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Datasheet for the decision of 20 May 2026

Case Number: T 0768/24 - 3.2.02

Application Number: 12784809.1

Publication Number: 2750630

IPC: A61F2/24

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Title of invention:
DEVICE FOR HEART VALVE REPLACEMENT

Patent Proprietor:
Twelve, Inc.

Opponent:
Abbott Cardiovascular Systems, Inc.

Relevant legal provisions:
EPC Art. 54, 56, 111(1), 83, 123(2)
RPBA 2020 Art. 11

Keyword:
Novelty - main request (no) - auxiliary request (yes)
Inventive step - auxiliary request (yes)
Amendments - added subject-matter - auxiliary request (no)
Sufficiency of disclosure - auxiliary request (yes)
Remittal - special reasons for remittal - (no)

Decisions cited:
T 0830/22, T 1888/22, T 0824/23

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Case Number: T 0768/24 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 May 2026

Appellant: (Patent Proprietor)	Twelve, Inc. 199 Jefferson Drive Menlo Park, CA 94025 (US)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Appellant: (Opponent)	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)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted/ electronically transmitted on 3 April 2024 concerning maintenance of the European Patent No. 2750630 in amended fo rm.**

Composition of the Board:

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

Summary of Facts and Submissions

I. Both the patent proprietor and the opponent appealed against the opposition division's interlocutory decision finding that the contested patent as amended on the basis of auxiliary request 30 filed during the oral proceedings before the opposition division complied with the requirements of the EPC.

II. The appellants' final requests at the end of the oral proceedings held before the Board on 20 May 2026, at the end of which the present decision was announced, were the following.

(a) The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, as an auxiliary measure, that it be maintained in amended form on the basis of one of auxiliary requests 30 to 64 filed with its statement of grounds of appeal, where auxiliary request 30 corresponds to the request found allowable by the opposition division.

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

III. The present decision refers to the following documents, cited in the decision under appeal:

D14 WO 2006/113906 A1
D26 WO 2011/072084 A2

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

1 "*A prosthetic heart valve device for treating a mitral valve, the prosthetic heart valve device comprising:*

1.1 *an expandable retainer (110) configured to engage cardiac tissue at or downstream of a native mitral valve annulus; and*

1.2 *a valve support (120) coupled to and extending in a downstream direction from the expandable retainer (110), wherein the valve support (120) is configured to support a prosthetic valve (130);*

1.3 *wherein the expandable retainer (110) is configured to conform to the shape of the native mitral valve annulus while the valve support (120) remains substantially unchanged,*

1.4 ***characterized in that*** *the prosthetic heart valve device is configured to be delivered intravascularly to a desired location in the heart while being in a delivery configuration within a delivery catheter.*"

V. Claim 1 of **auxiliary request 30** differs from claim 1 of the main request in that:

a) feature 1.2 has been amended as follows (amendment highlighted by the Board):

"*a valve support (120) coupled to and extending in a downstream direction from the expandable retainer (110), wherein the valve support (120) is configured to support a prosthetic valve (130), wherein the valve*

support includes a plurality of posts (122) connected circumferentially by a plurality of struts (124);"

and

b) the following wording has been inserted between features 1.2 and 1.3:

"*wherein the retainer (110) includes a plurality of flexible arcuate ribs (114) extending outward from the valve support (120) and in an upstream direction, the ribs being distributed around a perimeter of the valve support,*"

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

Main request - novelty in view of D26

The subject-matter of claim 1 as granted was novel in view of D26. D26 failed to disclose a prosthetic valve device comprising all features of claim 1 as granted in combination, in particular features 1.2 to 1.4.

Feature 1.2

The loops 146 shown in Figure 6 did not support the prosthetic leaflets and should not be treated as part of a valve support within the meaning of claim 1. Thus, even if they extended beyond the length of the stent, the valve support itself did not.

Furthermore, the tether attachment features 114 shown in the figures also belonged to the stent 112. Neither the figures nor the description directly and

unambiguously disclosed that the loops 146 extended beyond those tether attachment features.

In any event, paragraph [00147] stated that the leaflet assembly or leaflet wire form 148 and 146 was shown in Figure 6 only "for illustration purposes but would not be visible". This indicated that the wire support was not visible from the side of the valve device and therefore could not be derived from Figure 6 as extending downstream from the stent.

Paragraph [0098] also stated that "the entire leaflet assembly [was] housed within the stent body". Since the wire support formed part of the leaflet assembly, this disclosure contradicted the view that the wire support extended from the stent body in a downstream direction. Taken together, the inconsistencies and contradictory disclosures in D26 prevented feature 1.2 from being directly and unambiguously disclosed.

More generally, D26 contained inconsistencies in the drawings and reference signs. For example, visually similar, unlabelled loop-like structures appeared in Figures 2B and 3B, which were features of the stent and not of the wire support. This cast doubt on the direct and unambiguous identification of the loops 146 as part of the wire support.

Feature 1.3

The wire support 126 was made of an elastic, "spring-like" single wire. Paragraph [00143] described that the wire support could flex inwardly, expand outwardly, collapse when compressed and expand when deployed. Moreover, the unattached junctions 146 were able to move independently of one another and of the stent.

This disclosure did not show that the wire support remained substantially unchanged after implantation. On the contrary, it indicated that the wire support was deformable. The distorting forces exerted by the native annulus on the stent would be transmitted to the wire support received within that stent. The wire support would therefore also deform significantly in use and would not remain "substantially unchanged".

The embodiment of Figures 24A and 24B did not lead to a different conclusion. According to paragraph [0099], the connecting ring 154 merely "minimize[d]" inward deflection of the commissural posts; it did not prevent this deflection. To the contrary, this confirmed that deformation of the wire support could still occur.

In any event, the contested patent required more than the mere competence of the prosthetic valve. Paragraphs [0074] and [0086] of the patent allowed only slight deformation of the valve support, provided that the prosthetic valve remained intact and competent. D26 did not positively disclose that these requirements were met. Nor could the valve device of D26 simply be assumed to be functional in a manner satisfying feature 1.3. Prior-art documents could also disclose non-working embodiments.

Feature 1.4

The embodiments relied on for features 1.2 and 1.3 were not directly and unambiguously disclosed as being configured for intravascular delivery. The general passages in paragraphs [0049] and [00102] did not directly and unambiguously apply to these embodiments.

To the contrary, D26 consistently showed the valve devices with tether attachment features, and many embodiments, including those of Figures 6 and 20, were disclosed in combination with tethers for anchoring the device in the heart. Such tether-based anchoring presupposed an apical delivery route, not an intravascular route. The earlier decision T 830/22, concerning a similar disclosure, confirmed that tethers could not be treated as optional.

The presence of the connecting ring 154 in the embodiment of Figures 24A and 24B also called into question whether this device could be collapsed into a delivery configuration suitable for intravascular catheter delivery.

Auxiliary request 30

Added subject-matter

Claim 1 of auxiliary request 30 did not contain added subject-matter. The features referred to by the opponent were either implicit in claim 1 or were not inextricably linked with the features of claim 1.

Sufficiency of disclosure

The contested patent disclosed the invention as claimed in claim 1 of auxiliary request 30 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Novelty in view of D26

The subject-matter of claim 1 of auxiliary request 30 was novel in view of D26. D26 failed to disclose at

least the feature that the retainer includes a plurality of flexible arcuate ribs extending outward from the valve support and in an upstream direction. The segments 122 were part of the cuff 116 and were therefore offset from the wire support 126, meaning that they did not extend outward from the valve support within the meaning of claim 1.

Inventive step starting from D26

The subject-matter of claim 1 of auxiliary request 30 involved an inventive step starting from D26. Even if the objective technical problem were formulated merely as the provision of an alternative arrangement, the person skilled in the art would not have modified D26 so that the segments 122 extended from the wire support 126 within the meaning of claim 1 because such a modification would have been detrimental to the proper functioning of the prosthetic leaflets.

VII. The **opponent's arguments** relevant to the present decision can be summarised as follows.

Main request - novelty in view of D26

The subject-matter of claim 1 as granted was not novel in view of D26. D26 disclosed a prosthetic valve device comprising all features of claim 1 as granted, including features 1.2 to 1.4.

Feature 1.2

The cuff 116 and tubular stent 112 of D26 formed an expandable retainer. The wire support 126 supported the prosthetic leaflets 120 and was coupled to the stent 112. The loops 146 formed part of the wire support 126,

as confirmed *inter alia* by Figure 3E and paragraph [0143], which described them as junctions or commissural tips of the wire support. Figure 6 and paragraph [0060] directly and unambiguously disclosed that these structural wire support loops extended beyond the length of the stent. The same was apparent from Figure 20 and from the embodiment of Figures 24A and 24B, in which the tips of the wire support were joined by the connecting ring 154 located beyond the downstream edge of the stent. D26 therefore disclosed a valve support coupled to and extending in a downstream direction from the expandable retainer.

Feature 1.3

The expandable retainer formed by the cuff 116 and the stent 112 was configured to conform to the shape of the native mitral valve annulus since the cuff segments 122 could move independently and conform to the annular anatomy. The wire support 126 nevertheless remained "substantially unchanged" within the meaning of claim 1. The expression "substantially unchanged" did not exclude minor deformation, as confirmed by the contested patent itself, for example in paragraph [0074]. The spring-like properties of the wire support in D26 related to compression for delivery and expansion into the final functional shape, not to substantial deformation during use after implantation. In the final functional shape, the wire support necessarily maintained an operational shape allowing the prosthetic leaflets to coapt properly. The connecting ring 154, which minimised inward deflection of the commissural posts, further confirmed that deformation of the wire support after deployment was to be limited.

Feature 1.4

D26 disclosed that the disclosed prosthetic heart valve devices were configured for intravascular catheter delivery. Paragraphs [0049] and [00102] disclosed antegrade and retrograde catheter-based delivery approaches, including transvenous and transarterial access routes. These passages were not limited to an isolated embodiment but applied generally to all the prosthetic valve devices disclosed in D26. The tethers shown in some figures did not prevent this conclusion since tethers were optional. Paragraph [0113] disclosed that tines or barbs could be used in conjunction with, or in place of, one or more tethers, including all of them. Claims 34 and 35 likewise showed that anchoring could be achieved either with a combination of barbs and tethers or with barbs alone, i.e. without tethers. The connecting ring 154 did not prevent collapse into a delivery configuration suitable for intravascular delivery.

Auxiliary request 30

Added subject-matter

Claim 1 of auxiliary request 30 contained added subject-matter for the same reasons as claim 1 as granted. The claim resulted from unallowable intermediate generalisations because several features originally disclosed in combination with the claimed subject-matter had been omitted.

The application as filed disclosed intravascular delivery only in the context of a low-profile delivery configuration and, depending on the passage relied on, a percutaneous approach or the embodiments disclosed in

paragraphs [00111] to [00113]. These embodiments included further structural and functional features, such as the dimensions of the device; the arrangement of the retainer relative to the valve support; the relative flexibility or rigidity of the retainer, ribs and valve support; and the specific engagement of the native leaflets. Mechanical isolation of the valve support from the retainer was also missing from claim 1. The omission of these features extended the claimed subject-matter beyond the content of the application as filed.

Sufficiency of disclosure

The contested patent did not disclose the invention as claimed in claim 1 of auxiliary request 30 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Claim 1 did not expressly require the valve support to be mechanically isolated from the expandable retainer. As a result, the claim covered a significant number of non-working embodiments in which the valve support was not mechanically isolated from the forces exerted on the expandable retainer by the native anatomy. The person skilled in the art would therefore not be able to carry out the invention over the whole scope of claim 1.

The detailed embodiments in the patent could not remedy this deficiency because they only showed how to carry out the claimed invention when the valve support was mechanically isolated from the retainer. However, they did not enable the person skilled in the art to implement devices lacking such mechanical isolation.

Novelty in view of D26

The subject-matter of claim 1 of auxiliary request 30 was not novel in view of D26. D26 disclosed the additional feature that the retainer includes a plurality of flexible arcuate ribs extending outward from the valve support and in an upstream direction.

The wording of that feature did not require the ribs to extend directly, or to originate, from the valve support. The expressions "coupled to" and "extend from" were not synonymous, as was apparent from the claim itself and from paragraphs [0074] and [0121] of the contested patent. It was therefore not excluded that the ribs started with an offset relative to the valve support. This was also consistent with Figure 10C of the contested patent, which showed an initial portion of the ribs that did not itself extend in an upstream direction.

The segments 122 of the cuff 116 in D26, which constituted flexible arcuate ribs, therefore extended outward from the valve support and in an upstream direction.

Inventive step starting from D26

The subject-matter of claim 1 of auxiliary request 30 did not involve an inventive step in view of D26 alone.

The distinguishing feature identified by the Board, namely that the ribs extended outward from the valve support in the sense that they originated from it, without an offset, had no technical effect. The effect relied on by the patent proprietor, namely that the prosthetic valve remained unaffected by deformation of

the expandable retainer, did not arise from the absence of an offset between the ribs and the valve support. Likewise, paragraph [00139] of D26 disclosed that the cuff 116 conformed to the native valve anatomy by the segments 122 travelling or flexing up and down, hence without affecting the wire support received in the tubular stent. The position of the wire support along the stent was irrelevant, as was also apparent from paragraph [0143].

The distinguishing feature therefore merely provided an obvious alternative to the arrangement disclosed in D26. The person skilled in the art would have arrived at this alternative by a routine modification, without exercising any inventive skill.

The opponent had also raised, in writing, an inventive-step objection starting from D26 in combination with D14. At the oral proceedings before the Board, however, it confirmed that this objection was no longer relevant in view of the Board's conclusion on novelty.

Reasons for the Decision

1. Subject-matter of the contested patent

1.1 The contested patent relates to a prosthetic heart valve device for treating a mitral valve, the device being configured to be delivered intravascularly.

1.2 As explained in the description (see paragraphs [0008] to [0012]), mitral valve replacement, compared with aortic valve replacement, poses unique anatomical obstacles.

In contrast to the relatively symmetric and regular aortic valve, the mitral valve annulus has an irregular, non-circular and unpredictable shape. On the one hand, a mitral valve prosthesis which does not conform to the mitral valve annulus may lead to gaps in commissural regions of the native valve, resulting in perivalvular leaks. On the other hand, deformation of the valve prosthesis caused by the native anatomy may be detrimental to the proper operation of the valve prosthesis.

Furthermore, the mitral valve annulus lacks a substantial amount of radial support from surrounding tissue. As a result, radial forces on the mitral valve annulus, such as those imparted by an expanding stent, could lead to the collapse of the inferior portion of the neighbouring aortic tract, with potentially fatal consequences for the patient.

1.3 In view of this, the contested patent aims to provide a prosthetic heart valve device for treating a mitral valve which comprises an anchoring portion having the flexibility to conform to the variably shaped native mitral valve anatomy, while the prosthetic valve is protected from the resulting distorting forces exerted on the anchoring portion by the native valve anatomy (see paragraphs [0023] to [0025], [0074] and [0100]).

1.4 As shown in Figures 10B and 10C, reproduced below, a prosthetic heart valve device according to claim 1 as granted comprises an expandable retainer (110) configured to engage cardiac tissue at or downstream of the native mitral valve annulus (feature 1.1) and a valve support (120) coupled to and extending downstream from the retainer, the valve support being configured to carry a prosthetic valve (130) (feature 1.2).

In addition, the prosthetic heart valve device is configured to be delivered intravascularly to a desired location in the heart while being in a delivery configuration within a delivery catheter (feature 1.4).

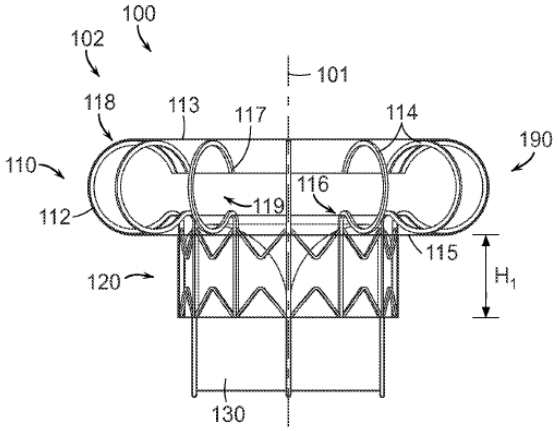


FIG. 10C

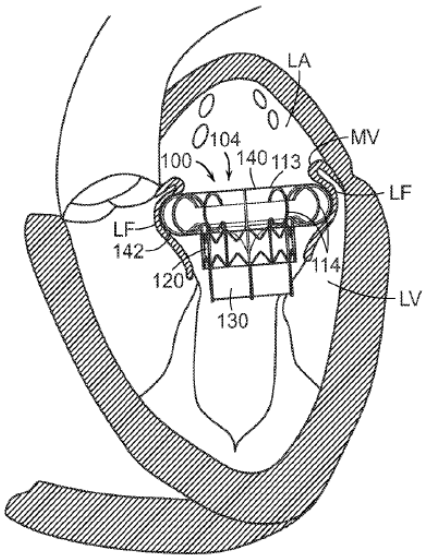


FIG. 10B

1.5 A central aspect of the claimed prosthetic heart valve device is that the expandable retainer (110) is configured to conform to the shape of the native mitral valve annulus after deployment "while the valve support (120) remains substantially unchanged" (feature 1.3). As described in paragraphs [0074] and [0086], when the valve device is deployed and operational, the cross-sectional shape of the valve support (120) can remain sufficiently stable when the retainer (110) is deformed by engagement with the tissue such that the prosthetic valve (130) remains intact and competent.

An example of how the expandable retainer (110) changes its shape from its expanded configuration (102) in the absence of any distorting forces to a deployed configuration (104) to accommodate the irregular shape of a native mitral valve (MV in the figure), while

preserving the shape of the valve support (120), is provided in Figure 17C, reproduced below, and described in paragraph [0094].

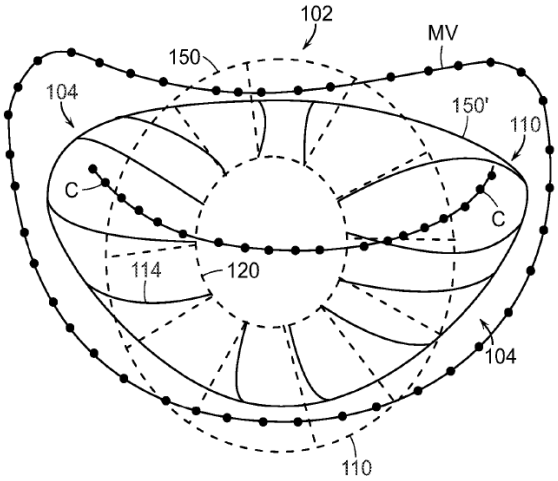


FIG. 17C

2. Main request - novelty in view of D26

2.1 The Board agrees with the opponent that the subject-matter of claim 1 of the main request is not novel in view of D26.

2.2 It is common ground that D26 discloses a prosthetic heart valve device for treating a mitral valve (feature 1) (see paragraph [0008]). As shown, for example, in Figures 6 and 20, reproduced below, this valve device comprises a cuff 116 and a tubular stent 112 which, in combination, constitute an expandable retainer configured to engage cardiac tissue at or downstream of a native mitral valve annulus (feature 1.1). This was not disputed by the patent proprietor.

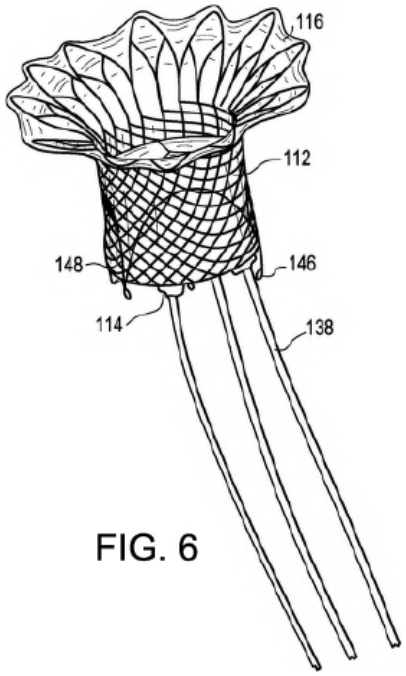


FIG. 6

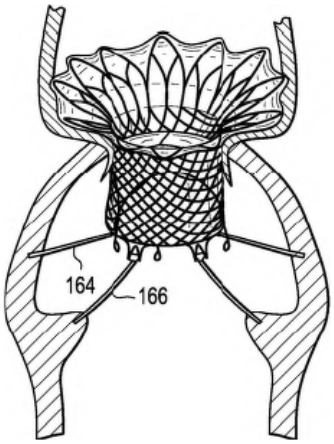


FIG. 20

2.3 Contrary to the patent proprietor's argument, D26 discloses embodiments of this valve device which also comprise the remaining features 1.2 to 1.4 of claim 1.

2.3.1 Feature 1.2: *a valve support coupled to and extending in a downstream direction from the expandable retainer, wherein the valve support is configured to support a prosthetic valve*

As apparent from the figures reproduced above and the exploded view of Figures 3A to 3E, and as described in paragraphs [0098] and [00143], the valve device in those embodiments further comprises a wire support 126 for supporting the leaflets 120 of a prosthetic valve. This wire support is attached, and thus coupled - at its upper portion - to the stent 112. It therefore anticipates a valve support coupled to the expandable retainer and configured to support a prosthetic valve.

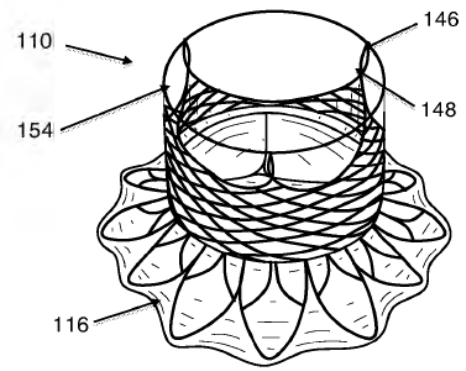
Furthermore, despite its schematic nature, Figure 6 unambiguously shows loops 146 of the wire support 126 extending beyond the downstream edge of the tubular stent 112. This disclosure is confirmed explicitly by the description of Figure 6 in paragraph [0060], according to which that figure is a top view of "one embodiment of a prosthetic valve according to the invention" and "shows [...] the structural wire support loops extending beyond the length of the stent" (emphasis added by the Board).

Hence, the wire support 126 extends, at least partly, in a downstream direction from the stent 112. It therefore extends in a downstream direction from the expandable retainer, which includes that stent, thereby anticipating feature 1.2. Contrary to the patent proprietor's argument, feature 1.2 does not require the whole valve support to extend from the retainer.

The same disclosure is found in Figure 20, in which similar loops extending beyond the downstream edge of the stent can likewise be unambiguously identified as the downstream tips of the wire support 126 received within the stent.

The opponent also referred to Figures 24A and 24B (see Figure 24A reproduced below), which show a similar embodiment in which, additionally, the loops 146 are adjoined at their downstream tips by a connecting ring 154 (see paragraphs [0099] and [00169]). Despite their schematic nature, these figures unambiguously show that the ring 154 and the loops 146 are arranged beyond the downstream edge of the stent, meaning that, in that embodiment as well, the wire support 126 likewise extends in a downstream direction from the stent.

FIG. 24A



Therefore, at least for those embodiments, D26 directly and unambiguously discloses that the valve support extends in a downstream direction from the expandable retainer, as required by feature 1.2.

The patent proprietor's arguments to the contrary are not convincing.

a) The patent proprietor argued that the loops 146 did not serve to support the leaflets of the prosthetic valve and accordingly should not be regarded as a part of a valve support within the meaning of claim 1. Thus, even if in D26 the loops themselves might extend beyond the length of the stent, the valve support that could be identified in D26, in any event, did not.

However, contrary to the patent proprietor's assertion, the loops 146 are an integral part of the wire support 126 supporting the leaflets. This is not only apparent from Figure 3E but also from paragraph [0143], which explicitly describes them as "junctions" or "commissural tips" of the wire support 126, meaning that the loops 146 are intended to support the commissures formed by the leaflets.

b) The patent proprietor also argued that the stent 112 further included tether attachment features 114 as shown in Figure 6, and that neither Figure 6 nor the description directly and unambiguously disclosed that the loops 146 extended beyond those features.

However, claim 1 does not exclude the possibility that additional features are attached to the expandable retainer at its downstream end, nor does feature 1.2 require the valve support to extend from the most downstream part of the expandable retainer. It is sufficient that the valve support extends in a downstream direction from a portion of the expandable retainer. Therefore, the presence of the tether attachment features 114 does not contradict the conclusion that D26 discloses feature 1.2.

c) The patent proprietor also referred to the statement in paragraph [00147] that the "leaflet assembly or leaflet wire form 148 and 146" is shown in Figure 6 "for illustration purposes but would not be visible" (emphasis added by the Board). According to the patent proprietor, this indicated that the wire support 126 was in fact not visible from the side of the valve device, and that, accordingly, it did not extend in a downstream direction from the stent.

However, the passage cited by the patent proprietor cannot be isolated from the remainder of the sentence, which specifies that the "wire form" "would not be visible through tissue or synthetic material, e.g. liner" (emphasis added) covering the cuff and the stent. Therefore, this passage does not contradict the disclosure discussed above in relation to Figure 6.

d) The patent proprietor also referred to paragraph [0098], which states that "the entire leaflet assembly is housed within the stent body" (emphasis added by the Board). According to the patent proprietor, this indicated that the wire support, which is part of the leaflet assembly, could not extend from the stent body.

However, the person skilled in the art would understand that this disclosure does not exclude that small portions of the wire support 126 at its very downstream end, such as the loops 146, may still extend in a downstream direction from the expandable retainer, as expressly disclosed in paragraph [0060] and Figure 6. This understanding is supported by the fact that the following paragraph, paragraph [0099], presents the embodiment including a connecting ring adjoining the tips of the wire support, with the ring and the tips clearly beyond the downstream edge of the stent, as discussed above in relation to Figures 24A and 24B, as one embodiment of the type of valve device described in paragraph [0098], in which the leaflets are supported by a wire support.

e) More generally, the patent proprietor argued that the figures contained several inconsistencies with regard to the loops, both in the drawings and in the reference signs. For example, unlabelled structures visually similar to them could be seen in Figures 2B and 3B, which indicated that they were features of the stent and not of the wire support 126. According to the patent proprietor, these inconsistencies prevented feature 1.2 from being regarded as directly and unambiguously disclosed in D26.

However, even if D26 admittedly contains some inconsistencies, these inconsistencies do not negate

the distinct and explicit disclosure that, as discussed above, the tips or loops 146 of the wire support extend beyond the downstream edge of the stent, hence from the identified expandable retainer, at least in some embodiments of D26.

2.3.2 Feature 1.3: *the expandable retainer is configured to conform to the shape of the native mitral valve annulus while the valve support remains substantially unchanged*

D26 discloses that the individual wire lobes or segments 122 of the cuff 116 can move independently so that "the cuff is able to conform to the [...] shape of the mitral annulus" (paragraph [0089]); see also paragraph [00135]: "sealing of the cuff against [...] tissue within and adjacent to the mitral annulus". It follows that the expandable retainer, which includes the cuff, is configured to conform to the shape of the native mitral valve annulus. This was not disputed by the patent proprietor.

In addition, contrary to the patent proprietor's view, the expandable retainer is configured to conform to the shape of the native mitral valve annulus, while the wire support 126 remains "substantially unchanged", as further required by feature 1.3.

This is because the expression "substantially unchanged", due to the term "substantially", does not exclude minor deformation, as conceded by the patent proprietor. This interpretation of feature 1.3 is also expressly supported by the description of the contested patent, which explains that "the valve support 120 can deform slightly" provided that "the prosthetic valve 130 remains intact and competent" (see paragraph [0074]; see also paragraphs [0080] and [0086]: "the

cross-sectional shape of the valve support 120 can remain sufficiently stable [...] such that the valve 130 remains competent"; emphasis added by the Board). Thus, feature 1.3 does not require the valve support to remain completely undeformed.

The situation is no different for the wire support 126 in D26. For the valve device to be functional after deployment, the leaflet assembly supported by the wire support 126 must necessarily remain competent. This requires that the wire support 126, likewise, substantially maintains its operational shape after deployment to ensure proper coaptation of the leaflets. As for the valve device of the contested patent, this does not exclude that the wire support 126 may undergo some minor deformation, in particular due to its "spring-like" properties. However, this deformation must necessarily remain limited and not be substantial. This conclusion is supported by paragraph [00143], which explains that the spring-like tension of the wire support 126 assists in "the proper orientation of the leaflets" once the prosthetic heart valve is expanded from a compressed stored shape to "its final functional shape". The person skilled in the art understands this passage as meaning that, in this final functional shape, the wire support provides a leaflet-supporting structure compatible with proper valve function.

This is also reflected in the described purpose of the connecting ring 154 in the embodiment of Figures 24A and 24B being to "minimize" the inward deflection of the commissural posts of the wire support (paragraph [0099]). Contrary to the patent proprietor's assertion, this indicates - not only for the embodiment of Figures 24A and 24B but also, more generally, for those of Figures 6 and 20 - that deformation of the wire

support 126 after deployment of the prosthetic valve device is possible but undesired and must therefore be avoided and minimised, as is the case for the valve support of claim 1. The fact that paragraph [0099] refers to minimising, rather than completely preventing, inward deflection is not decisive since feature 1.3 does not require a complete absence of deformation.

This understanding is consistent with the fact that D26 generally attributes the ability to conform to the native valve anatomy to the cuff rather than to the stent (see paragraph [00139]), the stent being consistently described and illustrated as tubular (see, for example, Figures 19 and 20).

The ability of the wire support 126 to deform to which the patent proprietor referred with reference to paragraph [00143] - including the ability of the unattached junctions of the wire support to move independently of one another and of the stent - does not relate to the post-deployment phase but to the pre-implantation and implantation phases, during which the valve device is first compressed into a collapsed, low-profile configuration for insertion into a delivery catheter and subsequently deployed within the heart. As stated above, paragraph [00143] explicitly describes the "spring-like" tension of the wire support 126 as "assist[ing] in the proper orientation of the leaflets once the prosthetic heart valve is expanded from a compressed stored shape to its final functional shape".

The patent proprietor's argument that D26 cannot be assumed to disclose a functional valve device is unconvincing. As stated above, D26 is directed to a prosthetic mitral valve device and describes the wire

support as assisting in "the proper orientation" of the leaflets in the "final functional shape" of the valve device. In the absence of any indication to the contrary provided in D26 or convincingly demonstrated by the patent proprietor, this disclosure is understood to relate to a valve device in which the leaflet assembly is functional after deployment.

2.3.3 Feature F1.4: *the prosthetic heart valve device is configured to be delivered intravascularly to a desired location in the heart while being in a delivery configuration within a delivery catheter*

D26 explicitly discloses in paragraph [0049] that "the prosthetic valve device is deployed by accessing the left heart using either an antegrade-trans(atrial) septal (transvenous-trans(atrial)septal) approach or a retrograde (transarterial-transaortic) catheter approach to enter the left heart, and deploying the prosthetic heart valve into the mitral annulus using the catheter delivery system" and in paragraph [00102] that the valve device is delivered "using either an antegrade or retrograde delivery approach using a flexible catheter system", i.e. intravascularly with the prosthetic valve device being in a delivery configuration within a delivery catheter, as defined by feature 1.4.

Paragraph [00102] is one of the paragraphs forming the section of the description entitled "Deployment within the valvular annulus", while paragraphs [0098] and [0099] are parts of the section entitled "Leaflet and Assembly Structure". The person skilled in the art understands that each of these sections of the description describes one aspect of the valve devices generally disclosed in D26. Contrary to the patent

proprietor's view, the person skilled in the art therefore understands that the delivery routes disclosed in paragraphs [0049] and [00102], including the intravascular one, apply generally to all the valve devices disclosed in D26, and thus to the embodiments under consideration discussed above, which comprise a wire support 126 as disclosed in paragraphs [0098] and [0099].

The patent proprietor contended that all the valve devices disclosed in D26 consistently comprised tether attachment features 114 and that most of them, including those of Figures 6 and 20, were indeed shown in combination with such tethers for anchoring the valve device in the heart. According to the patent proprietor, this indicated that such tethers were indispensable and, since such tether-based attachment presupposed an intercostal, and thus apical delivery, it meant that these embodiments were configured for apical delivery, not for intravascular delivery as required by feature 1.4. The patent proprietor referred in this regard to T 830/22, which concerned a patent application similar to D26, in which a similar conclusion had been reached. In any event, the presence of tether attachment features in the valve devices and a connecting ring in the embodiment of Figures 24A and 24B prevented the valve devices from being collapsed into a delivery configuration for intravascular delivery.

This is not persuasive.

In view of the general statements in paragraphs [0049] and [00102] applying to the embodiments of Figures 6, 20, 24A and 24B, as set out above, the person skilled in the art understands that the mere presence of tether

attachment features 114 does not mean that tethers must necessarily be attached when the device is configured for intravascular delivery. At least, their presence does not prevent the valve device from being delivered intravascularly.

The Board notes that paragraph [0132] merely states that tethers "may" be attached to the tether attachment features 114, this indicating that tethers are merely optional.

Furthermore, as argued by the opponent, the person skilled in the art understands from the disclosure in paragraph [00113], according to which tines or barbs may be used to anchor the valve device within the native valve annulus "in conjunction with, or in place of one or more tethers" (emphasis added by the Board), that all the tethers may be replaced by tines or barbs, i.e. that tether-based anchoring may be dispensed with. This is the case, in particular, because some valve devices disclosed in D26 comprise only one tether, as disclosed for example in paragraph [0019]. In other words, tethers and tether-based attachment of the valve devices in the heart are optional. As further submitted by the opponent, this is also supported by claims 34 and 35 of D26. Both claims depend on claim 1 and define alternatives. Whereas the prosthetic valve of claim 35 comprises "a combination of anchoring tethers and anchoring barbs" attached to the prosthetic heart valve for anchoring the valve into local tissue, the prosthetic valve of claim 34 instead comprises only "a plurality of anchoring barbs" for this purpose. The person skilled in the art infers from the comparison between these two claims that the valve of claim 34 comprises no tether at all.

The reference to T 830/22 concerning paragraph [00113] does not help the patent proprietor's case. In that decision (see Reasons 1.3.2 and 1.3.3), the deciding Board held that a passage of the application under consideration, paragraph [00369], the wording of which is identical to the wording of paragraph [00113] of D26, did not disclose that tethers were optional. However, the case at hand differs at least in that, unlike the application under consideration in T 830/22, D26 also includes claims 34 and 35, which expressly distinguish between anchoring with barbs alone and anchoring with a combination of tethers and barbs. The conclusion reached in T 830/22 is therefore not directly applicable to the present case.

Furthermore, contrary to the patent proprietor's argument, the disclosure concerning a possible intravascular delivery applies not only to the embodiments of Figures 6 and 20 but also to the embodiment of Figures 24A and 24B having a connecting ring 154, as described in paragraph [0099]. It would be illogical to provide the wire support 126 with spring-like properties to enable it to collapse into a delivery configuration and at the same time to provide a connecting ring which is non-collapsible, thereby preventing the valve device from being delivered intravascularly in a collapsed delivery configuration. In fact, the preceding sentences of paragraph [0099] describe collapsible concentric rings able to collapse into a delivery configuration and then expand to a functional shape. The person skilled in the art thus understands that the connecting ring 154 does not prevent the prosthetic valve device from being configured for intravascular catheter delivery as disclosed in paragraphs [0049] and [00102].

D26 therefore discloses feature F1.4 in combination with the preceding features of claim 1.

2.4 It follows that D26 discloses prosthetic valve devices comprising all features of claim 1 as granted in combination. The subject-matter of claim 1 is therefore not novel, and the main request is not allowable.

3. Auxiliary request 30

3.1 Added subject-matter

3.1.1 The Board agrees with the patent proprietor that claim 1 of auxiliary request 30 does not contain added subject-matter.

At the oral proceedings before the Board, the opponent did not provide any further comment on this issue but merely referred to its written submissions. As stated in the Board's preliminary opinion under Article 15(1) RPBA (see point 4.2.4), the opponent's added subject-matter objections are not convincing.

3.1.2 The opponent disputed the opposition division's findings concerning claim 1 as granted set out in Reasons 2.1 of the decision under appeal and contended that, like claim 1 as granted, claim 1 of auxiliary request 30 contained added subject-matter because several features disclosed in the application as originally filed in combination with the features of claim 1 (namely, the feature that the delivery was percutaneous and the features listed in the paragraph bridging pages 5 and 6 of the decision under appeal) had been impermissibly omitted from claim 1. In other words, the opponent considered claim 1 to result from

unallowable intermediate generalisations of the original disclosure.

However, an objection of unallowable intermediate generalisation cannot succeed merely by identifying features which have been omitted from the claim, as the opponent did. It must also be explained why the omission of these features adds subject-matter. In accordance with established case law of the boards, this explanation must show that the omitted features are inextricably linked with (some of) the claimed ones according to the original disclosure (see Case Law of the Boards of Appeal of the EPO, 11th edn., 2026 revision, II.E.1.9.1; as well as, for instance, decisions T 824/23, Reasons 1.7.1 and T 1888/22, third item of Reasons 3.2.2). In the present case, the opponent has not shown that the features allegedly omitted from claim 1 are inextricably linked with the claimed subject-matter in such a way that their omission provided the person skilled in the art with new technical information. The opponent's arguments are therefore not persuasive.

3.1.3 Indeed, the Board sees no reason to conclude that claim 1 contains added subject-matter.

a) As considered by the opposition division, it follows from feature 1.4, namely that the prosthetic valve device is configured to be delivered intravascularly while being in a delivery configuration within a delivery catheter, that the delivery is percutaneous and that the prosthetic valve device in the delivery configuration must have a low profile suitable for intravascular delivery. Hence, these further features are implicit in claim 1. There is therefore no intermediate generalisation, let alone an unallowable

one, in this respect, and the fact that claim 1 does not explicitly recite these further features does not add subject-matter.

b) The same applies to the feature that the valve support is mechanically isolated from the retainer. Original claim 3 already defines the functional relationship corresponding to feature 1.3, namely that the expandable retainer is configured to conform to the shape of the native mitral valve annulus while the valve support remains substantially unchanged, without requiring that the valve support be mechanically isolated from the retainer. This indicates that the application as originally filed does not present the feature that the valve support is mechanically isolated from the retainer as an additional limitation which is inextricably linked to feature 1.3 and must necessarily be included in the claim.

This understanding is confirmed by the passages of the original description relied on by the patent proprietor. Paragraphs [0076], [0080], [0082] and [0083] describe mechanical isolation in terms of the valve support remaining sufficiently stable, or not being substantially deformed, when the retainer is deformed by engagement with the native valve anatomy ("mechanically isolated [...] such that [...] does not substantially [affect/change/deform]"). Paragraph [0151] likewise discloses that such mechanical isolation may be achieved by the valve support having sufficient rigidity to "resist deformation" while the retainer is deformed and by selecting the location and means for coupling the valve support to the retainer to "mitigate the transmission of forces" through the retainer to the valve support.

Thus, in the application as originally filed, mechanical isolation is reflected in the functional requirement that the retainer can conform to the native mitral valve annulus while the valve support remains substantially unchanged, i.e. as defined in feature 1.3. The omitted feature is not presented as a further mandatory structural feature, separate from that functional relationship. Its omission as an explicit wording from claim 1 therefore does not provide the person skilled in the art with new technical information.

The fact that the opposition division may have reached a seemingly contradictory conclusion concerning claims 1 and 2 as granted is irrelevant. In any event, claim 2 as granted has been deleted from auxiliary request 30.

c) Furthermore, the person skilled in the art understands that the types of intravascular delivery approaches and associated structural features disclosed in paragraphs [00111] to [00113] of the application as originally filed are merely exemplary. This applies in particular to the dimensions of the device; the particular configuration in which the retainer at least partially surrounds and is coupled to the valve support; the relative flexibility or rigidity of the retainer, ribs and valve support; and the specific engagement of the native leaflets described for those embodiments. These features are not presented in the original application as being indispensable or in any way inextricably linked to the device being configured for intravascular delivery within a delivery catheter. The omission of these features from claim 1 therefore does not add subject-matter either.

3.2 Sufficiency of disclosure

3.2.1 The Board agrees with the patent proprietor that the contested patent discloses the invention as claimed in auxiliary request 30 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

3.2.2 At the oral proceedings before the Board, the opponent did not provide any further comment on this issue but merely referred to its written submissions. As stated in the Board's preliminary opinion under Article 15(1) RPBA (see point 4.2.4), the opponent's objection is not convincing.

3.2.3 The opponent's objection was based on the argument that since the mechanical isolation of the valve support from the expandable retainer was not expressly defined in claim 1, the scope of the patent allegedly covered a significant number of embodiments in which the valve support was not mechanically isolated from the expandable retainer. According to the opponent, in such embodiments, deformation of the expandable retainer caused by the native valve anatomy would be transmitted to the valve support, meaning that the valve support would no longer remain substantially unchanged and that the embodiments would therefore be non-working. The opponent therefore argued that the person skilled in the art would not be able to carry out the invention over the whole scope claimed.

However, this is not persuasive. Claim 1 explicitly requires, in feature 1.3, that the expandable retainer be configured to conform to the shape of the native mitral valve annulus while the valve support remains substantially unchanged. This functional requirement is

a limiting feature of the claim. Embodiments in which the valve support would not be mechanically isolated from the retainer, so that deformation of the retainer would be transmitted to the valve support to such an extent that the valve support no longer remained substantially unchanged, would therefore not fall within the scope of claim 1. It follows that the absence from claim 1 of an explicit limitation that the valve support is mechanically isolated from the retainer does not mean that the claim covers non-working embodiments in which the functional relationship defined in feature 1.3 is not achieved (see also point 3.1.3 b) above).

More generally, as set out by the opposition division in the decision under appeal (see Reasons 4.2), the person skilled in the art finds in the contested patent sufficient technical guidance, including several detailed examples, on how to implement the claimed features, in particular feature 1.3. This guidance includes, in particular, guidance on how to select the relative flexibility and rigidity of the retainer, ribs and valve support, and the location and means for coupling the valve support to the retainer to mitigate transmission of forces to the valve support.

It follows that the invention as claimed in auxiliary request 30 is sufficiently disclosed.

3.3 Novelty in view of D26

3.3.1 Claim 1 of auxiliary request 30 differs from claim 1 as granted on account of, *inter alia*, the additional feature that the retainer includes a plurality of flexible arcuate ribs extending outward from the valve support and in an upstream direction.

The Board agrees with the patent proprietor that D26 does not disclose this additional feature and that, accordingly, the subject-matter of claim 1 of auxiliary request 30 is novel in view of D26.

3.3.2 The opponent argued in its reply to the patent proprietor's statement of grounds of appeal (see paragraph bridging pages 20 and 21 of the reply) that the segments 122 of the cuff 116, which, in its view, constituted flexible arcuate ribs, extended both outwardly and in an upstream direction relative to the position of the structural wire support 126, thereby anticipating the additional feature.

According to the opponent, this was because the claim wording did not require the ribs to extend directly from the valve support (see the opponent's argument set forth in Reasons 9.2.1 on page 19, first paragraph, last sentence of the decision under appeal). The opponent also referred to the Board's communication under Article 15(1) RPBA (see point 3.14), in which the Board had indeed underlined that feature 1.2 contained two separate requirements for the valve support, namely that (i) it is coupled to the retainer and (ii) it extends from it. The person skilled in the art would understand from this distinction that "extending from" did not, in the context of claim 1, necessarily mean "coupled to" or "attached to".

At the oral proceedings before the Board, the opponent further defended this interpretation by referring to paragraph [0121] of the contested patent, according to which the arms 510 could be "coupled to and/or extend from" components of the device (emphasis added by the Board), and to paragraph [0074], according to which a

downstream portion 111 of the retainer 110 could be "coupled to or near" the upstream end 121 of the valve support 120 "and extend outward and in an upstream direction from the valve support" (emphasis added). According to the opponent, these passages supported the view that the ribs could start with an offset relative to the valve support. This was the case because the ribs comprised a first initial portion adjacent to the valve support that did not extend in an upstream direction but downstream, as shown in Figure 10C.

3.3.3 However, in deviation from the Board's preliminary opinion set out in its communication under Article 15(1) RPBA, the Board finds convincing the interpretation of the term "extend from" according to which D26 does not disclose ribs extending from the wire support, which the patent proprietor defended in its reply to the opponent's statement of grounds of appeal (see page 6, first two lines, of the reply), in its reply to the Board's communication (see point II.4 of the patent proprietor's submission of 27 April 2026) and at the oral proceedings before the Board.

According to this interpretation, "extend from" implies - at least in the context of claim 1 - a structural relationship and not merely a spatial orientation or relative positioning, i.e. it requires a point or region of origin from which the extending feature originates. As submitted by the patent proprietor, without such a structural relationship, almost any structure located around another, such as concentric rings or a cylinder around a rod, could be said to extend outward from that other structure merely because of its relative position.

It follows that the feature that the flexible arcuate ribs extend outwardly from the valve support requires the ribs to originate from the valve support. It is not sufficient that the alleged ribs are merely arranged radially outside and upstream of the valve support when viewed in the general geometry of the device.

However, D26 discloses the segments 122 as structures of the cuff 116 arranged around and offset from the wire support 126, thus not originating from the wire support 126.

The Board therefore agrees with the patent proprietor that the above-mentioned additional feature of claim 1 is not disclosed in D26. This conclusion applies even if, in favour of the opponent, the segments 122 are regarded as flexible arcuate ribs distributed around the perimeter of the valve support.

3.3.4 As further submitted by the patent proprietor, this understanding is fully compatible with the disclosure of the contested patent.

The Board sees no contradiction in paragraph [0074], in which the expression "coupled to or near the upstream end 121 of the valve support 120" specifies the region of the valve support from which the downstream portion 111 of the retainer 110 is coupled to the valve support before extending outwardly and upstream from the valve support. This passage does not support an interpretation according to which a structure that is clearly offset from the valve support may nevertheless be regarded as extending from it merely because it has a generally outward and upstream orientation relative to the valve support.

Nor does paragraph [0121] lead to a different conclusion. The fact that the arms 510 may be "coupled to and/or extend from" components of the device shows at most that "coupled to" and "extend from" are not synonymous. It does not mean that "extend from" is reduced to a mere spatial comparison with a remote reference structure.

Finally, the fact that Figure 10C may show a short initial portion of the ribs with a local orientation that is not upstream does not alter the interpretation of the additional feature of claim 1. The feature does not require every portion of each rib to extend in an upstream direction. It requires that the flexible arcuate ribs, considered as such, extend outward from the valve support and in an upstream direction. This interpretation is consistent with the illustrated embodiment of the contested patent but does not read on the segments 122 of D26, which are offset from the wire support 126.

3.3.5 For these reasons, the subject-matter of claim 1 of auxiliary request 30 is novel in view of D26.

3.4 Inventive step starting from D26

3.4.1 D26 alone

At the oral proceedings before the Board, the opponent raised an inventive-step objection against claim 1 of auxiliary request 30 based on D26 alone.

As set out below, this objection is not convincing. There is therefore no need for the Board to decide whether to admit it. Moreover, the patent proprietor did not object to its admittance.

The opponent's objection is based on the argument that the distinguishing feature of claim 1 identified by the Board, namely that the ribs extend from the valve support in the sense that they originate from it rather than being offset from it, had no technical effect. The technical effect described in the contested patent (for example, in paragraph [0074]) and put forward by the patent proprietor, namely that the prosthetic valve remained unaffected by the deformation of the expandable retainer, did not arise from the absence of an offset between the ribs and the valve support.

According to the opponent, this was no different in D26. As described in paragraph [0139], the cuff 116 conformed to the native valve anatomy by the segments 122 travelling or flexing up and down, likewise without affecting the wire support received in the tubular stent. The position of the wire support itself along the stent was irrelevant, as was also apparent from paragraph [0143].

It followed, for the opponent, that the distinguishing feature merely constituted an obvious alternative to the arrangement of D26, which the person skilled in the art would have arrived at by a mere routine modification, without exercising any inventive skill.

This is not convincing. Even if accepting, for the sake of argument and in favour of the opponent, the formulation of the objective technical problem starting from D26 as being the mere provision of an alternative arrangement, the Board concurs with the patent proprietor that the person skilled in the art would not, without hindsight, have modified the valve devices of D26 which comprise a wire support for supporting the

leaflets in the manner put forward by the opponent. This is because doing so would increase the sensitivity of the wire support to deformation of the segments 122 and thus be detrimental to the proper functioning of the leaflets. On the contrary, the presence of an offset between the upper junctions of the wire support 126 and the upstream portion of the tubular stent 112 from which the segments 122 extend outwardly minimises the influence of distortion of the cuff 116 on the wire support 126.

The person skilled in the art would therefore not have arrived at the subject-matter of claim 1 of auxiliary request 30 without exercising an inventive step.

3.4.2 D26 in combination with D14

The opponent confirmed at the oral proceedings before the Board that the inventive-step objection starting from D26 in combination with D14, which it had raised in its reply to the patent proprietor's statement of grounds of appeal (see page 21), was no longer relevant in view of the Board's conclusion on novelty. There is therefore no need for the Board to address this objection.

4. Remittal of the case to the opposition division

4.1 The opponent requested that the case be remitted to the opposition division for further prosecution.

In support of its request, the opponent argued that the reasons for which the Board, at the oral proceedings before it, had found the subject-matter of claim 1 of auxiliary request 30 to be novel over D26 differed from the reasons for which the opposition division had based

its conclusion on claim 1 of the request then on file as auxiliary request 29, which is identical to claim 1 of auxiliary request 30. The opposition division had instead relied on the finding that D26 did not disclose flexible arcuate ribs. The opponent argued that it should be given an opportunity to respond to this different assessment. In particular, the opponent explained that it would have referred to further documents if the opposition division had based its conclusion on the same reasoning ultimately adopted by the Board.

4.2 The Board does not accept this argument.

4.2.1 The meaning of the term "extend from" had already been discussed in the opposition proceedings. As stated in point 3.3.2 above, this is apparent from the decision under appeal itself (see Reasons 9.2.1, page 19, first paragraph, last sentence). It is also explicitly reflected in points 5.1.2.1 and 5.1.2.2 of the minutes of the oral proceedings before the opposition division, from which it is apparent that the interpretation of the term "extend from" ultimately adopted by the Board corresponds to that put forward by the patent proprietor in the opposition proceedings.

It is correct that the opposition division's conclusion on novelty did not depend on that interpretation but instead relied on the opposition division's conclusion that D26 did not disclose flexible arcuate ribs.

However, even if the opponent may have considered that there was no need during the opposition proceedings to file further evidence addressing the interpretation of "extend from", in view of the opposition division's conclusion on the ribs, the opponent should have

expected that the Board could reach, on appeal, different conclusions on these aspects.

The opponent had an opportunity to file, with its appeal submissions, any evidence or document on which it wished to rely in the event that the Board adopted the patent proprietor's interpretation of "extend from". However, it did not do so. Moreover, at the oral proceedings before the opposition division, the opponent expressly declared that it did not wish to discuss any further objections against claim 1.

4.2.2 Pursuant to Article 11 RPBA, the Board must not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

For the above reasons, the Board saw no such special reasons and consequently decided not to remit the case to the opposition division for further prosecution.

5. Conclusion

It follows from the foregoing that, while the main request is not allowable, none of the opponent's objections prejudices the maintenance of the contested patent as amended on the basis of auxiliary request 30. Since auxiliary request 30 corresponds to the request found allowable by the opposition division 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 Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated