Internal distribution code:

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

Datasheet for the decision of 27 May 2025

Case Number: T 2565/22 - 3.2.02

Application Number: 17199786.9

Publication Number: 3332740

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
SYSTEM FOR REPLACING A DEFICIENT NATIVE HEART VALVE

Patent Proprietor:
Edwards Lifesciences PVT, Inc.

Opponents:
Abbott Cardiovascular Systems, Inc.
Neovasc Tiara Inc.

Headword:

Relevant legal provisions:
EPC Art. 100(a), 100(c), 76(1), 54(2), 56
EPC R. 115(2)
RPBA 2020 Art. 13(2)

Keyword:
Summons to oral proceedings - continuation of proceedings without duly summoned party
Divisional application - subject-matter extends beyond content of earlier application (no) - after amendment
Novelty - (yes)
Inventive step - main request (no) - auxiliary request (yes)
Amendment after notification of Art. 15(1) RPBA communication - taken into account (no)

Decisions cited:
G 0001/15, T 2348/17

Catchword:

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 2565/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 27 May 2025

Appellant: (Patent Proprietor)	Edwards Lifesciences PVT, Inc. One Edwards Way Irvine, CA 92614 (US)
Representative:	Bird & Bird LLP Maximiliansplatz 22 80333 München (DE)
Appellant: (Opponent 1)	Abbott Cardiovascular Systems, Inc. 3200 Lakeside Drive Santa Clara, CA 95054 (US)
Representative:	LKGLOBAL Lorenz & Kopf Patentanwalt Attorney at Law PartG mbB Brienner Straße 11 80333 München (DE)
Party as of right: (Opponent 2)	Neovasc Tiara Inc. 2135 - 13700 Mayfield Pl Richmond, BC V6V 2E4 (CA)
Representative:	Clark, Jane Anne Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Decision under appeal:	**Interlocutory decision of the opposition division of the European Patent Office posted on 17 October 2022 concerning maintenance of the European Patent No. 3332740 in amended form.**

Composition of the Board:

Chair	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	Y. Podbielski

Summary of Facts and Submissions

I. Appeals were filed by the patent proprietor and by opponent 1 against the interlocutory decision of the opposition division finding that the then auxiliary request 5 filed during the oral proceedings before the opposition division met the requirements of the EPC.

II. Oral proceedings before the Board took place on 27 May 2025.

Opponent 2 made no request nor commented on the merits of the case, and they submitted on 17 February 2025 that they would not be attending the oral proceedings. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the oral proceedings took place in the absence of opponent 2.

The requests relevant to the decision were as follows.

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

The appellant-patent proprietor ("proprietor") requested that the decision under appeal be set aside and the patent be maintained as granted, or that the patent be maintained on the basis of one of the following requests: auxiliary request 1 filed during the oral proceedings before the opposition division, auxiliary request 2 filed on 12 January 2022, auxiliary request 3 filed during the oral proceedings before the opposition division, auxiliary request 4 filed as auxiliary request 3 on 12 January 2022, and auxiliary

request 5 filed during the oral proceedings before the opposition division.

III. Claim 1 of each of the **main request** (patent as granted) and of **auxiliary request 1** reads as follows (with feature numbering added in bold by the board).

1. "**[1.1]** A percutaneously implantable valve prosthesis device (20), the valve prosthesis device comprising:

[1.2] an annular support frame (22) made from nickel titanium shape memory alloy
[1.3] and provided with a plurality of longitudinally rigid support beams (23) of fixed length; and
[1.4] a valve assembly (28) comprising a flexible conduit having an inlet (24) and an outlet (26),
[1.5] made of pliant material (29) attached to the support beams (23) providing collapsible slack portions of the conduit at the outlet (26),
[1.6] whereby the valve prosthesis device (20) is suitable for crimping into a narrow configuration for positioning and expandable to a wider, deployed configuration so as to anchor in position at a desired target location,
[1.7] whereby when flow is allowed to pass through the valve prosthesis device (20) from the inlet (24) to the outlet (26) the valve assembly (28) is kept in an open position,
[1.8] whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly (28) collapse inwardly providing blockage to the reverse flow,
characterized in that
[1.9] the support beams (23) are provided with bores (25, 42), and

[1.10] the valve assembly (28) is made from pericardial tissue and is stitched to the support beams (23) with thread or fiber (46) through the bores (25, 42)-." [whereby the hyphen at the end of the claim is present in claim 1 of the main request but not in claim 1 of auxiliary request 1]

IV. Claim 1 of each of **auxiliary requests 2 and 3** includes the following amendments to claim 1 of the main request.

"characterized in that
the support beams (23) are incorporated with the annular support frame and are provided with bores (25, 42), and"

V. Claim 1 of each of **auxiliary requests 4 and 5** includes the following amendments to claim 1 of the main request.

"the valve assembly (28) is made from pericardial tissue, mounted within the annular support frame and is stitched to the support beams (23) with thread or fiber (46) through the bores (25, 42)."

VI. Dependent claims 3 and 12 of **auxiliary request 4** read as follows.

3. "The valve prosthesis device of any of the preceding claims, wherein the valve assembly is also attached to the support frame by sewing it to several anchoring points on the support frame."

12. "The valve prosthesis device of any of the preceding claims, wherein the support frame (22) is radially extended by forces exerted from within by a

deploying means so as to provide support against a body duct wall."

VII. The following documents are relevant to the present decision.

D1 WO 01/76510 A2
D2 WO 00/44313 A1
D34 US 975,750 (priority application)
D35 WO 03/047468 A1 (publication of the earlier application)
D76 Entry of the Collin's dictionary on "incorporate"

VIII. The arguments of opponent 1, where relevant to the present decision, can be summarised as follows.

Main request - added subject-matter for claim 1

The contested patent resulted from a divisional application that had been filed a long time after the earlier application D35.

D35 did not disclose the combination of features of claim 1 as granted. In particular, D35 did not disclose a support frame made from nickel titanium (feature 1.2) in combination with a valve assembly made of pericardial tissue (feature 1.10).

The dependent claims 2, 5, 9 and 11 of D35 only depended on claim 1 and could not provide a basis for the combination. This was all the more so as claim 1 as granted omitted the feature of claim 1 of D35 that the stent was deployed by exerting radial forces from within. Pages 3 to 14 of D35 recited a list of preferred embodiments without any pointer to the particular combination of claim 1. The first full

paragraph of page 21 of D35 disclosed a list of possible materials for the valve assembly. The subsequent paragraph disclosed a frame made from nickel titanium, but it referred to the frame described on page 20 and which was deployed by forces exerted from within by deploying means, feature absent in claim 1 as granted.

Page 36 of D35 referred to the preferred embodiment of Figure 26, which included a self-expandable stent made of a shape-memory alloy. However, it did not specify that the alloy was nickel titanium and it lacked other features present in claim 1 as granted. Additionally, there were other embodiments, such as that of Figure 24, which were expandable by forces from within and which did not require piercing the valve material.

Moreover, in view of claim 2 as granted, claim 1 as granted encompassed embodiments in which not all of the supports beams comprised a plurality of bores. However, such embodiments were not disclosed in D35.

Main request - priority right

The priority document D34 only disclosed embodiments with balloon-expandable stents. Hence, the priority was not valid for embodiments having self-expandable stents. In consequence, D1 was prior art under Article 52(2) EPC for those embodiments.

Main request - novelty over D1

D1 disclosed all of the features of claim 1 as granted.

In T 2348/17, dealing with a family member of the contested patent, it had been decided that D1 disclosed

a stent-based heart valve including rigid support beams with bores, wherein the leaflets were sutured to the support beams by stitching through these bores.

As regards feature 1.2 specifying that the frame was made from nickel titanium, D1 disclosed on pages 10 and 13 lists of materials including titanium and Elgiloy. The person skilled in the art would consider nickel titanium to be disclosed as part of these lists, since titanium itself was not a suitable material for the frame.

Main request - inventive step starting from D1

The subject-matter of claim 1 was not inventive in view of D1 combined with common general knowledge.

D1 disclosed that the frame was made of a shape memory alloy, and the only difference was that claim 1 specified nickel titanium as the material.

The contested patent did not associate any technical effect to this particular choice. Nickel titanium was a well known shape memory alloy commonly used for stents. It was thus not inventive to choose nickel titanium as the material.

Auxiliary request 1

Claim 1 of auxiliary request 1 had the same wording as claim 1 of the main request. Consequently, the same objections applied.

Auxiliary request 2 - inventive step starting from D1

The feature added to claim 1 specifying that the support beams were incorporated with the annular support frame was disclosed in D1. The support beams were defined in D1 by the commissure posts 42 together with the inserts 72. The commissure posts 42 extended from the tubular base 40, forming one body. The inserts 72 were part of the support beams in the assembled device.

Consequently, the subject-matter of claim 1 was not inventive in view of D1 combined with common general knowledge.

Auxiliary request 3

Claim 1 of auxiliary request 3 had the same wording as claim 1 of auxiliary request 2. Consequently, the same objections applied.

Auxiliary request 4 - inventive step starting from D1

The feature added to claim 1 of auxiliary request 4 was disclosed in D1. Claim 1 did not specify that the valve assembly had to be mounted entirely within the annular support frame. The leaflet section 32 could be considered as the valve assembly within the meaning of claim 1, and it had to be mounted within the annular support frame so as to provide the functionality of a valve. The leaflet section 32 was mounted within the support beams and thus within the support frame.

Even if the feature added to claim 1 of auxiliary request 4 was regarded as not disclosed in D1, it did

not involve an inventive step. The person skilled in the art, faced with the problem of reducing the thickness of the annular support frame, would arrange the posts 42 in the same circumferential surface as the remainder of the annular support frame, thus resulting in a valve assembly mounted within the annular support frame.

Auxiliary request 4 - admittance of the inventive-step objection starting from D2

The subject-matter of claim 1 was not inventive when starting from D2. In the statement of grounds of appeal, an objection starting from D2 had been raised against claim 1 as granted. The feature added to claim 1 of auxiliary request 4 was undoubtedly disclosed in D2. Therefore, the objection raised against claim 1 as granted equally applied to claim 1 of auxiliary request 4 and should be admitted into the appeal proceedings.

Auxiliary request 4 - added subject-matter

As correctly concluded in the decision under appeal, dependent claims 5, 7, 10, 14 and 16 comprised added matter. Also dependent claim 12 comprised added matter, as it was not originally disclosed that the support frame was radially extendable.

Auxiliary request 5

Claim 1 of auxiliary request 5 had the same wording as claim 1 of auxiliary request 4. Consequently, the same objections applied.

IX. The proprietor's arguments, where relevant to the present decision, can be summarised as follows.

Main request - added subject-matter for claim 1

Claim 1 did not comprise subject-matter that extended beyond the content of the earlier application D35.

The history of the case was irrelevant for assessing whether there was added subject-matter.

D35 disclosed that nickel titanium was the preferred material for the frame (page 4, fifth paragraph, and page 21, second paragraph). It also disclosed that the pliant material of the valve assembly was preferably pericardial tissue (page 4, first paragraph, and page 21, first paragraph). Although D35 mentioned other materials for the valve assembly, pericardial tissue was the only biological tissue specifically proposed. Both features were described together in subsequent paragraphs on page 21, which formed part of a general description pertaining to all embodiments. Dependent claims 5 and 9 of D35 also provided support for the materials of the valve assembly and the frame, respectively.

The valve prosthesis was not linked in D35 to any particular deployment mechanism. Instead, D35 provided support for a self-expandable frame (Figure 26 and page 36).

D35 explicitly disclosed on page 4, seventh paragraph, the feature of the support beams provided with bores.

Main request - priority right

What was recited in granted claim 1 was derivable from the priority application D34. D34 was generic as to the mechanism of expansion of the frame. It was irrelevant that the application from which the patent derived contained further subject-matter.

The reference in D34 (page 13, lines 18 to 20) to a shape memory alloy made of nitinol was a reference to self-expandable stents because the mode of expansion was enshrined inherently in the material and its shape memory properties. Several prior art documents showed that a shape memory material referred to a self-expanding material, and that nitinol stents were self-expanding.

Main request - novelty over D1

The subject-matter of claim 1 was novel over D1.

D1 did not disclose feature 1.2, as nickel titanium was not mentioned at all.

D1 did not disclose features 1.9 and 1.10 either. Unlike in the claim underlying the decision T 2348/17, the inserts 72 of D1 could not form part of the support beams within the meaning of granted claim 1. This was because, in view of features 1.2 and 1.3, a person skilled in the art would understand that the support beams were part of the frame and were therefore made of nickel titanium. Furthermore, it was technically impossible to make the bores required by features 1.9 and 1.10 in a material such as nickel titanium by stitching.

Main request - inventive step starting from D1

A person skilled in the art would not have used nickel titanium for the frame of D1.

D1 did not have a particular focus on self-expandable stents and even disclosed that the tubular base 40 was expanded using a balloon. Although nickel titanium was known at the time and used for making self-expandable stents, such stents had not necessarily to be made from this material and other materials were known. Prior art documents reported that, at the time, stents were predominantly made of stainless steel and further research was required on nickel titanium with respect to its biocompatibility. Nothing prompted the person skilled in the art to choose nitinol over any of the other materials for self-expandable heart valves.

It was unclear for the person skilled in the art what would have happened if the posts 42 of D1 were made from the same material as the tubular base 40 and the stent of D1 was crimped and extended again. The posts 42 could then have a tendency to bend back.

Consequently, the subject-matter of claim 1 was inventive when starting from D1.

Auxiliary request 1

Claim 1 had the same wording as claim 1 of the main request and it was inventive when starting from D1 for the same reasons.

Auxiliary request 2 - inventive step from D1

The feature added to claim 1 of auxiliary request 2 was not disclosed in D1. To incorporate something meant to include something, as confirmed by the entry of the dictionary in D76. Also paragraphs [0003] and [0091] of the contested patent supported this understanding. Accordingly, claim 1 required the support beams to be an integral part of the annular support frame, i.e. to be a single piece. The inserts 72 of D1 were not incorporated with the stent but separate from it, in order to reduce stress on the leaflet section 32 as taught by D1 on page 11, lines 14 to 16. Therefore, the subject-matter of claim 1 was inventive when starting from D1.

Auxiliary request 3

Claim 1 of auxiliary request 3 had the same wording as claim 1 of auxiliary request 2 and it was inventive when starting from D1 for the same reasons.

Auxiliary request 4 - inventive step from D1

Claim 1 required the complete valve assembly to be mounted within the annular support frame. In D1, it was mounted above the tubular base 40 and not within it. Even if the posts 42 were to be regarded as forming part of the frame, the loops 70 of the leaflet section 32 were outside the frame. Therefore, D1 did not disclose the feature added to claim 1 of auxiliary request 4.

D1 taught on page 11, lines 21 to 26, that the leaflet section 32 should be arranged above the tubular base 40

to increase the life of the valve, thereby teaching away from mounting the valve assembly within the support frame as required by claim 1. Therefore, the subject-matter of claim 1 was inventive when starting from D1.

Auxiliary request 4 - admittance of the inventive-step objection starting from D2

The objection starting from D2 should not be admitted. Claim 1 of auxiliary request 4 corresponded to claim 1 of the request which was upheld by the opposition division. If opponent 1 wanted the objection starting from D2 to be considered, it should have raised it against claim 1 as upheld in the statement of grounds of appeal, or at least in the reply to the appeal. In the written submissions, the feature added to auxiliary request 4 had not been discussed in relation to D2.

Auxiliary request 4 - added subject-matter

There was no added subject-matter in relation to dependent claims 3 and 12.

Regarding claim 3, the earlier application D35 disclosed that it was preferred that the attachment of the valve assembly was not made only to the support beams, but also employing further attachment points. This could be derived from several passages (the penultimate paragraph of page 21; page 12, lines 6 to 7; page 33, lines 17 to 19; Figures 23e and 44a).

The opposition division correctly decided that there was no added matter in claim 12.

Auxiliary request 5

Auxiliary request 5 did not comprise dependent claim 3, nor any of the other dependent claims found to include added matter in the decision under appeal. Claim 1 of auxiliary request 5 had the same wording as claim 1 of auxiliary request 4 and it was inventive when starting from D1 for the same reasons.

Reasons for the Decision

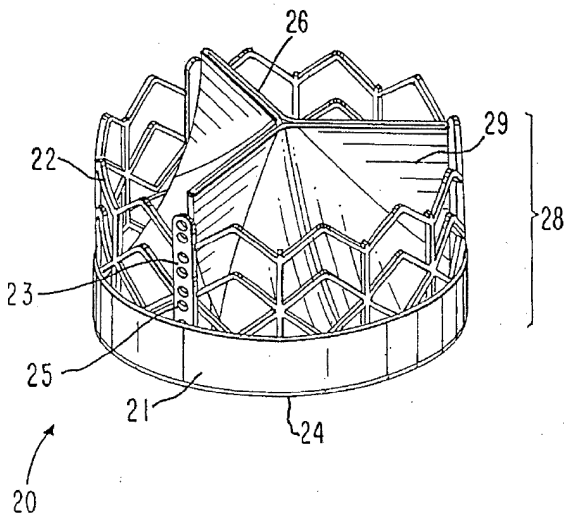
1. Patent

1.1 The patent relates to an implantable valve prosthesis device. The device can be crimped into a narrow configuration, suitable for percutaneous catheterisation to the desired location, and then expanded to a deployed configuration. Claim 1 is the only independent claim.

1.2 The claimed device comprises an annular support frame and a valve assembly. The support frame is provided with a plurality of longitudinally rigid support beams provided with bores. The valve assembly, which allows forward flow from an inlet to an outlet but blocks reverse flow, is made from pericardial tissue and is stitched to the support beams through the bores.

1.3 Figure 1 reproduced below shows a valve prosthesis device which has, on the one hand, a valve assembly 28 with an inlet 24, an outlet 26 and a cuff portion 21; and on the other hand an annular support frame 22 with support beams 23 having bores 25 to allow stitching of valve assembly 28 to support beams 23.

FIG.1



2. Main request - added subject-matter - claim 1

2.1 The fact that the contested patent derives from a divisional application filed several years after the earlier application (D35) does not imply that it comprises added subject-matter. Whether Article 100(c) EPC prejudices the maintenance of the patent as granted depends only on whether or not the subject-matter of the patent extends beyond the content of the application as filed or of the earlier application as filed.

2.2 Opponent 1 submitted that the earlier application D35 did not disclose feature 1.2 (in particular "nickel titanium") in combination with feature 1.10 (in particular "the valve assembly is made from pericardial tissue").

2.3 D35 discloses nickel titanium as the preferred material for the frame (page 4, line 12; page 21, line 10; claim 9). It also discloses that the valve assembly can

preferably be made from biological tissue and in particular from pericardial tissue, which is the only specifically proposed biological tissue (page 4, lines 1 to 2; page 21, lines 3 to 4; claim 5). The fact that the two materials are the preferred ones represents a pointer to their combination. Therefore, this combination is not an arbitrary selection of features, nor does it result in any new technical information. Rather, it is clear to the person skilled in the art that the earlier application teaches the combination of features 1.2 and 1.10.

2.4 Opponent 1 submitted that claim 1 as granted omitted the feature "adapted to be deployed by exerting substantially radial forces from within by means of a deployment device", which was present in claim 1 of D35, thus resulting in added subject-matter.

2.5 D35 discloses that the stent has to be expandable (see e.g. page 21, second full paragraph, and page 22, fourth paragraph; see also claims 42 and 43), and it also discloses in the embodiment of Figure 26 a valve provided with a self-expandable frame (page 36, second paragraph), i.e. a frame that expands without a deployment device exerting radial forces from within. Therefore, D35 discloses deployment either by radial forces from within or by using a self-expandable frame, providing a basis for omitting the disputed feature from claim 1 of D35. The person skilled in the art knows that Ni-Ti shape memory alloy frames can be used for both types of deployment. For the same reason, even if the frame described in the second full paragraph on page 21 of D35 was considered to refer to the frame expanded by forces from within in the "embodiments" mentioned in the sentence bridging pages 20 and 21, a

person skilled in the art would derive that the expansion by forces from within can be omitted.

2.6 As submitted by opponent 1, the self-expandable embodiment of Figure 26 does not disclose all of the features of granted claim 1. However, this is not the issue at stake, since granted claim 1 is not directly based on the embodiment of Figure 26. Instead, this embodiment serves to establish what a person skilled in the art would derive from D35 regarding the expandable frame.

2.7 The fact that other embodiments of D35 include other features, as highlighted by opponent 1 in relation to Figure 24, does not alter the conclusion that the disputed combination of features in granted claim 1 is disclosed in the aforementioned passages of D35.

2.8 Opponent 1 submitted that the wording "valve prosthesis device is suitable for crimping ... and expandable" was not disclosed in the earlier application. However, this wording is literally disclosed on page 21, lines 12 to 14.

2.9 Opponent 1 also submitted that the wording "annular support frame" was not disclosed. Although the wording is not identical, an annular support frame is disclosed in D35 (see e.g. page 3, sixth full paragraph; page 21, third full paragraph; claim 2).

2.10 Opponent 1 argued that feature 1.9, in view of claim 2 as granted, did not require each support beam to comprise a plurality of bores and resulted in added subject-matter. Feature 1.9 is literally disclosed on page 4, seventh paragraph, of D35. Moreover, as noted in the decision under appeal (first paragraph of

page 14), D35 discloses on page 22, lines 23 to 25, that the support beams are optionally provided with bores. An identical disclosure is present in the corresponding passage of the application as filed, also on page 22, lines 23 to 25. There is thus no added subject-matter in relation to feature 1.9.

2.11 In summary, the objections of added subject-matter against claim 1 as granted are not convincing.

2.12 Main request - priority right

2.13 The proprietor submitted in the written procedure that for each feature of claim 1 a basis can be found in the priority application D34. In their communication the Board expressed the preliminary view that only a partial priority was validly claimed. At the oral proceedings the proprietor did not provide any further argument but merely referred to its written submission in this respect. The explanations provided by the Board are essentially as follows.

2.14 Compared with D34, granted claim 1 has been broadened by deleting the feature "adapted to be deployed by exerting substantially radial forces from within by means of a deployment device".

2.15 Claim 1 can be regarded as a generic OR-claim in the sense of G 1/15. The two alternatives comprised by the claim are:

(a) a device comprising a support frame "adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state", such as a balloon-expandable stent; and

(b) a device comprising a support frame which is not adapted in this way, i.e non-balloon-expandable or self-expandable.

2.16 Contrary to the proprietor's submission, D34 does not disclose the mechanism by which the frame expands in a generic way. Even though the expansion mechanism is not specified each time the frame is mentioned, D34 is directed to devices adapted to be deployed by exerting substantially radial forces from within by means of a deployment device (see, for example, page 3, lines 12 to 13; page 13, lines 1 to 4; claims 1, 39 and 41). Unlike D35, D34 does not disclose any self-expandable frames or deployment methods that do not involve deployment means such as a balloon catheter. The fact that nitinol is disclosed as a material for the frame in D34 does not imply that its shape memory properties are used to provide a self-expandable frame, i.e. a stent made of nitinol is not necessarily self-expanding even though this material has been used for this purpose in several prior art documents. Therefore, D34 does not disclose the combination of features of granted claim 1 without the feature omitted by granted claim 1.

2.17 The Board is thus of the opinion that only part (a) above enjoys priority. Accordingly, D1 is prior art under Article 54(2) EPC for part (b) and can be considered in deciding whether there has been an inventive step.

3. Main request - novelty over D1

3.1 D1 discloses in the embodiment of Figures 1 to 5 a heart valve prosthesis 20 with a flexible tubular member 22 and a support stent 24. The support stent

comprises a tubular base 40 and a plurality of upstanding commissure posts 42 (page 9, lines 4 to 5). The flexible tubular member 22 includes a leaflet section 32 formed from pericardial tissue (page 8, lines 20 to 21 and 28). Inserts 72 are used to secure loops 70 of the leaflet section 32 to the commissure posts 42. In particular, stitches 74 secure the loops 70 to the inserts 72, and stitches 76 secure each insert 72 to the respective commissure post 42 (page 10, line 23 to page 11, line 2).

3.2 It is disputed whether the embodiment of Figures 1 to 5 of D1 anticipates features 1.2 (in particular "made from nickel titanium shape memory alloy"), 1.9 and 1.10.

3.3 With regard feature 1.2, D1 discloses that the commissure posts and a wireform supporting prosthetic leaflets "may be formed of stainless steel, titanium, or Elgiloy" (see sentence bridging pages 9 and 10 and page 13, lines 4 to 5). Opponent 1 argued that the person skilled in the art would consider nickel titanium to be disclosed as part of this list of materials. However, titanium is a metal and does not anticipate a nickel titanium shape memory alloy; even if titanium itself was not a suitable material for the posts, as argued by opponent 1, this does not imply that titanium would be construed by a person skilled in the art as referring specifically to nickel titanium shape memory alloy. Elgiloy refers to a different shape memory alloy that does not comprise titanium. Therefore, D1 does not anticipate feature 1.2.

3.4 The proprietor argues that D1 does not disclose features 1.9 and 1.10 as inserts 72 cannot be part of the support beams because features 1.2 and 1.3 require

the support beams to be made from nickel titanium shape memory alloy.

3.5 However, feature 1.2 only defines the material of the annular support frame, leaving open what the support beams that it is provided with according to feature 1.3 are made of. The inserts 72 together with the commissure posts 42 of D1 can thus be considered to define support beams within the meaning of claim 1.

3.6 The parties referred to decision T 2348/17, which dealt with a family member of the contested patent. That decision assessed novelty of claim 1 as granted in that case over the same document (referred to as D11a in that decision), and the inserts 72 together with the posts 42 were also together considered to define support beams within the meaning of that claim (see point 1.2.3 of the reasons).

3.7 D1 discloses that stitches 74 stitch the leaflet section 32 to the inserts 72 (see Figures 3 to 4 and page 10, lines 30 to 31). The stitches 74 pass through corresponding bores made in the inserts 72, meaning that the inserts (and thus the support beams within the meaning of claim 1) are provided with bores. Therefore, D1 anticipates features 1.9 and 1.10.

3.8 It follows that D1 anticipates all of the features of claim 1 except that the annular support frame is made from nickel titanium shape memory alloy (feature 1.2).

4. Main request - inventive step from D1

4.1 The proprietor submits that D1 does not have a particular focus on self-expandable stents and even discloses that the tubular base 40 (i.e. the annular

support frame within the meaning of claim 1) is a non-expanding stent that is expanded using a balloon (page 9, lines 14 to 18).

4.2 D1 discloses however that the tubular base 40 may be self-expandable or expandable on the application of heat, i.e. using shape memory material (see page 7, lines 26 to 28 and page 9, line 21). As D1 discloses all of the features of claim 1 except that the annular support frame is made specifically from nickel titanium shape memory alloy, the problem to be solved is therefore how to select a suitable material for manufacturing the annular support frame.

4.3 Nitinol is a nickel titanium shape memory alloy. It is common ground that, at the filing date, nitinol was a well-known self-expanding material used for making self-expandable stents. The proprietor submits that nitinol was only one out of a number of known materials suitable for self-expandable stents, and that D1 did not provide any teaching to prompt the person skilled in the art to choose nitinol over any of the other known materials such as stainless steel. The opponent highlights that no technical effect specific for nitinol has been mentioned.

4.4 The Board is of the opinion that the selection of a manufacturing material such as nitinol for a self-expandable stent is a mere obvious selection among a number of known alternatives for which the person skilled in the art knew the respective advantages and disadvantages. Hence, the selection of nitinol as the material does not involve an inventive step in view of D1 combined with common general knowledge.

4.5 The proprietor argues that it was unclear for the person skilled in the art what would have happened if the posts 42 were made from the same material as the tubular base 40 and the stent of D1 was crimped and extended again, and contends that the posts 42 could have a tendency to bend back.

4.6 This argument is speculative, relates only to an optional embodiment (D1, page 10, lines 3 to 4), and is contradicted by the explicit teaching of D1 that the tubular base in the embodiment of Figures 1 to 5 can be self-expandable.

4.7 It follows that the subject-matter of claim 1 of the main request does not involve an inventive step when starting from D1.

5. Auxiliary request 1 - inventive step starting from D1

5.1 Claim 1 of auxiliary request 1 has the same wording as claim 1 of the main request. For the same reasons set out above in relation to the main request, the subject-matter of claim 1 of auxiliary request 1 does not involve an inventive step when starting from D1.

6. Auxiliary requests 2 and 3 - inventive step starting from D1

6.1 Claim 1 of each of auxiliary requests 2 and 3 further specifies that the support beams "are incorporated with the annular support frame", feature which was defined in claim 18 as granted. It is disputed whether or not D1 discloses this feature.

6.2 It is necessary to establish how to construe the feature. The proprietor refers to D76, in which

"incorporate" is defined as meaning to include, and argues that claim 1 requires the support beams to be an integral part of the annular support frame. The proprietor also points out that, should there be any doubts regarding the interpretation, this is the meaning supported by the contested patent. The proprietor referred to two passages and two figures of the patent.

6.3 The first passage of the contested patent cited by the proprietor reads "[t]he valvular tissue forms a continuous surface and is provided with guiding means formed or incorporated within," (paragraph [0003], discussing a prior art prosthesis). This passage uses "incorporated within" and not "incorporated with" as in claim 1. Furthermore, contrary to the proprietor's submission, it cannot be derived from this passage that "incorporated within" is synonymous with "formed within" because the two terms are in an "or"-relationship. Hence, the first passage does not provide any guidance on how to construe "incorporated with" in claim 1.

6.4 The second cited passage of the contested patent, in paragraph [0091], reads "An important aspect of certain embodiments of the present invention is the provision of rigid support beams incorporated with the support stent that retains its longitudinal dimension while the entire support stent may be longitudinally or laterally extended". The cited passage uses the same term as claim 1 but it does not provide any guidance as to its meaning. According to the proprietor, when then considering Figures 1 and 26, it would be clear that the support beams are an integral part of the annular support frame. However, the fact that some Figures are not inconsistent with a meaning does not mean that this

is necessarily the meaning to be used to construe the term, especially if other interpretations consistent with the embodiments are possible. In summary, the meaning submitted by the proprietor cannot be derived from the specification.

6.5 D76 mentions various possible meanings of "incorporate", and the meaning used by the proprietor does not correspond to how "incorporated with" would be understood in claim 1. The Board construes "incorporated with" as meaning that the support beams are combined, joined or united with the frame so as to form one body, a meaning which is consistent with the embodiments pointed out by the proprietor. Moreover, the term refers to the device in the assembled state, since the claim is directed to the device in this condition.

6.6 In the device of D1, the posts 42 are united with the tubular base 40 so as to form one body (see Figures 1 to 3, page 9, lines 4 to 5 and page 10, lines 3 to 4). When the device of D1 is assembled, the inserts 72 are secured to the posts 42 by the stitches 76 (see Figures 2 and 3 and page 10, line 31 to page 11, line 2). Therefore, in the device of D1 the support beams (to which the posts 42 and the inserts 72 belong) are incorporated with the annular support frame as required by the feature added to claim 1 of each of auxiliary requests 2 and 3.

6.7 It follows that, as for the main request, D1 anticipates all of the features of claim 1 except that the annular support frame is made from nickel titanium shape memory alloy. For the same reasons set out above in relation to the main request, the subject-matter of claim 1 of each of auxiliary requests 2 and 3 does not

involve an inventive step in view of D1 combined with common general knowledge.

7. Auxiliary request 4 - inventive step starting from D1

7.1 Opponent 1 submits that the feature added to claim 1 of auxiliary request 4 is anticipated in D1 because the leaflet section 32 of D1 must be mounted within the annular support frame to provide the functionality of the valve and because the leaflet section 32 is mounted within the posts 42, at least partly.

7.2 The bottom part of Figure 1 of D1 shows a support stent 24 that comprises a tubular base 40 and commissure posts 42 that extend from it. The part that corresponds to the "annular support frame" within the meaning of claim 1 is the tubular base 40. The upper part of the support 24 in Figure 1 of D1, where only the end of the posts 42 is present and the tubular base 40 is no longer present, is not annular and not part of the annular support frame.

7.3 Even if the leaflet section 32 (without the fabric section 34) were considered to be the valve assembly within the meaning of claim 1, in D1 the leaflet section 32 is entirely located above the tubular base 40, hence not mounted within it as required by claim 1 of auxiliary request 4 (see Figure 3; see also page 8, lines 20 to 21 and 26 to 27 and page 9, lines 9 to 10, from which it is clear that the leaflet section 32 starts at a height above the tubular base 30). Contrary to the assertion by opponent 1, a prosthetic valve can be functional without the feature added to claim 1, for example with the construction shown in D1.

7.4 It follows that the feature added to claim 1 defines a further distinguishing feature.

7.5 Opponent 1 argues that starting from D1 and faced with the problem of reducing the thickness of the annular support frame, the person skilled in the art would arrange the posts 42 in the same circumferential surface as the remainder of the annular support frame.

7.6 Even if the posts 42 were arranged at the circumferential surface of the annular support frame, the portion of the posts 42 projecting above the tubular base 40 would not be part of the annular support frame within the meaning of claim 1. Furthermore, D1 explicitly teaches that arranging the fabric section 34 so that its axial dimension exceeds that of the tubular base 40 has the advantage of reducing wear resulting from contact between the leaflet section 32 and the tubular base 40, thereby increasing the life of the valve (page 11, lines 21 to 26), i.e. D1 teaches that the leaflet section 32 is to be located above the tubular base 40, and not within it. Therefore, D1 teaches away from the solution defined by claim 1.

7.7 It follows that the subject-matter of claim 1 is inventive when starting from D1.

8. Auxiliary request 4 - admittance of the inventive-step objection starting from D2

8.1 At the oral proceedings before the Board, opponent 1 submitted that claim 1 of auxiliary request 4 lacked an inventive step when starting from D2. Opponent 1 argued that the feature added to claim 1 of auxiliary request 4 was obviously disclosed in D2, so that the

objection starting from D2 which had been raised against the main request in the statement of grounds of appeal equally applied to auxiliary request 4 and should be admitted.

8.2 The Board disagrees with this assessment. If a party submits an inventive-step objection against a claim, without providing any further explanation, this objection is in principle not considered to apply to a claim which includes further features.

8.3 If opponent 1 considered the added feature to be disclosed in D2, it should have submitted and substantiated this in its statement of grounds of appeal, as claim 1 of auxiliary request 4 is identical to the claim 1 found to be allowable in the decision under appeal. There is however no indication in opponent 1's statement of grounds of appeal or elsewhere in opponent 1's written submissions during the appeal proceedings that the feature added to claim 1 of auxiliary request 4 was disclosed in D2, nor any reference to D2 in connection with claim 1 of auxiliary request 4 or of auxiliary request 5, which had been found to be allowable in the decision under appeal.

8.4 The objection against claim 1 of auxiliary request 4 is thus an amendment within the meaning of Article 13(2) RPBA and must, in principle, not be taken into account unless there are exceptional circumstances justified with cogent reasons by opponent 1.

8.5 There are however no exceptional circumstances justifying the admittance, at such a late stage of the proceedings, of the inventive-step objection starting from D2 against claim 1 of auxiliary request 4. The

Board therefore decided not to take the objection into account (Article 13(2) RPBA).

9. Auxiliary request 4 - added subject-matter - dependent claims

9.1 The decision under appeal found that several dependent claims of the patent as granted, which are still present in auxiliary request 4, comprised subject-matter extending beyond the content of the earlier application as filed. The proprietor contests this finding. Moreover, opponent 1 disputed the finding in the decision under appeal that claim 12 did not comprise added subject-matter.

9.2 Claim 3

9.2.1 Neither of page 12, lines 6 to 7, or page 21, penultimate paragraph, of the earlier application D35 discloses that the valve assembly is stitched to support beams and also attached to the support frame by sewing it to anchoring points.

9.2.2 Figures 23a to 23e show a method of manufacturing the device (see page 33, second full paragraph). In Figure 23e there is a vertical line through bores of a support column 385, but in the absence of a corresponding explanation in the description it cannot be directly and unambiguously derived from this line that the valve assembly is stitched to the support beams as defined in feature 1.10. Moreover, Figure 23e and page 33 disclose attachment to the support frame by sewing only together with other closely related features which are not present in claim 3 (e.g. that the attachment is made "by suturing the bottom part around the valve 379 tightly to prevent leakage, and

around the cut fabric line 376"). The embodiment of Figure 44 uses two layers of PET 571 and 572 to connect the leaflets 570 to the frame 575 (see page 45, lines 2 to 7). These features are closely related to the attachment as specified in claim 3, but are absent from claim 3. Hence, claim 3 would be at best an unallowable intermediate generalisation of the embodiments shown in Figures 23e and 44.

9.2.3 Claim 3 therefore comprises subject-matter extending beyond the content of the earlier application as filed and infringes Article 76(1) EPC. It follows that, for this reason alone, auxiliary request 4 is not allowable.

9.3 Claim 12

9.3.1 As noted in the decision under appeal, the paragraph bridging pages 20 and 21 of the earlier application D35 (and the same paragraph of the application as filed) provides a basis for claim 12. Hence, there is no added subject-matter in relation to claim 12.

10. Auxiliary request 5

10.1 Claim 1 of auxiliary request 5 is identical to claim 1 of auxiliary request 4. For the reasons set out above in relation to auxiliary request 4, the objections of lack of inventive step against claim 1 of auxiliary request 5 are not convincing.

10.2 Compared with auxiliary request 4, in auxiliary request 5 several dependent claims have been deleted. From the remaining dependent claims, an added-matter objection was only present against claim 5, which corresponds to claim 12 of each of the main request and

of auxiliary request 4. For the reasons set out above in connection with claim 12 of auxiliary request 4, claim 5 does not comprise added subject-matter.

10.3 There are thus no objections prejudicing the maintenance of the patent on the basis of auxiliary request 5. As it corresponds to the version found allowable in the decision under appeal, both appeals are to be dismissed.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated