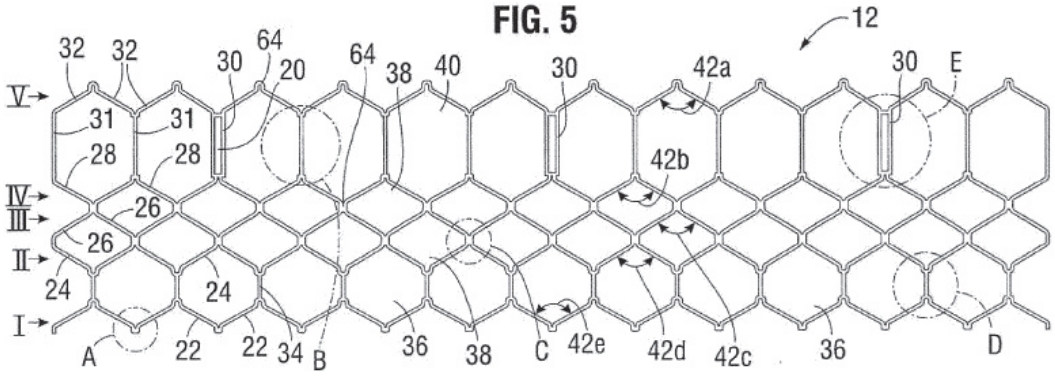


FIG. 5



1.2 The frame includes an inflow row of openings (36) at an inflow end portion of the frame, an outflow row of openings (40) at an outflow end portion of the frame, and at least one intermediate row of openings (38) (two such intermediate rows of openings in the example shown in the figures reproduced above) between the inflow row of openings and the outflow row of openings (features 1.2.1 to 1.2.3).

1.3 Features 1.2.4 to 1.2.4.1.2 define the structure of the outflow row of openings in more detail and specify how the commissure window frame portions are integrated in this row of openings. In particular, the outflow row of openings is formed by an upper and an intermediate circumferentially extending rows of angled struts (28, 32) arranged end-to-end, these intermediate rows of angled struts being interconnected by a plurality of axially extending struts (31) and the plurality of commissure window frame portions.

According to the patent description (see paragraph [0032]), securing the commissure window frame portions at their upper and lower ends to the adjacent rows of angled struts provides a robust configuration which enhances the valve's fatigue resistance under cyclic loading compared with known configurations in which cantilevered struts are used for supporting the commissures of the leaflet structure.

1.4 In addition, the valve comprises an annular inner skirt (16) positioned within the frame and secured to the inside thereof, each of the leaflets comprising a lower edge having a scalloped shape which is sutured to the inner skirt between respective commissures of the leaflet structure.

Main request - claim 12 - added subject-matter

2. The descriptions and drawings of the parent and divisional applications as filed are substantially identical, with the claims of the parent application being included as a list of embodiments in paragraph [0115] of the description of the divisional application. Consequently, the content of the parent application as filed, which corresponds to the content

of D6, constitutes the relevant disclosure for the assessment of added subject-matter under both Articles 76(1) and 123(2) EPC. This content is referred to as "the original disclosure" in the following.

3. At the oral proceedings before the Board, the parties did not make any further comments on whether claim 12 as granted contained added subject-matter, but referred to their written submissions. The Board therefore confirmed its preliminary view on this issue expressed in its communication under Article 15(1) RPBA (see point 4.1.3), according to which claim 12 as granted contains added subject-matter. This is so for the following reasons.

The second alternative in claim 12 as granted defines the frame as comprising "a cobalt-chromium alloy", without any further limitation. On a plain reading, the wording of claim 12 thus relates to a cobalt-chromium alloy *in general*, i.e. one that may not contain nickel.

The Board agrees with the opponents that this alternative is not disclosed in the original disclosure.

Contrary to the patent proprietor's argument, the mention of a cobalt-chromium alloy in paragraph [053] of the original disclosure does not provide a basis for this alternative. The examples given in parentheses in paragraph [053], namely "*e.g.*, a cobalt-chromium or a nickel-cobalt-chromium alloy", are merely examples (as indicated by the term "*e.g.*") of the "nickel based alloy" genus disclosed immediately before. Therefore, the "cobalt-chromium alloy" example must be understood as referring to a cobalt-chromium alloy that itself contains nickel, contrary to the patent proprietor's

view. The Board notes in this respect that, in metallurgical practice, alloys marketed as cobalt-chromium alloys frequently also contain nickel.

It follows that cobalt-chromium alloys *in general*, i.e. alloys not necessarily containing nickel, are not directly and unambiguously disclosed in the original disclosure, with the result that claim 12 as granted contains added subject-matter. This also confirms the opposition division's corresponding conclusion in the decision under appeal (see Reasons 20.5).

For this reason alone, the main request is not allowable.

Auxiliary request 1a

4. Admittance

The patent proprietor filed auxiliary request 1a for the first time in the entire proceedings with its submission of 15 January 2026, i.e. after the notification of the Board's communication under Article 15(1) RPBA. Therefore, the admittance of this request into the appeal proceedings is subject to Article 13(2) RPBA.

Despite its late filing, the Board found it justified to take auxiliary request 1a into account. Indeed, as put forward by the patent proprietor, this request only includes claim 1 as granted, which appeared allowable according to the Board's preliminary opinion set out in the communication under Article 15(1) RPBA (see points 4.2.1, 5 and 6). Hence, by deleting all dependent claims auxiliary request 1a overcame all the objections that the Board had found convincing (see point 4.1 of

the communication), without giving rise to any new issues and without shifting the case, thereby streamlining the upcoming discussion at the oral proceedings and enhancing procedural economy. There were therefore exceptional circumstances which justified to take auxiliary request 1a into account.

Furthermore, the opponents did not object to its admittance into the appeal proceedings.

5. Added subject-matter

5.1 Claim 1 as granted does not contain added subject-matter and complies with Articles 76(1) and 123(2) EPC. As set forth below and consistent with the Board's preliminary opinion expressed in its communication under Article 15(1) RPBA (see point 4.2.1), the opponents' objections to the contrary are unconvincing.

In view of this conclusion, there is no need for the Board to address the question of the admittance of the arguments put forward in this regard by opponent 1 in its statement of grounds of appeal, which was contested by the patent proprietor in its written submissions but not addressed again at the oral proceedings.

5.2 It is common ground that the original disclosure does not disclose an embodiment explicitly comprising all features of claim 1 as granted in combination.

The opponents' added subject-matter objections essentially follow two lines of argument.

Firstly, it was submitted that claim 1 resulted from the combination of features "cherry-picked" from different embodiments originally disclosed, even though

the original disclosure provided no support for such combination. In addition, certain features of claim 1 as granted, namely the "end-to-end" arrangement of the angled struts forming the outflow row of openings (feature 1.2.4) and the existence of "junctions" defined by these angled struts (features 1.2.4.1.1 and 1.2.4.1.2) as claimed, were said not to be disclosed at all in the original disclosure.

Secondly, it was argued that in any event the features of claim 1 as granted were inextricably linked to a number of further features, the omission of which from claim 1 as granted constituted an unallowable intermediate generalisation of the original disclosure.

Neither line of argument is convincing, for the reasons set out below under points 5.3 and 5.4, respectively.

5.3 *Disclosure of the combination of features of claim 1 as granted in the original disclosure*

5.3.1 According to the "gold standard", which is the relevant test for assessing compliance with Articles 76(1) and 123(2) EPC, the original disclosure within the limits of which an amendment to a European patent application can be made without adding subject-matter is what a person skilled in the art would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the originally filed description, claims and drawings (see G 2/10, Reasons 4.3). Hence, considering only subject matter that is literally disclosed in its entirety in a single passage of the originally filed description, claims and drawings to be originally disclosed would not be in accordance with the gold standard.

5.3.2 The subject-matter of claim 1 is based on those valve embodiments originally disclosed which have a frame comprising, as defined in claim 1 as granted, an inflow row of openings at an inflow end portion of the frame (feature 1.2.1), an outflow row of openings at an outflow end portion of the frame (feature 1.2.2) including a plurality of axially extending commissure window frame portions, each comprising an enclosed opening between first and second axially oriented side struts (features 1.2.4.1 and 1.2.4.1.3), and at least one intermediate row of openings between the inflow row of openings and the outflow row of openings (feature 1.2.3).

Those embodiments include the prosthetic valve 10 shown in Figure 2 and described in paragraphs [050] *ff.*, which comprises the frame 12 shown in Figures 4 and 5 (see point 1. above and paragraphs [054] and [055] of the original disclosure) or the alternative frame 50 shown in Figure 12 (see paragraph [062]) - both frames comprising two intermediate rows of openings.

In addition, like the valve of claim 1 as granted, the valve 10 further comprises a leaflet structure 14 with a plurality of leaflets 40 positioned within the frame and mounted to the commissure window frame portions (feature 1.3.2), the lower edge of the leaflets having a scalloped shape (feature 1.3.2.1) (see paragraphs [051] and [055]), as well as an inner skirt 16 positioned within the frame and secured to its inside (feature 1.3.1), to which the lower edge of the leaflets is sutured (feature 1.3.2.1) (see paragraphs [050], [064] and [073]).

5.3.3 Furthermore, contrary to the opponents' argument, the valve 10 also comprises the following features.

a) End-to-end arrangement of the struts of the outflow row of openings (see feature 1.2.4)

Contrary to the opponents' argument, the angled struts 28, 32 forming the outflow row of openings of the frame 12 are "arranged end-to-end" in the sense of feature 1.2.4, even though the ends of two adjacent angled struts that connect to a commissure window frame portion may appear as spaced from each other in Figure 10, reproduced below.

FIG. 9

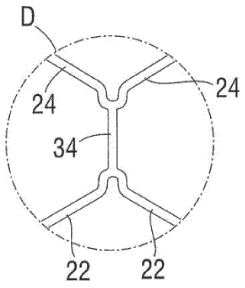
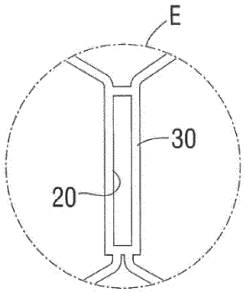


FIG. 10

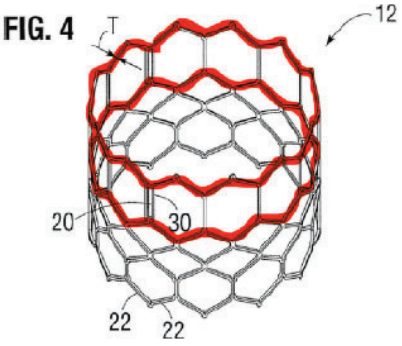


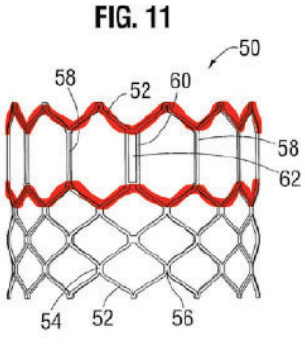
It is true, as submitted by the opponents, that the original disclosure discloses such an "end-to-end" arrangement *verbatim* only for the first row I of angled struts 22 of the inflow row of openings (see paragraph [054] and Figure 9 reproduced above).

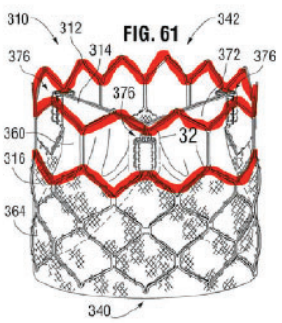
However, the person skilled in the art understands from paragraph [054] of D6 and the corresponding paragraph [0031] of the patent in suit that in both documents the expression "arranged end-to-end" merely describes the arrangement of the angled struts 22 in a continuous ring-like sequence around the circumference of the frame so as to form the described circumferentially extending first row I of angled struts. The presence of intermediate connecting portions where the ends of the

struts 22 are connected to axially extending struts 34 does not interrupt the continuity of this circumferential row of angled struts. Nor does the term "end-to-end" rule out the presence of slight spacing between the corresponding ends of two adjacent angled struts.

Such an arrangement is clearly observed not only for the second row II of angled struts 24 of the inflow row of openings (see Figure 9) - which the opponents did not contest, in spite of the term "end-to-end" not being used *verbatim* in relation to that row in paragraph [054] either - but also for the angled struts 28 and 32 forming the outflow row of openings. These struts, similarly, form circumferentially extending fourth and fifth rows IV and V of struts, as highlighted by the patent proprietor in the annotated figures shown on page 14 of its reply to the opponents' statements of grounds of appeal, reproduced below. As for the axially extending struts 34 connected to the first row of angled struts 22, slight spacing between the adjacent ends of two adjacent angled struts 28, 32 - or the presence of axially extending struts 31 - does not interrupt the continuity of these circumferential rows of angled struts.







The person skilled in the art therefore considers the angled struts 28, 32 forming the outflow row of openings to be, likewise, arranged end-to-end as

defined by feature 1.2.4, even if this is not disclosed expressly as for the angled struts 22 of the inflow row. Similar considerations apply to the frame 50. It follows that feature 1.2.4 does not add subject-matter.

b) Junctions (see features 1.2.4.1.1 and 1.2.4.1.2)

The opponents' objection to the term "junction" used in features 1.2.4.1.1 and 1.2.4.1.2 is based on the argument that paragraph [054] of the original disclosure, from which the wording of these features is derived, did not disclose any such "junctions" but only referred to the "location[s]" defined by the convergence of the ends of two angled struts, which was more general.

This is also unconvincing. The person skilled in the art understands from paragraphs [054] and [055] that where the ends of two adjacent angled struts 28, 32 converge at one location from which a commissure window frame portion 30 extends and to which this commissure window frame portion is connected, as shown in Figure 10, there must be something "joining" the ends of the angled struts 28, 32 at least to each other and to the commissure window frame portion, i.e. a "junction". Nothing more is implied by the term "junction" used in features 1.2.4.1.1 and 1.2.4.1.2. Therefore, using the term "junction" to refer to that location does not add matter, even if this term is not expressly used to this end in the original disclosure.

5.3.4 It follows that the combination of features of claim 1 as granted is disclosed in the original disclosure, contrary to the opponents' argument.

5.4 Allegedly unallowable intermediate generalisation

5.4.1 It is common ground that a number of further features of the valve 10 originally disclosed have been omitted from claim 1 as granted. The opponents' further added subject-matter objections, addressed below, are based on the contention that several of these omitted features were, however, inextricably linked with the features of claim 1 as granted, with the consequence that claim 1 as granted was, according to the opponents, in any case based on an unallowable intermediate generalisation of the original disclosure.

The Board disagrees also in this regard.

5.4.2 To succeed, an objection of an unallowable intermediate generalisation in a claim must not only identify the features allegedly impermissibly omitted from the claim, but also explain why their omission introduces added subject-matter. According to established case law of the Boards of Appeal, this explanation requires demonstrating that the omitted features are inextricably linked with (some of) the claimed features according to the original disclosure (see Case Law of the Boards of Appeal of the EPO, 11th edn., 2025, II.E. 1.9.1, as well as, for instance, decisions T 1762/21, catchword, T 824/23, Reasons 1.7.1 and T 1888/22, third item of Reasons 3.2.2). Only in this case is the person skilled in the art presented with technical information which they would not derive directly and unambiguously, using common general knowledge, from the original disclosure, thereby giving rise to subject-matter in accordance with G 2/10 ("gold standard"). The same criteria have also been applied by the UPC Court of Appeal to assess the allowability of an intermediate

generalisation in its decision UPC_CoA_464/2024 of 25 November 2025 (see in particular Reasons 81, 97, 103 and 104).

As set forth below, the omission of the features referred to by the opponents does not present the person skilled in the art with new information which extends beyond the original disclosure, but instead remains within the limits of what the person skilled in the art derives directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the original disclosure as a whole.

5.4.3 One central argument put forward by the opponents in support of an inextricable link is that the original disclosure was entirely directed to providing prosthetic heart valves having a reduced crimped profile. In their view, this followed from paragraph [006], which would present this reduction as the single overarching objective of the disclosure. The reduction of the crimped profile would therefore constitute a defining and indispensable aspect of the invention, such that the features of claim 1 as granted could not be allowably isolated from the further features of the valve 10 contributing to this objective.

This is not convincing. While it is correct that reduction of the valve's crimped profile is one of the core objectives of the original disclosure, the person skilled in the art does not derive that this objective constitutes a limiting principle governing the disclosure as a whole. Rather, they understand that the original disclosure discloses a number of further distinct technical measures and associated advantages relating to prosthetic heart valves which are not

inextricably linked to the reduction of the crimped profile. What is more, the person skilled in the art recognises that the various technical solutions disclosed for achieving a reduced crimped profile are themselves not inextricably linked to each other.

Notably, from paragraph [055] of the original disclosure, the person skilled in the art infers that by integrating the commissure window frame portions in the outflow row of openings of the frame as defined in features 1.2.4.1 to 1.2.4.1.3, the valve's fatigue resistance under cyclic loading is enhanced compared with known configurations in which cantilevered struts are used to support the commissures of the leaflet structure. The person skilled in the art recognises that such enhancement is achieved independently and regardless of the further features referred to by the opponents, even though these features may (also) contribute to the reduction of the valve's crimped profile. These features are addressed in turn below (see also in this regard T 1011/23, Reasons 2).

5.4.4 Larger size of the openings of the outflow row (see feature 1.2.2)

It is true that designing the openings 40 of the outflow row as "relatively large and [...] sized to allow portions of the leaflet structure 14 to protrude, or bulge, into and/or through the openings 40 when the frame 12 is crimped" is described in paragraph [056] as a way of minimising the crimping profile of the valve.

However, the person skilled in the art recognises this design of the outflow row merely as an advantageous feature, not one inextricably linked with the other claimed features of the frame. Not sizing the outflow

openings 40 as explained in paragraph [056] would just result in a larger crimping profile and would not prevent the integration of the commissure window frame portions in the outflow row as defined in claim 1. It follows that feature 1.2.2 does not add subject-matter.

5.4.5 Design and function of the junctions (see features 1.2.4.1.1 and 1.2.4.1.2)

Opponent 1 also argued that even if the original figures were considered to form the basis for features 1.2.4.1.1 and 1.2.4.1.2, as held in the decision under appeal (see Reasons 19.4), the specific box-shaped design of the "junctions" allegedly disclosed in these figures could not, in any event, be allowably omitted from claim 1 as granted.

This is not convincing. As set out in point 5.3.3 b) above, the person skilled in the art recognises from paragraphs [054] and [055] that the specific design of these junctions - which is not described in detail in these paragraphs - is irrelevant as long as they are defined by the convergence of the ends of the angled struts and they are connected to an end of a commissure window frame portion, i.e. as they are in accordance with claim 1 as granted. Omitting their specific design from claim 1 as granted therefore does not add subject-matter.

Furthermore, in its submission of 11 April 2025 and with reference to T 56/23 - another appeal case concerning a similar prosthetic heart valve derived from the same original disclosure - opponent 2 submitted, for the first time in the present proceedings, that the junctions referred to in features 1.2.4.1.1 and 1.2.4.1.2 could in fact not be

allowably isolated from their function disclosed in paragraph [057] of "prevent[ing] full closure" of the openings of the outflow row, thereby allowing for a reduced crimped profile.

This objection had been considered relevant by the deciding Board in T 56/23 (see Reasons 1.7.4 and 1.7.5). In line with its preliminary opinion expressed in the communication under Article 15(1) RPBA, the present Board decided at the oral proceedings to admit this objection. The question of its admittance, which had been contested by the patent proprietor in its written submissions, was not further addressed by the parties at the oral proceedings.

In substance, however, this objection is not convincing. As discussed above for the size of the openings of the outflow row, the person skilled in the art recognises the specific function of the junctions disclosed in paragraph [057] as an advantageous feature, albeit one not inextricably linked with the other claimed features of the frame. Designing the junctions without this function would just lead to the leaflet material being constrained within the crimped frame and thus to the valve having a larger crimping profile. However, this would not prevent the integration of the commissure window frame portions in the outflow row as defined in claim 1 as granted.

5.4.6 Features of the intermediate row(s) and inflow row of openings (see features 1.2.3 and 1.2.1)

a) Number of intermediate rows of openings

Contrary to the opponents' arguments, the person skilled in the art understands from the original

disclosure that the number of intermediate rows of openings in the frames 12 and 50 of Figures 5 and 12, two, is merely exemplary.

The specific description of the frame 12 in paragraph [054] does not present this number as anything other than an example, with paragraph [054] merely describing "the illustrated embodiment" shown in Figure 5. Similar considerations apply to the frame 50, whose description in paragraph [062] only refers in general terms to "multiple" rows of angled struts forming the frame, i.e. without any limitations as to the exact number of rows of openings.

In addition, the person skilled in the art finds in paragraph [012] the disclosure of a frame comprising, like the frames 12 and 50, an inflow row of openings and an outflow row of openings connected to each other by "at least one intermediate row of openings". Even assuming, as argued by the opponents, that paragraph [012] relates to embodiments different from those including the frames 12 and 50, the person skilled in the art still derives from this passage that the original disclosure also foresees, at least implicitly, that the frames 12 and 50 could likewise include generally "at least one intermediate row of openings" as defined in feature 1.2.3 of claim 1 as granted.

b) Larger size of the openings of the inflow row

Furthermore, neither paragraph [012] nor the detailed description of the frame 12 in the original disclosure establishes an inextricable link between the number of intermediate rows of openings (at least one according to paragraph [012], and exactly two in the frame 12)

and the openings of the inflow row being larger than those of the intermediate rows of openings, contrary to the opponents' argument.

Even if the second sentence of paragraph [012] clearly refers to "the" openings defined in the preceding sentence, the person skilled in the art does not infer any such inextricable link from the mere juxtaposition of these two sentences.

Nor do they derive such an inextricable link from the specific disclosure in paragraph [061] that the openings 36 of the inflow row of the frame 12 are larger than the openings 38 of the two intermediate rows of openings. From this, they merely conclude that designing the openings of the inflow row to be larger than those of the intermediate rows enables the valve comprising such a frame to adopt a tapered shape when crimped, making it easier to accommodate an outer skirt - which is not claimed in claim 1 as granted - at the inflow end of the valve, without increasing its overall crimped profile. However, this feature is not indispensable, in particular as shown by the frame 50, presented as an alternative to the frame 12, which comprises openings of the inflow row of substantially the same size as the openings of the intermediate rows. The person skilled in the art therefore understands that the relative size of the openings of the inflow row is not inextricably linked with the remaining features of the frame 12. Omitting this feature from features 1.2.3 and 1.2.1 therefore does not add subject-matter.

c) Design of the openings of the intermediate row(s)

Contrary to the opponents' argument, the person skilled in the art also understands that the specific diamond shape of the openings of the intermediate rows of the frames 12 and 50, which results from these openings being defined by circumferentially extending rows of angled struts arranged end-to-end, is only illustrative. Whereas the outflow row must be formed by two such rows of angled struts to enable the commissure window frame portions to be secured at their upper and lower ends to the rest of the frame 12, thereby providing the robust configuration described in paragraph [055] of the original disclosure, the way how the intermediate rows of openings are formed does not affect the integration of the commissure window frame portions in the outflow row. This applies even if the diamond shape of the opening of the intermediate rows may itself have advantages, for example in allowing the "dog-boning effect" referred to by the opponents. In any case, the disclosure in paragraph [012] of a general frame structure with an inflow row, an outflow and at least one intermediate row in between does not specify any particular shape for the openings of the frame.

It follows that feature 1.2.3 does not add subject-matter.

5.4.7 Weave structure of the inner skirt (see feature 1.3.1)

The opponents also argued that all originally disclosed valve embodiments comprising an annular inner skirt secured to the inside of the frame, as defined by feature 1.3.1, were disclosed only in combination with the further limitation that the inner skirt comprised a weave of a first set of strands with a second set of strands, both the first and second sets of strands

being non-parallel with the axial direction of the valve, for example in paragraph [019]. Since such a weave structure was important for the proper functioning of the valve, the opponents argued that it could not be allowably omitted from claim 1 as granted.

This is also unconvincing. Paragraph [064] of the original disclosure discloses that the inner skirt 16 of the valve 10 can be "secured to the inside of frame 12 via sutures 70" without any reference to the weave structure of the inner skirt. In any case, paragraph [067] presents the weave structure disclosed in paragraph [019] as a preferred but optional feature ("the skirt 16 is desirably woven [...]"). For example, paragraph [072] discloses that the inner skirt can alternatively be formed from woven elastic fibres, some of which run parallel to the axial direction of the inner. It follows that the omission from claim 1 as granted of the specific weave structure referred to by the opponents does not add subject-matter.

5.4.8 Outer skirt (see feature 1.3.1)

The opponents also argued that there was no basis in the original disclosure for omitting from claim 1 as granted the outer skirt originally disclosed for the valve 10. According to them, the outer skirt was inextricably linked to the inner skirt positioned inside the frame defined in feature 1.3.1.

This is also unconvincing. As submitted by the patent proprietor, the person skilled in the art would see no inextricable link between the inner skirt and the outer skirt of the valve. The original disclosure contains several embodiments of a valve comprising an inner skirt secured to the inside of the frame but no outer

skirt, such as in original claim 22 and paragraph [019].

5.4.9 Leaflets having side tabs, commissure window frame portions being depressed inwardly (see feature 1.3.2)

The opponents also objected to feature 1.3.2, arguing that the original disclosure, in particular paragraphs [052] and [086], claim 9 and Figure 56, provided no basis for claiming "a plurality of commissure portions that extend outwardly through a respective commissure window frame portion" while omitting that (i) the commissure portions were formed by side tabs of the leaflets which extended through the enclosed openings of the commissure window frame portions and were sutured to the side struts defining these enclosed openings, and (ii) the commissure window frame portions were depressed radially inwardly to minimise the crimped profile of the valve.

The Board also disagrees in this regard.

Original claim 9 discloses a leaflet structure comprising a plurality of "commissure portions that extend outwardly through respective commissure windows" of the frame, i.e. with the same level of generalisation as in feature 1.3.2, without specifying in detail how these commissure portions are formed, in particular whether they further include feature (i).

It is true that claim 9 refers to "commissure windows" and not to "commissure window frame portions" as in feature 1.3.2. However, the person skilled in the art recognises that these terms are interchangeably used in the original disclosure, sometimes even in the same paragraph (see for example paragraph [086] which

equally refers to the "commissure windows", "window frame portions" and "commissure window frames" 30).

In addition, it is irrelevant that, at the same time, claim 9 also discloses feature (ii). From paragraph [086] the person skilled in the art understands that this feature merely allows to minimise the valve's crimped profile. However, here again, this advantageous effect does not demonstrate any inextricable link between feature (ii) and the fact that the commissure portions of the leaflets extend outwardly through respective commissure windows. Designing the commissure windows, or commissure window frame portions, without them being depressed as disclosed in claim 9 would just result in a larger crimping profile and would not prevent their integration in the outflow row as defined in claim 1 as granted.

Therefore, contrary to the opponents' argument and contrary to the opposition division's finding in the decision under appeal (see Reasons 18), feature 1.3.2 does not add subject-matter either.

5.4.10 It follows that the subject-matter of claim 1 as granted is not based on an unallowable intermediate generalisation of the original disclosure, contrary to the opponents' argument.

6. Sufficiency of disclosure

At the oral proceedings before the Board, the parties did not make any further submissions on the issue of sufficiency of disclosure, but merely referred to their written submissions. The Board therefore saw no reason to depart from its preliminary opinion expressed in the communication under Article 15(1) RPBA (see point 5),

according to which the person skilled in the art would have no difficulty in carrying out the claimed invention using common general knowledge and the information contained in the patent.

The opponents' objections to the contrary are not convincing. In particular, when carrying out the claimed invention, the person skilled in the art would naturally exclude any non-working embodiment, such as valves with a high number of rows, if this high number of rows were to hinder the valve's proper operation.

7. Novelty and inventive step in view of D5

Contrary to the opponents' view, the subject-matter of claim 1 as granted is novel in view of D5 and involves an inventive step starting from that document.

7.1 The opponents' objections in this respect are based on the embodiment of a prosthetic heart valve shown in Figure 12, reproduced below, and described in paragraph [0134] of D5.

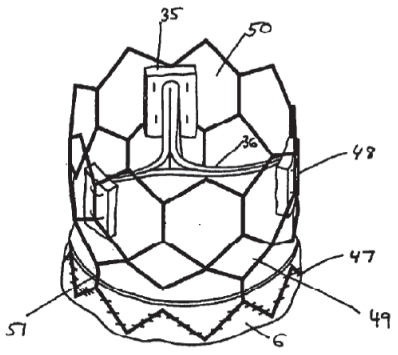


FIG. 12

The following passage of paragraph [0134] is central to the assessment of novelty and inventive step:

"*In this embodiment, the outflow rim (48) of the anchoring structure is comprised of diamond (49) and hexagon (50) shaped structures which facilitate collapsibility and dynamic compliance. 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.*"

7.2 It is common ground that this embodiment comprises a frame ("anchoring structure") and a leaflet structure ("valve") secured to the inside of the frame by "stitch[ing]" the commissure portions ("commissural tabs") 35 of the leaflets (see Figure 9) to axially extending struts defining the hexagon-shaped elements of the frame.

Accordingly, the frame of this embodiment does not comprise any "slots" through which the commissural tabs of the leaflets would be inserted, as disclosed in D5 for the preceding embodiments shown, for example, in Figures 6A to 6C (see Figure 6C reproduced below showing such a slot 21).

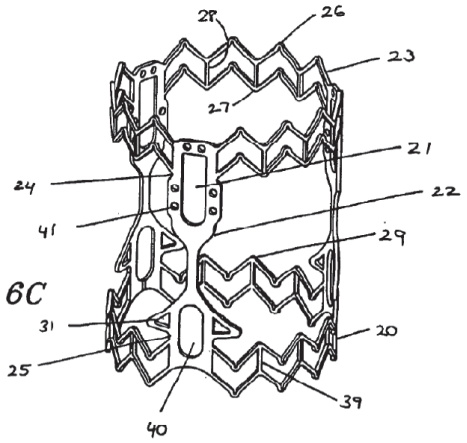


FIG. 6C

Therefore, this embodiment does not comprise any commissure window frame portions (features 1.2.4.1 to 1.2.4.1.3) through which a plurality of commissure

portions of the leaflet structure extend outwardly (feature 1.3.2).

For this reason alone, the subject-matter of claim 1 as granted is novel over this embodiment.

7.3 The opponents did not contest this understanding based on the explicit disclosure of paragraph [0134].

However, they argued that the wording "can be stitched [...] rather than being secured via slots" (emphasis added by the Board) in paragraph [0134] implicitly disclosed, in addition to the embodiment described above, a further alternative embodiment in which the anchoring structure of Figure 12 was provided with slots 21 for attaching the commissural tabs of the valve (as shown in Figure 6C), instead of these tabs being stitched to the hexagon-shaped elements of the outflow rim (as shown in Figure 12). According to the opponents, this alternative embodiment was novelty-destroying.

The Board disagrees.

At most, the wording "rather than being secured via slots" indicates that, in other embodiments of D5, commissural tabs can be secured via slots, as indeed disclosed for the embodiments shown in Figures 6A to 6C. In this sense, paragraph [0134] merely acknowledges an alternative attachment technique described elsewhere in D5.

However, the negative formulation introduced by the expression "rather than" clearly distinguishes the embodiment of Figure 12 from those slot-based embodiments and teaches that, in the embodiment under

consideration ("In this embodiment"), stitching is used instead of slots. The term "can" in the expression "can be stitched" merely expresses the suitability of the disclosed hexagon-based anchoring structure for stitching and does not disclose implicitly that the commissural tabs could alternatively be secured by means of slots.

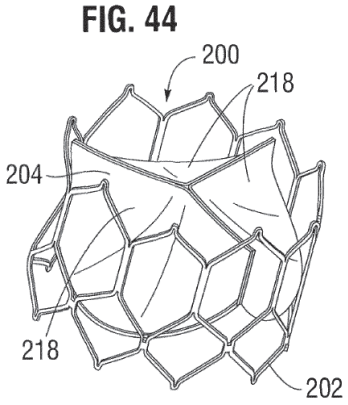
Consequently, contrary to the opponents' argument, the cited passage of paragraph [0134] does not provide a direct and unambiguous disclosure of an alternative embodiment combining the anchoring structure of Figure 12 with slots for securing the commissural tabs.

7.4 The opponents further contended that, even if the subject-matter of claim 1 as granted were considered to differ from D5 (at least) on account of the attachment of the leaflet commissure portions via commissure window frame portions (features 1.2.4.1 to 1.2.4.1.3 and 1.3.2), these distinguishing features could not, in any event, confer an inventive step.

7.4.1 Opponent 2 argued that the contested patent itself did not attribute any particular technical effect to the use of commissure window frame portions other than achieving the robust configuration described in paragraph [0032] of the patent. According to opponent 2, such a robust configuration was already achieved in the embodiment of Figure 12 of D5, since the commissural tabs were stitched to struts integrated in the outflow row of openings of the frame.

Opponent 2 further referred to Figure 44 and paragraph [0064] of the contested patent. The frame shown in Figure 44, reproduced below, comprises hexagon-shaped elements in the outflow row, similar to the frame of

Figure 12 of D5. According to opponent 2, paragraph [0064] presented suturing the leaflets to the frame and providing the frame with commissure window frame portions to assist in suturing the leaflets as two alternative attachment mechanisms, without identifying any specific technical advantage associated with the latter.



Consequently, opponent 2 formulated the objective technical problem solved by features 1.2.4.1 to 1.2.4.1.3 and 1.3.2 as being merely the provision of an alternative attachment mechanism for the commissure portions of the leaflet structure. Opponent 1's inventive-step objection follows essentially the same line of reasoning.

7.4.2 Opponent 2 argued that the person skilled in the art at least understood from the wording "rather than being secured via slots" in paragraph [0134] of D5 that securing the commissural tabs by stitching or via slots constituted equivalent alternatives. While opponent 1 acknowledged that the terms "rather than" expressed a preference for stitching, it likewise submitted that this wording at least suggested the slot-based alternative.

Accordingly, the opponents concluded that the person skilled in the art starting from the embodiment of Figure 12 of D5 would be motivated by paragraph [0134] to replace the stitching of the commissural tabs with a slot-based attachment as disclosed in the preceding embodiments of D5.

To this end, the person skilled in the art would merely replace the axially extending struts to which the commissural tabs are stitched with slots, or commissure window frame portions, and use these to secure the commissural tabs. As acknowledged in paragraph [0064] of the contested patent, there would be no technical difficulty in doing so.

Moreover, according to opponent 2, D19 would likewise motivate the person skilled in the art to make this modification. D19 disclosed commissure window frame portions ("longitudinal posts") for securing the commissure portions of valve leaflets, what is more in the context of similar hexagon-shaped frame openings (see for example Figure 3 and paragraph [0057]); see also the discussion of D19 in point 8. below.

In this way, the person skilled in the art would, according to the opponents, arrive at the subject-matter of claim 1 as granted without exercising an inventive step.

7.4.3 Even when accepting the opponents' formulation of the objective technical problem in view of features 1.2.4.1 to 1.2.4.1.3 and 1.3.2, this line of reasoning is not convincing.

As submitted by the patent proprietor, the person skilled in the art understands from the cited passage

of paragraph [0134] of D5 that an anchoring structure comprised of diamond- and hexagon-shaped elements, as shown in Figure 12, "facilitate[s] collapsibility and dynamic compliance" compared, implicitly, to the anchoring structures disclosed earlier in D5, which all comprise a plurality of slots 21 supported by posts 22 for securing the leaflet commissural tabs, and no such diamond- and hexagon-shaped elements. The further disclosure that, in the embodiment of Figure 12, the tabs are stitched to the hexagon-shaped elements "rather than being secured via slots" is consistent with this teaching.

In view of this teaching, the person skilled in the art starting from Figure 12 would not, without hindsight, modify the frame so as to introduce slot-based attachment, since this would negatively affect the properties explicitly emphasised in paragraph [0134] and thus run counter to the teaching of D5.

Nor would D19 prompt the person skilled in the art to make such a modification. The longitudinal posts disclosed in D19 for attaching the leaflets to the frame are explicitly presented as "providing additional stability to the first end 12 of the stent" (see paragraph [00057]). Implementing such longitudinal posts in the frame of Figure 12 of D5 would therefore be detrimental to its collapsibility and dynamic compliance and would thus also run counter to the explicit teaching of paragraph [0134], for the same reason as set out above.

Furthermore, D19 consistently discloses the presence of "crowns" at the outflow end of the frame, with the attachment posts arranged in a further intermediate row of openings (see point 8.1.3 below) and not integrated

in an outflow row of the frame, as required by claim 1 as granted. Therefore, even if, *arguendo*, the person skilled in the art were to implement such longitudinal posts in the frame of Figure 12 of D5, they would not arrive at the subject-matter of claim 1 as granted.

Therefore, the person skilled in the art starting from D5 would not arrive at the subject-matter of claim 1 as granted without exercising an inventive step.

7.4.4 Opponent 2's reference to paragraph [0064] and Figure 44 of the contested patent is also unconvincing. The relevant question for the assessment of inventive step is not whether the person skilled in the art *could* arrive at the subject-matter of claim 1 as granted, but rather whether they *would* do so in view of the prior art and common general knowledge. As set out above, this is not the case here.

8. Inventive step starting from D19

Contrary to the opponents' view, the subject-matter of claim 1 as granted involves an inventive step starting from D19.

8.1 The parties disagree already on the identification of the distinguishing features of claim 1 as granted over D19, in particular on whether D19 discloses commissure window frame portions positioned in the outflow row of openings, as required by features 1.2.4 to 1.2.4.1.2.

8.1.1 The embodiments of valve frames disclosed in D19 typically have the structure shown in Figure 32, reproduced below with annotations added by opponent 2 (in colour in opponent 2's reply to the patent proprietor's statement of grounds of appeal, page 169).

This structure generally comprises "longitudinal posts" for attaching the valve leaflets in the row of openings marked "row I", and a number of "crowns" (shown in white in the annotated figure on the right) extending from that row in the outflow direction. The number of crowns is variable, for example six, as in Figure 32, or twelve (see paragraph [00062]).

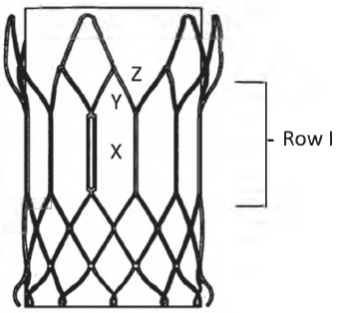


Fig. 32

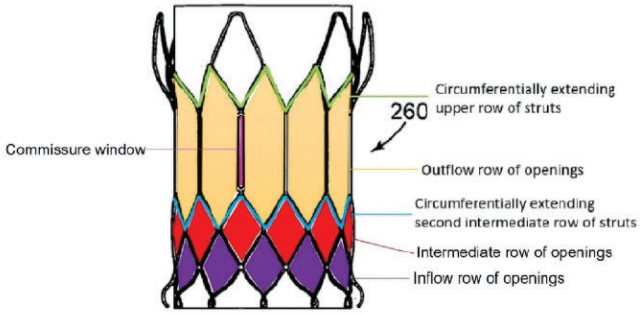


Fig. 32

8.1.2 The opponents' reasoning is based on the feature mapping onto Figure 32 shown above. In their view, row I anticipated the claimed outflow row of openings. This was consistent with the fact that the struts Z of the openings X of row I were the last struts encountered by the blood before it exits the valve at point Z.

In addition, row I was the last row of the frame in the outflow direction formed by circumferentially extending rows of angled struts arranged end-to-end, as required by feature 1.2.4. Moreover, this row incorporated axially extending struts and commissure window frame portions, namely the longitudinal posts, as required by features 1.2.4.1 to 1.2.4.1.2. The presence of crowns extending from row I was irrelevant since feature 1.2.2 did not exclude the presence of further additional elements extending from the outflow row.

The opponents further argued that in contrast to row I, the crowns themselves did not form a row of openings, since they were not connected to each other and were therefore not formed by circumferentially extending rows of angled struts arranged end-to-end as required by feature 1.2.4.

In any event, the opponents submitted that feature 1.2.2 did not require the claimed outflow row to be the very last row of openings of the frame at its outflow end. Rather, this feature did not exclude the presence of more than one outflow row. Therefore, row I still constituted an outflow row even if the crowns were themselves regarded as defining a further outflow row.

8.1.3 The Board disagrees and instead concurs with the feature mapping put forward by the patent proprietor, shown in the annotated figure provided on page 22 of its statement of grounds of appeal and reproduced below.

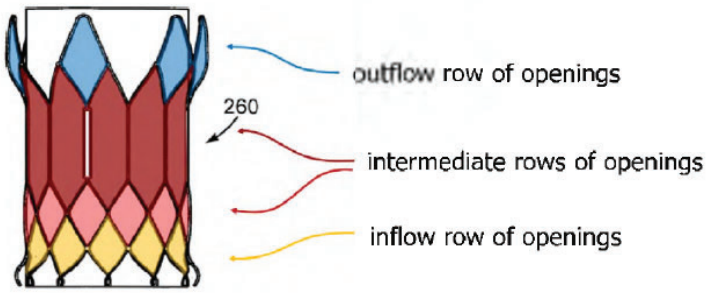


Fig. 32

The plurality of crowns provided at the outflow end of the frame in Figure 32, as in the various other embodiments of frames disclosed in D19, define a series of openings along the circumference of the frame which are all aligned at the same axial height. Taken together, the crowns therefore form a row of openings. Moreover, since this row of openings is arranged at the

outflow end portion of the frame, it constitutes an outflow row of openings as defined by feature 1.2.2.

This conclusion holds irrespective of the precise number of crowns at the outflow end, in particular whether this number is smaller than the number of openings in row I, as is the case in the embodiment of Figure 32, which has only six crowns. Claim 1 as granted does not require the outflow row to comprise the same number of openings as other rows of the frame. Nor is it decisive that the row of openings defined by the crowns is not formed by two circumferentially extending rows of angled struts arranged end-to-end. This merely reflects that D19 does not disclose feature 1.2.4 and sub-features 1.2.4.1 to 1.2.4.1.2.

Furthermore, the person skilled in the art understands from the wording of features 1.2.1 to 1.2.3 that the claimed outflow row of openings is the final row of openings of the frame in the flow direction. Although, as argued by the opponents, this wording does not exclude the possibility that the outflow row includes further structural elements, a row of openings would not be regarded as an outflow row if the frame comprised a further row of openings located further in the flow direction. In this case, the former row would instead constitute an intermediate row of openings within the meaning of claim 1 as granted.

The person skilled in the art therefore does not consider row I as an outflow row of openings within the meaning of feature 1.2.2, but rather as one of several intermediate rows of openings within the meaning of feature 1.2.3.

Consequently, the longitudinal posts identified by the opponents as commissure window frame portions are not positioned in the outflow row of openings, as required by features 1.2.4 to 1.2.4.1.2, but in an intermediate row adjacent to the outflow row. This understanding is in line with the consistent disclosure in D19 that the longitudinal posts are positioned in the central region of the frame (see paragraph [0060]), and thus not at its outflow end portion.

It follows that the subject-matter of claim 1 differs from the disclosure of D19 at least by features 1.2.4 to 1.2.4.1.2.

8.1.4 The Board further agrees with the opposition division (see Reasons 28) that, without the benefit of hindsight, the person skilled in the art starting from D19 would neither remove the crowns from the outflow end portion of the frame - which are consistently present across all the embodiments described in D19 and thus form part of the basic stent architecture disclosed in D19 - nor relocate the longitudinal posts into the outflow row formed by the crowns. Either modification would run counter to the teachings of D19, in particular that, as stated above, the longitudinal posts are positioned in the central region of the frame and not at its outflow end portion. The opponents have not provided any convincing arguments to the contrary. D20, cited in relation to further features of claim 1 as granted concerning the inner skirt, does not affect this assessment.

Therefore, the person skilled in the art starting from D19 would not arrive at the subject-matter of claim 1 as granted in an obvious manner and without hindsight.

The subject-matter of claim 1 as granted therefore involves an inventive step starting from D19.

9. Further novelty and inventive-step objections

9.1 At the oral proceedings before the Board, the parties did not make any further submissions on the other novelty and inventive-step objections raised by opponent 2 in its written submissions on appeal, but merely referred to their written submissions. The Board therefore saw no reason to depart from its preliminary opinion in this respect expressed in the communication under Article 15(1) RPBA (see point 6.2), which it also confirms below.

9.2 Novelty and inventive step in view of D25

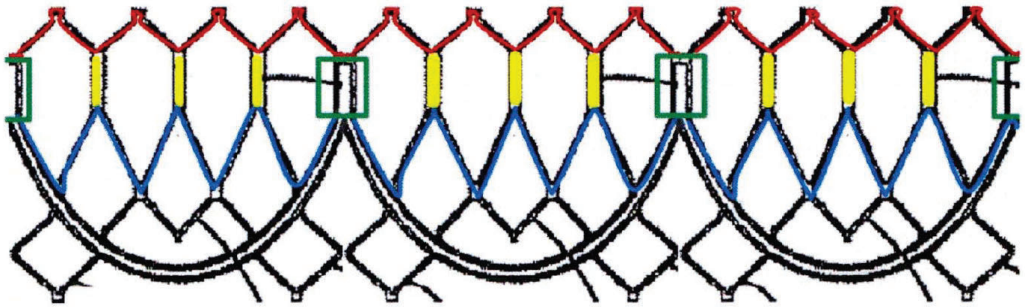
9.2.1 The patent proprietor contended that opponent 2 had raised the novelty objection in view of D25 against claim 1 as granted only after expiry of the opposition period and that this objection had not been sufficiently substantiated. For these reasons, the patent proprietor requested that it not be admitted into the appeal proceedings.

However, the minutes of the oral proceedings before the opposition division indicate that the admittance of a novelty objection in view of D25 raised against claim 1 of the request then on file as auxiliary request 1 was discussed, and that the opposition division decided to admit this objection (see points 5.4 to 5.6 of the minutes). Although the written decision is silent on the issue of admittance, the objection is discussed in detail in substance in the reasons (see Reasons 25.4 and 25.5). The decision under appeal was therefore based on this objection.

This novelty objection applies directly to claim 1 as granted, which is broader than claim 1 of the auxiliary request considered in the decision under appeal. Consequently, contrary to the patent proprietor's view, this objection is to be taken into account in the appeal proceedings.

9.2.2 The novelty objection is, however, not convincing.

Opponent 2 submitted that the subject-matter of claim 1 as granted lacked novelty in view of a valve similar to those shown in Figures 1 and 4 of D25, but comprising a frame constructed by repeating three times the frame pattern shown in Figure 13 - as illustrated in Figure 3 for a different frame pattern. The "triplicate illustration" provided on page 53 of opponent 2's statement of grounds of appeal and reproduced below illustrates the resulting complete frame.



According to opponent 2, such a frame would comprise an outflow row of openings formed by a circumferentially extending upper row of angled struts arranged end-to-end (highlighted in red in opponent 2's statement of grounds of appeal) and a circumferentially extending intermediate row of angled struts arranged end-to-end (highlighted in blue), the two rows being interconnected by a plurality of axially extending struts (highlighted in yellow).

However, even if this construction were to define multiple commissure window frame portions (highlighted with green boxes) connecting the upper and intermediate rows of angled struts, as argued by the opponent, the lower ends of these commissure window frame portions would resemble those shown - for a different frame pattern - in Figure 9A, reproduced below.

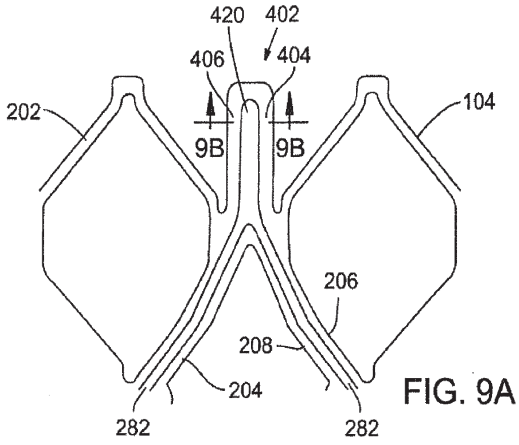


FIG. 9A

As apparent from this figure, the upper ends of two adjacent angled struts of the intermediate row (corresponding to struts 206 in Figure 9A) would be separated by the curved gap (having the reference sign 282 in Figure 9A) running between the upper and lower frame elements 202 and 204 (see paragraph [0051]). Therefore, as held by the opposition division in the decision under appeal (see Reasons 25.5), these ends would not converge so as to define a junction to which a lower end of a commissure window frame portion is connected, as required by feature 1.2.4.1.2. Indeed, as set out in point 5.3.3 b) above, the term "junction" requires that the two angled struts be connected to each other so as to define a junction. At most, the convergence of the upper ends of the two struts of the lower frame element (corresponding to struts 208 in Figure 9A) would define a junction. However, these struts do not form the outflow row of openings.

The subject-matter of claim 1 as granted is therefore novel over D25.

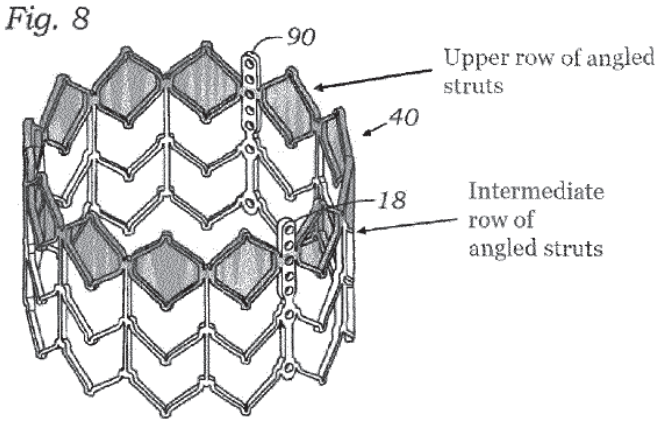
9.2.3 As regards inventive step starting from D25, opponent 2 referred, in its reply to the proprietor's statement of grounds of appeal (see point 3 on page 28), to section D.III of one of its submissions filed in the opposition proceedings, attached as Annex HL1 to the reply. However, this section does not substantiate any inventive-step objection starting from D25 (see the last three lines on page 21 of Annex HL1).

9.3 Inventive step starting from D20 and from the SAPIEN valve (D1)

In its reply to the proprietor's statement of grounds of appeal (see points 4 and 5 on page 28), opponent 2 submitted additional inventive-step objections against claim 1 as granted starting from either the valve disclosed in Figure 8 of D20 or the SAPIEN valve, which, according to the opponent, would form part of common general knowledge. Opponent 2 did not substantiate these objections in detail in its reply, but merely referred to passages of its earlier submissions in the opposition proceedings (see the aforementioned Annex HL1, and Annex C attached to opponent 2's statement of grounds of appeal).

Irrespective of whether the substantiation requirement under Article 12(3) RPBA is met, which the Board questioned in its communication under Article 15(1) RPBA (see point 6.4), these objections are in any event not convincing.

9.3.1 With regard to the valve disclosed in Figure 8 of D20, the person skilled in the art would, for reasons similar to those set out above in relation to D19, consider only the outermost row of diamond-shaped openings to constitute an outflow row of openings, as also reflected in the annotated figure provided at the top of page 57 of Annex C, reproduced below, in which the outflow row is highlighted in dark grey.



However, although this outflow row is formed by a circumferentially extending upper row of angled struts arranged end-to-end and a circumferentially extending intermediate row of angled struts arranged end-to-end, these rows are interconnected only at junctions defined by the convergence of the lower ends of two adjacent angled struts of the upper row and the convergence of the upper ends of two adjacent angled struts of the lower row. Contrary to the opponent's argument, these junctions do not themselves constitute axially extending struts as defined by feature 1.2.4.1.

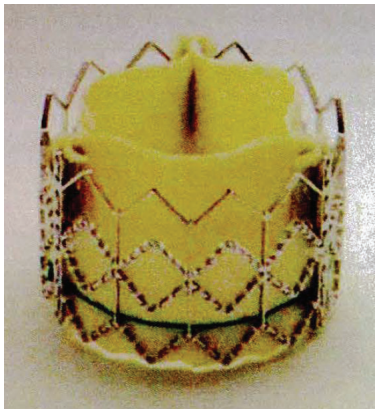
Therefore, even if the person skilled in the art were to replace the attachment posts 90 in the valve of Figure 8 with commissure window frame portions, for example as known from D19, as argued by opponent 2, they would not, without hindsight, arrive at an outflow row of openings with axially extending struts and

commissure window frame portions as defined by features 1.2.4.1 to 1.2.4.1.2.

Opponent 2's further lines of argument rely on alternative interpretations of the outflow row of openings. According to one interpretation, claim 1 would not exclude the possibility of an outflow opening containing an additional strut, such that one outflow opening would effectively define two sub-openings (as illustrated in the figure shown in the middle of page 57 of Annex C). According to a second interpretation, individual rows of openings could partially overlap (as illustrated in the figure shown at the top of page 59 of Annex C). The Board does not find either interpretation convincing. Both constructions are artificial and do not reflect a technically sensible reading of Figure 8 from the perspective of the person skilled in the art.

The subject-matter of claim 1 as granted therefore involves an inventive step starting from D20.

9.3.2 The SAPIEN valve is shown, for example, on page 104 of D1, reproduced below.



It is true that, in this valve, the outflow row of openings of the frame comprises axially extending

struts interconnecting the upper and intermediate rows of angle struts arranged end-to-end which form the outflow row.

However, these two rows of angled struts are arranged parallel to each other. Consequently, even if the person skilled in the art were to replace some of the axially extending struts with commissure window frame portions in order to attach the leaflet structure, for example as known from D25, as argued by the opponent, the lower end of each commissure window frame portion would be connected to a junction defined by the convergence of the lower ends of two angled struts of the intermediate row of angled struts, rather than their upper ends as required by feature 1.2.4.1.2.

The subject-matter of claim 1 as granted therefore involves an inventive step starting from the SAPIEN valve.

10. Concluding remark; description

It follows from the foregoing that none of the opponents' objections prejudice the maintenance of the contested patent in amended form on the basis of auxiliary request 1a.

Furthermore, neither opponent 2 nor the Board identified any need to adapt the description to this claim request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:
   - claim 1 of auxiliary request 1a filed with the patent proprietor's submission of 15 January 2026
   - description and drawings of the patent specification

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated