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**Datasheet for the decision
of 27 September 2019**

Case Number: T 1224/16 - 3.2.08

Application Number: 09160105.4

Publication Number: 2119417

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

Atraumatic prosthetic heart valve prosthesis

Patent Proprietor:

Sorin Group Italia S.r.l.

Opponent:

Boston Scientific Corporation

Headword:

Relevant legal provisions:

EPC Art. 100(c), 123(2), 100(a), 54, 56

Keyword:

Amendments - extension beyond the content of the application
as filed (yes)- auxiliary request 1 - intermediate
generalisation
Novelty - (no) - new auxiliary request 1 (no)
Inventive step - new auxiliary request 2 (yes)

Decisions cited:

Catchword:



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Case Number: T 1224/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 27 September 2019

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
8 March 2016 concerning maintenance of the
European Patent No. 2119417 in amended form.**

Composition of the Board:

Chairwoman P. Acton
Members: C. Herberhold
Y. Podbielski

Summary of Facts and Submissions

- I. By decision posted on 8 March 2016 the Opposition Division decided that European patent No. 2119417 as per the second request then on file, and the invention to which it related, met the requirements of the EPC.
- II. The patent proprietor (appellant 1) and the opponent (appellant 2) lodged an appeal against that decision. Both appeals were duly filed and reasoned.
- III. Oral proceedings before the Board took place on 27 September 2019.

At the end of the oral proceedings the requests of the parties were as follows:

Appellant 1 requested that the decision under appeal be set aside and the patent be maintained on the basis of the first auxiliary request filed with the grounds of appeal on 15 July 2016, or on the basis of the new first or the new second auxiliary request, both filed during the oral proceedings before the Board.

Appellant 2 requested that the decision under appeal be set aside and the patent be revoked.

- IV. Claim 1 of the first auxiliary request (claim 1 corresponding to claim 1 as granted) reads as follows:

"**(A)** A heart valve prosthesis (10) adapted for minimally invasive delivery to an implantation site of a patient, the implantation site having an annulus (16), a Valsalva sinus (VS), and an aortic tunica intima, the prosthesis comprising:

- (B) an anchoring structure (400) having a radially collapsed configuration for delivery and a radially expanded configuration for deployment;
- (C) a valve (410) coupled to the anchoring structure (400) and configured such that in the expanded configuration, the valve permits blood flow through the lumen in a first direction and substantially prevents blood flow through the lumen in a second direction generally opposite the first direction;
- (D) wherein the anchoring structure (400) includes a generally cylindrical portion adapted to engage an annular vessel wall at the implantation site;
- (E) wherein the generally cylindrical portion includes an outflow portion (435) adapted to engage the vessel wall at a location distal to the Valsalva sinus (VS);
- (F) wherein, in the expanded configuration, the outflow portion (435) tapers inwardly towards a distal end, such that the distal end imparts less force than a proximal portion upon the aortic tunica intima,

the heart valve prosthesis being **characterized in that**

- (G) the outflow portion (435) includes a proximal outflow ring (465) and a distal outflow ring (460),
- (H) wherein the distal outflow ring (460) has a tapered configuration, such that a distal end of the distal outflow ring (460) has a smaller diameter than a proximal end of the distal outflow ring (460),
- (I) **and in that** the distal end of distal outflow ring (460) is disposed between about 0.5 and about 3 mm closer to a longitudinal axis (X_1) of the anchoring structure (400) than is a distal end of the proximal outflow ring (465)."

Feature assignment of claim 1 as in appellant 1's statement of grounds, page 3 and as used by the parties

during oral proceedings before the Board. Feature assignment for the requests filed during oral proceedings ("new" auxiliary requests) added by the Board.

- V. Claim 1 of the new auxiliary request 1 differs from claim 1 of auxiliary request 1 in the following amendment of feature H and in the addition of features J and K (amendments are underlined):

(H') wherein the distal outflow ring (460) has a tapered configuration and narrows in diameter in a distal direction, such that a distal end of the distal outflow ring (460) has a smaller diameter than a proximal end of the distal outflow ring (460), **(I) and in that** the distal end of distal outflow ring (460) is disposed between about 0.5 and about 3 mm closer to a longitudinal axis (X_1) of the anchoring structure (400) than is a distal end of the proximal outflow ring (465)

(J) wherein the proximal outflow ring (465) and the distal outflow ring (460) are coupled together, the proximal outflow ring (465) being disposed proximal to the distal outflow ring (460), and

(K) wherein the proximal outflow ring (465) extends generally parallel to the longitudinal axis (X_1) of the anchoring structure (400)."

- VI. Claim 1 of the new auxiliary request 2 differs from claim 1 of the new auxiliary request 1 in that the following feature was added:

"(L) wherein the outflow portion (435) is covered with a protective material to prevent trauma to or tearing of the aortic tunica intima".

VII. The following documents played a role in the present decision:

D2: Grube et al., "Valvular Heart Disease", "First Report on a Human Percutaneous Transluminal Implantation of a Self-Expanding Valve Prosthesis for Interventional Treatment of Aortic Valve Stenosis", Catheterization and Cardiovascular Interventions, 66: 465-469, 2005;

D3: Boudjemeline et al., "Percutaneous Pulmonary Valve Replacement in a Large Right Ventricular Outflow Tract", JACC, 43(6), 1082-1087 (2004);

D5: WO-A-2006/127765;

D9: WO-A-2008/070797;

D17a: Grube, E. et al, "Percutaneous Implantation of the CoreValve Self-Expanding Valve Prosthesis in High-Risk Patients With Aortic Valve Disease: The Siegburg First-in-Man Study", Circulation (AHA), Volume 114:1616-1624, October 10, 2006;

D17b: Set of figures from the above paper under the title "Percutaneous Implantation of the CoreValve Self-Expanding Valve Prosthesis in High Risk Patients With Aortic Valve Disease", Grube, E. et al, Circulation (AHA), Volume 114(14): 1616-1624, October 10, 2006;

D18: Extracts from a presentation held by Eberhard Grube at TCT Asia, Seoul, April 29, 2010;

D19: Buellesfeld et al, "Aortic Root Dimensions Among Patients With Severe Aortic Stenosis Undergoing Transcatheter Aortic Valve Replacement", JACC, Vol. 6, No. 1: 72-83, 2013;

VIII. The essential arguments of appellant 2 can be summarised as follows:

Auxiliary request 1 - extension beyond the content of the application as originally filed

The subject-matter of claim 1 of auxiliary request 1 was essentially a combination of the subject-matter of claims 1, 3 and 4 with the addition of feature I. Uncontestedly, the only disclosure of feature I was in the last sentence of paragraph [0025] of the description as filed (see the A2 publication). This disclosure was, however, in functional and structural context with the particular embodiment of Figures 4A and B, as described in paragraphs [0024] and [0025]. Isolating feature I from this context resulted in an unallowable intermediate generalisation. In particular, paragraph [0024] disclosed the heart valve prosthesis to comprise appendages (450), which projected into the Valsalva sinus in order to anchor and stabilise the anchoring structure at the implantation site. These appendages were essential for correct longitudinal positioning of the device and thus for the intended prevention of trauma to the aortic intima. Furthermore, feature I was only disclosed in the context of a proximal and a distal outflow ring coupled together, with the proximal ring extending generally parallel to the longitudinal axis. Paragraphs [0024] and [0025] clearly described the particular embodiment of Figures 4A and 4B, starting with more general features and coming to more specific features, of which feature I

was the most specific. In view of this drafting no weight could be attributed to the wording "according to one embodiment" or the like. Indeed, if these introductory phrases were taken seriously, there would then be no basis at all for claiming the different features in combination in a single claim, in particular as claims 3 and 4 as filed had been drafted directly dependent only on claim 1 as filed.

In this context it had to be noted, that feature I could also not be considered merely a more narrow definition of claim 4 as filed, because claim 4 defined a tapered configuration of the distal outflow ring in which the distal end of the distal outflow ring had a smaller diameter than the proximal end of the distal outflow ring, whereas feature I defined that the distal end of the distal outflow ring was disposed closer to the longitudinal axis of the anchoring structure than was the distal end of the proximal outflow ring. Taking feature I out of its context thus changed the claimed offset's reference point, not only with respect to the original disclosure in paragraph [0025], but also with respect to claim 4 as filed.

Furthermore, as argued in the written proceedings, the subject-matter of dependent claims 5, 6, 7, 9-11 extended beyond the original disclosure. The respective subject-matter was not disclosed in combination with the subject-matter of original claim 4 - which was now part of the independent claim - or with the embodiment of Figures 4A/4B, and could at best be found somewhere in the description without any relationship with the now claimed subject-matter.

New Auxiliary request 1 - lack of novelty

The subject-matter of claim 1 of new auxiliary request 1 was not new over the Core Valve bioprosthesis as disclosed in D2 and D17b. Figure 1A of D17b was a high-resolution photograph of said prosthesis. Because of its exact lateral perspective without any distortion or parallax errors, the photograph allowed the determination of the diameters of the part to be inserted into the aortic annulus as well as of the distal end of the distal outflow ring and of the distal end of the proximal outflow ring. As the typical diameter of the aortic annulus was a known anatomic fact, see D19, the photograph could be scaled and the claimed offset be determined. In this respect, it was not the calculated value which mattered, but the fact that basically for every anatomically reasonable diameter assumed for the prosthesis' lower third - which is supposed to sit in the aortic annulus - an offset value in the claimed range resulted. As could be further seen on the photograph, the lateral projection of the proximal outflow ring's wire struts was generally parallel to the longitudinal axis of the prosthesis, just as in the embodiment of Figures 4A/4B of the invention. Thus, the CoreValve prosthesis shown in D17b, Figure 1A disclosed features I and K.

As to feature E, which appellant 1 had identified as a further differentiating feature, D2 explicitly disclosed that the upper part of the CoreValve prosthesis expanded for fixation in the ascending aorta, see D2, page 466, left column last paragraph, and that the prosthesis had self-positioning properties due to the long fixation part in the ascending aorta which facilitated co-axial positioning, see page 467, last paragraph. The outflow portion was

thus adapted to engage the vessel wall at a location distal to the Valsalva sinus, which was also a necessary consequence of the device's length and which was further in accordance with the schematic representation in D18, second page, right drawing.

Consequently, claim 1 was not novel.

New Auxiliary request 2 - lack of original disclosure, lack of inventive step

Claim 1 of new auxiliary request 2 as well as several dependent claims lacked original disclosure essentially for the reasons also discussed in writing with respect to the dependent claims of the first auxiliary request.

Furthermore, the subject-matter of claim 1 of new auxiliary request 2 did not involve an inventive step.

With claim 1 of new auxiliary request 1 being not novel, the only differentiating feature which could justify an inventive step was the outflow portion being covered with a protective material to prevent trauma to or tearing of the aortic tunica intima. The claimed protective effect was, however, intrinsic to any covering material provided on a prosthesis. Such coverings had been used for ages in combination with intravascular prosthesis, D3, Figure 1 being just one example. The person skilled in the art would thus find it obvious to apply a cover to the D2/D17 prosthesis in order to prevent trauma or tearing of the aortic tunica intima. Of course, in doing so, the skilled person would take care that the ostia of the coronary arteries remained accessible to the blood flow. The subject-matter of claim 1 of new auxiliary request 2 thus did not involve an inventive step.

IX. The essential arguments of appellant 1 can be summarised as follows:

Auxiliary request 1 - no extension beyond the content of the application as originally filed

As pointed out by appellant 2, claim 1 of auxiliary request 1 was a combination of the subject-matter of claims 1, 3 and 4 as originally filed, wherein a specific tapering pattern as disclosed in paragraph [0025] last sentence was selected. However, the features disclosed in paragraph [0025] were in no way inextricably linked. To the contrary, they were consistently presented as alternatives, the sentences being all introduced using wording like "according to one embodiment" or "according to some embodiments". Furthermore, there was not a single disclosure of any synergy between the appendages and the tapering pattern for effectuating atraumaticity of the device. Indeed, claim 1 as filed already referred to the inward taper towards a distal end as imparting less force upon the aortic tunica intima, without the appendages being part of the claimed subject-matter. Furthermore, claim 4 as filed provided basis for further defining the tapered configuration of the distal outflow ring, without the additional features disclosed in paragraphs [0024] and [0025] for the particular embodiment of Figures 4A and 4B. In particular, there was no need for the proximal outflow ring to extend generally parallel to a longitudinal axis or for the two outflow rings to be coupled together as long as the outflow portion tapered and did not flare out, which did not exclude an intermediate portion between the proximal and distal outflow ring. Indeed, the objections of applicant 1

were clarity objections rather than added matter objections.

To conclude, further detailing the final taper could not amount to an unallowable intermediate generalisation.

As to the features claimed in dependent claims 5, 6, 7, 9-11, these found basis in originally filed dependent claims 10, 11, 13-17 and in paragraphs [007],[0025],[0028] and [0029] of the description as originally filed.

New Auxiliary request 1 - novelty

The CoreValve prosthesis as disclosed in documents D2 and D17 differed in several features from the claimed subject matter.

Firstly, the claim required the outflow portion, i.e. both the proximal as well as the distal outflow ring to engage the vessel wall distal to the Valsalva Sinus (feature E). As could be seen from D5 or D9, Figures 84, 85 this was not the case for the CoreValve prosthesis, which was not surprising in view of the prosthesis length of 5 cm and an average length of the Valsalva sinus of 2.2 cm, see D19.

Secondly, the proximal outflow ring identified by appellant 2 was bulbous and not parallel to the longitudinal axis (feature K).

Thirdly, it was simply not possible to derive the claimed offset (feature I) with the required standard of a clear and unambiguous disclosure from the photographs in D2 or D17, which were not orthogonally taken and which comprised a parallax error and possibly image processing artefacts. Furthermore, the

measurements and calculations based thereon included too many unproven assumptions. As to document D18, this document was post-published and featured another generation of the CoreValve prosthesis and it could not support a certain implantation site before the priority date.

Therefore, the subject-matter of claim 1 was novel.

*New Auxiliary request 2 - original disclosure,
inventive step*

The subject-matter claimed in new auxiliary request 2 did not extend beyond the original disclosure for the reasons already discussed with respect to the original disclosure of the dependent claims.

Furthermore, the subject-matter of claim 1 was inventive.

The subject matter of claim 1 of new auxiliary request 2 differed from prior art D2/D17 at least in that the outflow portion was covered with a protective material to prevent trauma to or tearing of the aortic tunica intima. Although cover materials had been used in the prior art of intravascular prosthesis, there was no hint towards their use for prevention of trauma to the aortic intima. In particular, D3 cited by appellant 2, disclosed a polytetrafluoroethylene membrane covering a pulmonary valve replacement prosthesis to guarantee perfect sealing of the device. Employing such a membrane to a different valve prosthesis for a different purpose was clearly an *ex post facto* approach. Moreover, covering the device as disclosed in D3 would, firstly, leave the pointy ends of the prosthesis uncovered and thus not solve the

problem to prevent trauma to the aortic wall. It would, secondly, shut off the coronary arteries from the blood flow and thereby kill the patient. Consequently, the modification suggested by appellant 2 was neither obvious nor feasible.

The subject matter of claim 1 thus involved an inventive step.

Reasons for the Decision

1. Auxiliary request 1 - extension beyond the content of the application as originally filed.
 - 1.1 As pointed out by the parties, the subject-matter of claim 1 of auxiliary request 1 combines the features of claims 1, 3 and 4 as originally filed (features A-H) with a feature disclosed in the last sentence of paragraph [0025] of the description as originally filed (feature I). Claims 3 and 4 as filed were drafted directly dependent on claim 1 as filed.
 - 1.2 According to appellant 2 the combination of the features of original dependent claims 3 and 4 with feature I was only disclosed in paragraphs [0024] and [0025] in the context of the particular embodiment shown in Figures 4A and 4B, which, however, further comprised anchoring appendages and included 2 outflow rings coupled together with the proximal outflow ring extending generally parallel to a longitudinal axis of the support structure. Omission of these features amounted to an unallowable intermediate generalisation.
 - 1.3 According to feature I, the distal end of the distal outflow ring is disposed between about 0.5 and about 3 mm closer to the longitudinal axis than is the distal

end of the proximal outflow ring. The wording of feature I thus defines the taper of the outflow portion by use of a first reference point on the distal outflow ring (its distal end) and a second reference point on the proximal outflow ring (also the distal end). This is different from the definition in claim 4 as originally filed which defines the tapered configuration using reference points exclusively on the distal outflow ring, namely the distal end of the distal outflow ring and the proximal end of the distal outflow ring. Feature I thus is not only a narrower definition of what had been defined in claim 4 as filed.

Moreover, the disclosure of feature I at the end of paragraph [0025] cannot be read in isolation, but is dependent on the first part of the paragraph. Indeed, the proximal outflow ring, the distal part of which is used in the definition of feature I, is introduced at the beginning of paragraph [0025] in the context of two outflow rings coupled together, the proximal outflow ring being disposed proximal to the distal outflow ring, the proximal outflow ring extending generally parallel to a longitudinal axis of the support structure and the distal outflow ring narrowing in diameter. It is true that paragraph [0025] then introduces further features with the phrase "according to some/other/one embodiment(s)", namely the alternative linear or concavely curved form of the distal outflow ring and the particular offset defined in feature I. All these further features stand, however, in the context introduced before. Indeed, the distal outflow ring is said to extend linearly from the distal end of the proximal outflow ring just as the offset in feature I is defined with respect to the distal end of the proximal outflow ring. Taking

feature I out of this context, according to which the distal and proximal rings are coupled together and the proximal outflow ring extends generally parallel to a longitudinal axis, results in a definition of the distal outflow ring's taper different from the disclosure at the end of paragraph [0025], and thus in the skilled person being confronted with new technical information with respect to the original disclosure.

For this reason, the subject-matter of claim 1 extends beyond the disclosure of the application as originally filed.

It is noted that amending claim 1 in order to overcome said objection - as done in claim 1 of the new auxiliary request - not only brings the subject matter in line with the disclosure in paragraph [0025], but also results in the disclosure of paragraph [0025] being a suitable basis for combining the subject-matter of dependent claims 3 and 4 with the subject matter of claim 1 as filed.

- 1.4 On the other hand, the omission in the subject-matter of claim 1 of the anchoring appendages disclosed for the embodiment of Figures 4A and 4B does not present the skilled person with new technical information. This is because already claim 1 as originally filed assigned the effect of the distal end imparting less force than the proximal portion upon the aortic tunica intima to the particular inwardly tapering configuration of the outflow portion, without any mention of the anchoring appendages. Consistently, dependent claims 3 and 4 as filed, which further define the outflow portion, do likewise not mention the appendages. While claiming the heart valve prosthesis with the particular configuration of the outflow portion, but without the

anchoring appendages, forms a generalisation with respect to the embodiment shown in Figures 4A and 4B, this generalisation does not provide the skilled person with new technical information beyond the original disclosure.

With the generalisation being justified in view of the original disclosure, the argument according to which the appendages were technically essential for correct longitudinal positioning of the device, can constitute no more than an objection under Article 84, which for a granted claim (claim 1 of auxiliary request 1 is identical to claim 1 as granted) is not to be examined in opposition appeal proceedings.

1.5 Dependent claims

The subject matter of dependent claims 5, 6, 7, 9 to 11 finds basis either in general parts of the description as originally filed, such that the person skilled in the art understands these features to be applicable to the different prostheses disclosed, or in the specific paragraph [0025] on which the invention now focuses. In particular, paragraph [0007] discloses the anchoring support structure to be possibly self-expanding (claim 5), paragraph [0025] discloses the distal outflow ring to extend along a curved, concave (from the perspective of the longitudinal axis) path, i.e. it discloses the distal outflow ring to curve away from the aortic tunica intima (claim 6). Furthermore, paragraph [0028] discloses the outflow portions of the anchoring structures to be blunt, so as to reduce the risk of snagging or tearing the vessel wall at the implantation site (claims 7 and 9), the outer surface of the anchoring structure being smooth and free from rough edges (claim 10), as well as the outside surface of the

anchoring support structure including a lubricious coating (claim 11).

Consequently, the subject matter of dependent claims 5, 6, 7, 9 to 11 does not extend beyond the content of the application as originally filed.

2. New auxiliary request 1

2.1 Article 100(c) and 123(2) EPC

No further objections against the claims of new auxiliary request 1 were raised with respect to Articles 100(c) and 123(2) EPC. The objections raised in the written proceedings against the dependent claims have been discussed above in the context of the first auxiliary request.

2.2 Novelty

Documents D2 and D17 (in particular D17b, Figure 1A) refer to an aortic heart valve prosthesis known in the field as the CoreValve prosthesis. During the oral proceedings, it was common ground between the parties that the CoreValve prosthesis represented in Figure 1A comprised features A-D and F-H of claim 1 of the new auxiliary request 1.

2.2.1 Feature E

According to feature E, the claimed heart valve prosthesis has a generally cylindrical portion including an outflow portion adapted to engage the vessel wall at a location distal to the Valsalva sinus. Even if said outflow portion is defined to include a proximal outflow ring and a distal outflow ring,

feature E does not require both rings to be in full lateral contact with the vessel wall at a location distal to the Valsalva sinus. For the outflow portion being adapted in the claimed way it suffices that the outflow portion's distal end provides such engagement. With this definition in mind, even the implantation of a different generation CoreValve prosthesis shown in Figures 84 and 85 of D5 or D9 would fall under feature E in that its distal outflow ring's distal end engages the vessel wall at a location distal to the Valsalva sinus. Therefore, contrary to appellant 1, these documents cannot prove that the outflow portion of the valve according to D2/D17b could not possibly be adapted to engage the vessel wall at a location distal to the Valsalva sinus.

Furthermore, D2, page 466, left column lower paragraph, discloses the upper part of the valve to expand for fixation in the ascending aorta to "ax the system". According to the disclosure, this resulted in the device having (see page 467, right column last paragraph) self-positioning properties due to the long fixation part in the ascending aorta, which facilitated coaxial positioning. An outflow portion which did not engage the vessel wall at a location distal to the Valsalva sinus would hardly qualify as having a long fixation part in the ascending aorta. Moreover, the claimed engagement is in accordance with the position of the device shown in Figure 3A of D2 (please refer in this respect to the high quality version of D2 available at Wiley online library) and with D18, page 2, right upper image. The respective drawing shows a device having the configuration of the CoreValve prosthesis as in D2 and D17b.

It is noted that, even though D18 is post-published, it still can be used in support of an inherent property of the prosthesis.

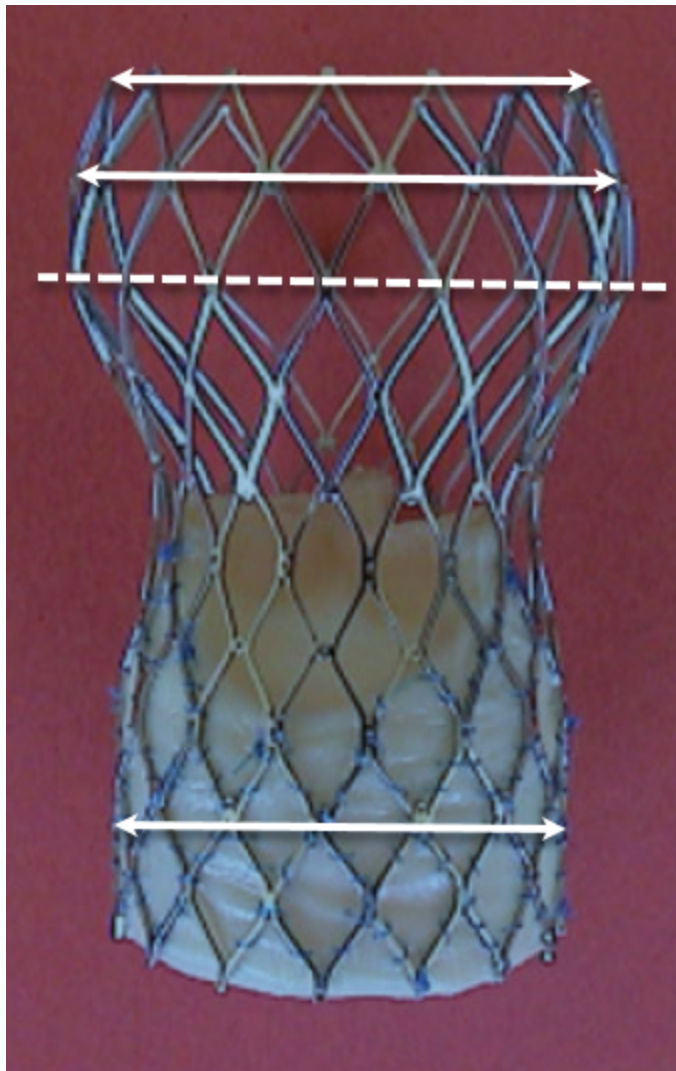
Thus, D2/D17b disclose feature E.

2.2.2 Feature I

Appellant 2 relies on measurements taken on Figure 1A of D17b, which is reproduced below. The white arrows and the dashed line have been added for reference.

Essentially appellant 2 measures the respective diameters at the distal end of the distal outflow ring (upper arrow, 6.4 cm - measurements taken on a high-quality print-out of Figure 1A as distributed during the oral proceedings), at the distal end of the proximal outflow ring (middle arrow, 7.2 cm) and at the part to be inserted into the aortic annulus (lower arrow, 6.0 cm).

In this interpretation, the distal outflow ring is located between the two upper arrows and the proximal outflow ring is located between the middle arrow and the dashed line. No objection to this assignment was raised during the oral proceedings.



According to appellant 2, as the lower third of the prosthesis needed to fit within the aortic annulus, it needed to have a diameter between 2 and 3 cm (as was conventional for aortic valves and as could also be determined from the anatomic data in D19, Table 2). As further demonstrated during the oral proceedings, no matter whether the lower third diameter of the prosthesis was scaled to an aortic annulus diameter of 20 mm, 30 mm or even 35mm, calculating the difference in distance from the longitudinal axis for the distal end of the proximal outflow ring and the distal end of the distal outflow ring always resulted in a value within the claimed range. Appellant 1, on the other

hand argued that no measurements could be taken at all from the photograph due to parallax errors and possible distortions by image processing.

Although great care has to be taken when trying to derive absolute values from photographs, in this particular case the Board is convinced that Figure 1A of D17b can be used as evidence that the prosthesis shown discloses feature I for the reasons set out below.

D17b, Figure 1B is a photograph, not a patent drawing. As can be derived from the mesh structure shown, the picture was taken in an almost perfect side view. Even if the editors of the journal in which the picture was published had changed its aspect ratio, the same x-axis scaling factor would have been applied in the upper and lower part of the image. The Board is thus convinced that the ratio between the diameters taken at the arrows is sufficiently correct for novelty evaluation in the present case.

It also cannot be denied that the lower third of the prosthesis needs to fit into the aortic annulus. It thus needs to have - for sealing reasons - a diameter slightly larger than the annulus. According to D19, Table 2, the diameter of the aortic annulus measured in 177 cases was between 20,5 mm and 26 mm. It is thus a safe assumption in favour of appellant 1 (and indeed the only one required) that the outer diameter of the prosthesis at the lower arrow lies somewhere in-between a range of 15 mm to 35 mm. As pointed out by appellant 2, this is in accordance with commercially available aortic CoreValve prosthesis having a diameter at their aortic annulus implantation site of 23, 26 or 29 mm. Using for scaling the diameter values at the

location of the arrows as measured by appellant 2 (appellant 1 protested against measurements being made in general, but not against the particular values derived from the figure), one can calculate an offset of the two diameters as claimed in feature I of 1,01 mm (assuming a lower prosthesis outer diameter of 15 mm) and of 2,35 mm (assuming a lower prosthesis diameter of 35 mm). Both values are safely within the claimed broad range of between 0.5 and 3 mm, which corresponds to a reduction of radius between 0,3 and 20%. This would be the case even if further taking into account - in favour of appellant 1 - large margins for any error allegedly caused by parallax or distortion artefacts. As the claim defines the offset between the two diameters, it does not play a role whether the offset between the inner or the outer diameters is used. The Board is thus convinced that the offset of the prosthesis shown in Figure 1A of D17b will inevitably fall within the claimed range.

This does, however, by no means imply that the Board is of the opinion that any of the above calculated values itself are clearly and unambiguously disclosed. Rather the calculations convincingly show by taking into account very cautious estimates that the prior art prosthesis must have an offset value within the claimed range.

- 2.2.3 Appellant 1 further was of the opinion that D2/D17 did not disclose a prosthesis wherein the proximal outflow ring extended generally parallel to the longitudinal axis (X_1) of the anchoring structure (feature K). However, as can be seen in the picture reproduced above, the most lateral sections of the proximal outflow ring (between the middle arrow and the dashed line) project essentially on a line parallel to the

longitudinal axis. In this respect, the situation is almost identical to the one in Figure 4B of the patent in suit (proximal outflow ring No. 465) which shows an embodiment of the invention. Thus, the prior art prosthesis discloses an outflow ring extending generally parallel to the longitudinal axis of the anchoring structure.

2.2.4 To conclude, the subject-matter of claim 1 of new auxiliary request 1 is not novel.

3. New Auxiliary request 2

3.1 No further objections were raised under Articles 100(c) or 123(2) EPC. With respect to original disclosure of feature L and of the dependent claims, reference is made to point 1.5 above (feature L was claimed in dependent claim 8 of auxiliary request 1).

3.2 Inventive step

3.2.1 Closest prior art is the valve prosthesis disclosed in D2/D17b. It is common ground that this prosthesis at least does not comprise an outflow portion which is covered with a protective material to prevent trauma to or tearing of the aortic tunica intima (feature L).

3.2.2 The technical effect lies in the protection of the aortic tunica intima, thus solving the problem of preventing trauma to or tearing of the aortic tunica intima.

3.2.3 Appellant 2 was of the opinion that covers had been used for ages in valvular prosthesis, that their protective effect was inherent and well known and that the person skilled in the art would, following e.g. the

teaching of D3 provide the D2/D17 device with such a protective cover, thereby coming in an obvious way to a prosthesis falling under the claim.

- 3.2.4 However, while D3 indeed discloses a PTFE membrane sutured to a stent valve, this disclosure is in the context of a different valve (the pulmonary valve) and for a different purpose ("to guarantee the perfect sealing of the device", see page 1083, left column second sentence). Conversely, prevention of trauma to the aortic tunica intima or to any other vessel wall by use of the PTFE membrane is not mentioned. Neither could appellant 2 point to any prior art document in which said technical effect was mentioned. When looking for a solution to the problem posed, the person skilled in the art thus had no reason to consider the membrane used in D3 for solving the problem.

Moreover, the membrane disclosed in D3 leaves the distal end of the prosthesis' outflow portion free, thereby exposing the vessel wall to the rather pointy ends of the stent (see D3, Figure 1B). The person skilled in the art thus would not derive from the disclosure of such a membrane an inherent vessel wall protective effect with respect to its outflow portion.

Furthermore, applying the membrane as disclosed in D3, Figure 1B to the prior art prosthesis of D2/D17b would shut off the coronary arteries from the blood flow (a problem which does not exist when implanting the D3 prosthesis as foreseen at the pulmonary valve).

- 3.2.5 There is thus neither a pointer in D3 to the claimed solution, nor is it evident that the D3 membrane would solve the problem posed, nor can the teaching of D3 be

applied to the closest prior art without substantive modification thereof.

The combination of the teaching of D2/D17b with that of D3 thus does not lead in an obvious way to the subject-matter of claim 1 of new auxiliary request 2 which consequently involves an inventive step.

3.3 No objections were raised against the amended description.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division with the order to maintain the patent in the following version:

Claims 1-11 according to the new second auxiliary request filed during the oral proceedings before the Board.

Description: Columns 1-4 and 7 of the patent specification and columns 5-6 filed during the oral proceedings before the Board.

Figures 1-4B of the patent specification.

The Registrar:

The Chairwoman:



D. Magliano

P. Acton

Decision electronically authenticated