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**Datasheet for the decision
of 19 October 2018**

Case Number: T 2348/17 - 3.2.08

Application Number: 02804403.0

Publication Number: 1441672

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
IMPLANTABLE PROSTHETIC VALVE

Patent Proprietor:
Edwards Lifesciences PVT, Inc.

Opponents:
Boston Scientific Corporation
Isarpatent
LUDWIG, Gabriele

Headword:

Relevant legal provisions:
EPC Art. 100(a), 54, 111(1)

Keyword:

Novelty - (no) - main request (no) - auxiliary request (no)
Remittal to the Opposition Division

Decisions cited:

G 0003/14

Catchword:



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Case Number: T 2348/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 19 October 2018

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
9 October 2017 concerning maintenance of the
European Patent No. 1441672 in amended form.

Composition of the Board:

Chairwoman P. Acton
Members: C. Herberhold
Y. Podbielski
A. Björklund
C. Schmidt

Summary of Facts and Submissions

- I. By decision posted on 9 October 2017 the Opposition Division decided that European patent No. 1441672 as per the 8th auxiliary request then on file, and the invention to which it related, met the requirements of the EPC.
- II. Appellant 1 (patent proprietor) and appellant 2 (opponent 1) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. With letter dated 13 April 2018 the Board granted appellant 2's request that the proceedings be accelerated.
- IV. Oral proceedings before the Board were held on 19 October 2018.

The parties as of right (remaining opponents 3 and 4; former opponent 2, Medtronic, Inc., having already withdrawn its opposition) did not attend although duly summoned. In accordance with Rule 115(2) EPC and Art. 15(3) RPBA oral proceedings were held in their absence.

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

Appellant 1 (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 the patent be maintained on the basis of auxiliary request 8 filed on 14 February 2014, or, if none of these requests could be granted, that

the case be remitted to the Opposition Division for further prosecution.

Appellant 2 (opponent 1) requested that the decision under appeal be set aside and that the patent not be maintained on the basis of the main request or auxiliary request 8, and that the case be remitted to the Opposition Division for further prosecution with regard to any remaining request not decided upon by the Opposition Division.

VI. Claim 1 of the main request (corresponding to claim 1 as granted) reads as follows:

"1. A valve prosthesis device (20) suitable for implantation in body ducts, the device comprising:
2. an expandable support frame (22)
2.1 comprising a deployable construction
2.1.1 adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and
2.1.2 adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location,
2.2 the support frame being provided with a plurality of longitudinally rigid support beams (23) of fixed length; and
3. a valve assembly (28)
3.1 comprising a flexible conduit having an inlet (24) and an outlet (26),
3.2 made of pliant material (29) attached to the support beams (23) providing collapsible slack portions of the conduit at the outlet (26),
4. whereby when flow is allowed to pass through the valve prosthesis device (20) from the inlet (24) to the outlet (26) the valve assembly (28) is kept in an open

position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly (28) collapse inwardly providing blockage to the reverse flow,

characterized in that

5. the support beams (23) are provided with bores (25, 42) and

6. the valve assembly (28) is stitched to the support beams (23) with thread or fiber (46) through the bores (25, 42)."

The feature assignment is as used by the parties and as in the impugned decision.

VII. Auxiliary request 8:

Claim 1 of the auxiliary request 8 is based on claim 1 of the main request with the following additional features:

"the outlet (26) is tapered with respect to the inlet (24) and the support frame (22) at the outlet (26) is wider in diameter than the pliant material (29) forming the outlet (26)."

VIII. The following documents play a role in the present decision:

D11a: WO-A-01/76510;

BB39: printout from the Merriam-Webster dictionary, entry for "bore".

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

Main request - Novelty

D11a was relevant for novelty, either under Article 54(3) or under Article 54(2) EPC.

The document disclosed a flexible tubular member 22 including a leaflet section 32 which was stitched to inserts 72 at 74 with thread or fibers. The inserts themselves were further stitched to the upper section 48 of commissure posts 42 with stitches 76.

Aperture 80 in commissure post 42 as well as aperture 78 in insert 72 were "bores" even in appellant 1's too narrow interpretation of the term, as they were pre-formed apertures in the material, from which the material in the hole was taken away by machining.

However, also the holes through which the stitches 74 - connecting leaflet section 32 to inserts 72 - were running, had to be considered "bores". As evidenced by BB39 the term "bore" described nothing more than a hole or a perforation, i.e. something created by a piercing action, such as e.g. by a pen piercing a business card. Whether the material originally at the bore's location was removed, still connected to the piercing instrument's exit site or pressed aside towards the periphery of the bore, was of no importance. Thus boring the needle through the inserts 72 upon creation of the stitches 74 resulted in "bores" in the inserts.

This was also in accordance with the patent specification, which disclosed that the support beams could be manufactured by injection moulding or any other suitable way. Hence "bores" in the sense of the patent were not limited to the result of a particular machining, drilling, piercing or boring action. Bores

were, indeed, nothing more than holes, which allowed - as the patent defined it in paragraph [0021] "stitching or tying of the valve assembly to the beams".

It had further to be kept in mind that claim 1 defined a product and not a method of manufacturing the product. It was thus only required that on the finished product there were bores in the support beams and that the valve assembly was stitched to the support beams with thread or fibers through these bores. Whether the bores had been there before the act of stitching was irrelevant.

D11a disclosed further that the valve assembly was stitched to the support beams with thread or fiber. Contrary to appellant 1's perception, the term "thread or fiber" did in no way define a sub-selection of materials, in particular textile materials, to be used for the stitches disclosed in D11a. As evidenced by the patent specification itself, the term "thread" comprised in particular "threads of gold", see e.g. paragraph [0113], whereas the term fiber included "PU, PET or other" fibers, see column 10, lines 28-31. Given this broad construction of the term "thread or fiber" in the patent specification, the stitches 74 and 76 shown in Figures 2 and 3 of D11a clearly qualified as stitches by thread or fiber, stitching the valve assembly to the support beams.

With the above interpretation of the terms "bore" and "thread or fiber" in mind, the disclosure of D11a was novelty destroying for the subject-matter of claim 1 as granted, no matter whether the claimed longitudinally rigid support beams were to be seen in the posts No. 46/48, in the inserts 72 or in a combination of the two.

As to the first interpretation, even appellant 1 accepted that commissure posts 46/48, i.e. 42, were longitudinally rigid and provided with bores 80. Furthermore, following Figure 43b of the patent, the term valve assembly included the pliant material being provided with additional attachment means. It was thus legitimate to likewise consider the "valve assembly" according to claim 1 to comprise pliant material 32 as well as inserts 72. Thus, the valve assembly 22 - of which inserts 72 in this interpretation were considered a part - was stitched to the support beams 46/48 with thread or fiber 76 through the plurality of bores 80. Nothing more was claimed.

Also if - in a second interpretation - only the inserts 72 were considered to form "the longitudinally rigid support beams of fixed length", D11a disclosed all features claimed. As mentioned before, the bores through which stitches 74 extended qualified as "bores with which the support beams were provided". Furthermore, the valve assembly 22 was stitched to the inserts 72 - which in this interpretation were not part of the valve assembly, but formed the support beams - with thread or fiber 74 through these bores. The inserts furthermore had to be considered longitudinally rigid 72 and of fixed length. Firstly, it had to be assumed that they were made of "Delrin" or of "other suitable polymer", i.e. from a material intrinsically having sufficient rigidity, in analogy to the material used in the embodiment of Figure 12, see D11a, page 15, line 23-26. In this context it had to be taken into account that the patent, see paragraph [0105], considered "support beams" made from the mechanically similar plastic material PU sufficiently rigid. Anyway, the term rigid was only a relative term without a clear

cut-off and the functionality allegedly following thereof was not claimed. Secondly, also their task of preventing pliant material from escaping through axial slots 54 and of preventing its wrinkling within the longitudinal extension of axial slot 54, required inserts 72 to be sufficiently rigid and of fixed longitudinal length.

Lastly, also if commissure posts 46/48 and inserts 72 together were understood to form the longitudinally rigid support beams claimed, D11a was novelty destroying. In this context it had to be emphasized that the patent itself supported the concept of support beams being a combination of plastic inserts and the support frame, see the Figure 9 embodiment and paragraph [0106].

To conclude, D11a was novelty destroying for the subject-matter of claim 1, no matter whether the support beams were seen in the commissure posts 46/48, the inserts 72 or a combination of both.

Auxiliary request 8 - Novelty

The additional features claimed in auxiliary request 8 were likewise known from D11a, which disclosed an initially tubular valve assembly, Figure 1, 22. Whereas the inlet remained at the original diameter, the outlet diameter was reduced due to the loops of pliant material which were drawn through the axial slots 54. This inevitably resulted in the outlet being tapered with respect to the inlet.

Furthermore, the diameter of the support frame, which was defined through the commissure posts, was wider than the diameter of the pliant material forming the

outlet. In this context, it had to be taken into account that firstly - according to the patent - the support frame could well incorporate the support beams, just as was the case in the support stent 24 of D11a, and that secondly, the loops of pliant material 70 did not "form the outlet", such that - analogous to the situation in the patent, Figure 43 - the "pliant material forming the outlet" comprised only the material forming the fluid conduit. This pliant material was fully within the circle defined by commissure posts, i.e. it was smaller in diameter than the support frame at the outlet. According to page 8, line 28 the pliant material was pericardial tissue such that a stretching of the material leading to an extension of the outlet over the diameter of the commissure posts could be excluded.

Conversely, the functional feature according to which a permanent clearance was to be provided in the open state between the material forming the outlet and the support frame at the outlet was not claimed. It could thus not be used to differentiate the subject-matter over the disclosure of D11a. Whereas it was true that the claim was considerably unclear, this did not mean that its features could be augmented *ad libitum* from the description. To the contrary, as decided in G 3/14 , such lack of clarity had to be lived with. In doing this, the unclear features had to be given the broadest sensible interpretation, in order not to have the patent proprietor profit from the lack of clarity for which he himself was ultimately responsible.

Consequently, claim 1 was not novel.

Remittal to the Opposition Division

The requests now remaining to be treated by the Board had never been discussed in opposition proceedings, neither with respect to their admission into the proceedings, nor in substance. It was thus requested to remit the case back to the Opposition Division. While it was true that appellant 2 had requested acceleration, the need for accelerated treatment arose only from the Opposition Division's decision to maintain the patent on the basis of auxiliary request 8.

- X. The essential arguments of Appellant 1 can be summarised as follows:

Main request - Novelty

Claim 1 as granted mentioned only three elements: the support frame, the valve assembly and the support beams. There was no indication that the support beams might be composed of several elements or were a mere prolongation of the commissure posts. Thus, the only elements of D11a which could reasonably be assigned to the claimed term "support beams" were the commissure posts 42. Consequently, tubular base 40 had to be the support frame and tubular leaflet section 32 was the valve assembly. Following this assignment, there was, however, no connection between the valve material and the support beams. Only inserts 72 were connected to the support beams, but these could not be considered part of the valve assembly. Nor was an indirect connection of the valve assembly to the support beams via additional elements such as inserts 72 part of the claimed subject-matter. Therefore, claim 1 was novel over the disclosure of D11a when commissure posts 42

were equated with the rigid support beams of fixed length.

Even if the rather artificial approach was taken into account, according to which the support beams were considered to comprise both the commissure posts as well as the inserts, this did not change the above analysis, because the holes pierced into inserts 72 by stitchings 74 did not qualify as "bores" in the sense of the claim for the reasons set out below:

Firstly, as clearly derivable from the claim language, the bores had to be present before the valve assembly was stitched to the beams.

Secondly, a "bore" was something resulting from removal of material, e.g. by drilling or laser drilling, or alternatively resulted from an initial lack of material, e.g. from injection molding around a core. It did, however, not have the material pressed aside on the inner side walls of the hole or the material removed from the hole still adherent to the exit periphery of the canal, which both were typical of needle stitching holes.

Thirdly, a bore had a smooth periphery.

Consequently, on the basis of these physical differences, the stitching perforations in inserts 72 did not qualify as bores.

Furthermore, claim 1 required the valve assembly to be stitched to the support with thread or fiber. In paragraph [0123], last sentence, the patent drew a clear distinction between "threads", "wires" and "other attachment means". It was thus clear that the term

"thread or fiber" only referred to textile material, not to metal wires. A valve prosthesis with the so defined specific stitching material was therefore novel over the valve prosthesis of D11a which only disclosed stitches made of some unspecified material in general.

In addition, D11a did not clearly and unambiguously disclose that the inserts were longitudinally rigid and of fixed length. The role of the inserts in D11a was to prevent the valve assembly from slipping through axial slots 54, a task for which no longitudinal rigidity was required. By contrast, the support beams claimed had to be of fixed length in order to allow dispensing with the provision of slack material in the valve assembly. D11a was silent on that functionality and there was also no intrinsic disclosure of the D11a insert material being suitable for that task. To the contrary, because of the material being piercable by suturing, a certain suppleness and softness had to be assumed.

For the same reason the other artificial approach considering the inserts 72 alone to represent the support beams could not jeopardize the novelty of claim 1.

Auxiliary request 8 - Novelty

According to established case law of the EPO as well as German patent law, before comparing the subject-matter claimed with the prior art, the claim had to be properly construed. For this purpose, reference had to be made to the description and the drawings. In the present case it became unambiguously clear from the disclosure in paragraph [0147] of the patent that the technical features additionally claimed in claim 1 of auxiliary request 8 had to result in the creation of a

clearance distance between the pericardial leaflets 563 and frame 560, this being of major importance in the protection of the pericardium from abrading against the frame. The valve prosthesis of D11a did not exhibit this clearance distance between the outlet of the valve assembly and the support frame and already for this reason did not deprive the claim of novelty.

Even if one followed appellant 2's argument that the commissure posts 46/48 defined the support frame at the outlet, it was entirely unclear how a "diameter" of these three isolated entities was to be determined. Indeed these three structures did not define a diameter at all. For the interpretation of such a term, again, reference had to be made to the description, which as discussed above, clearly required the creation of a permanent clearance.

Even if one followed appellant 2's reasoning that a circle defined by the three commissure posts were to be considered defining the support frame's diameter at the outlet, the pliant material forming the outlet still extended through the axial slots 54. It was thus wider in diameter than the support frame, contrary to what was claimed. In this context, the last part of claim 1 which defined the pliant material as "the pliant material...forming the outlet..." could not be construed to restrict the relevant parts of the pliant material to the parts thereof forming the outflow. The outlet, and consequently the diameter at the outlet was determined by the whole of the pliant material, which was clearly exterior to the support frame at the outlet.

Furthermore, D11a did not indicate that the material of the tubular leaflet section was tensioned or inelastic.

It might thus well be that in use it extended even further outwards. Indeed, the multiple hatchings shown in Figure 2 of D11a were indicative of slack in the material and thus supportive of that interpretation.

Consequently, D11a did not clearly and unambiguously disclose the features of claim 1 of auxiliary request 8, which was thus novel.

Remittal to the Opposition Division

As to appellant 2's request for a remittal to the Opposition Division, appellant 1 agreed that in the present case a remittal was appropriate and likewise requested the Board to remit the case.

Reasons for the Decision

1. Main request - Novelty

1.1 Relevance of Document D11a for novelty

D11a was published on 18 October 2001, after the priority date of the patent (11 October 2001) but before its filing date (11 October 2002).

The filing date of D11a (5 April 2001) is before the priority date of the patent (11 October 2001).

Thus, if the priority of the patent is invalid, D11a will be prior art in accordance with Article 54(2) EPC; if on the other hand, the priority of the patent is valid, D11a will be prior art under Article 54(3) EPC 1973, provided that the requirements of Article 54(4) EPC and Rule 23a EPC 1973 are fulfilled.

The WO-application D11a has entered the European regional phase on 19 September 2002 (as EP1 267 753) with the designation fees being paid for AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LI, LU, MC, NL, PT, SE, TR. D11a is thus prior art for the co-designated contracting states.

The patent itself likewise emerged from an international application, which has entered the European regional phase designating: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LI, LU, MC, NL, PT, SE, SK, TR.

As to the states which are not co-designated (BG, CZ, EE, SK), the European Patent Register indicates that the respective designations have lapsed in 2011.

In case the priority of the patent is valid, D11a will thus form prior art under Article 54(3) EPC 1973 for all remaining (i.e. not yet lapsed) contracting states.

To conclude, independently of the validity of the patent's priority, maintenance of the patent as granted will only be possible if the subject-matter claimed is novel over the disclosure of D11a. This was common ground between the parties.

1.2 It is helpful to distinguish between the following three interpretations of Figures 1-3 of D11a:

a) the posts **46/48**, i.e. **42**, are considered to be the "longitudinally rigid support beams of fixed length";

b) the "inserts" **72** are considered to be the "longitudinally rigid support beams of fixed length"

c) posts **42** and "inserts" **72** together are considered to be the "longitudinally rigid support beams of fixed length".

- 1.2.1 Interpretation (a): the posts **46/48**, i.e. **42**, are considered to be the "longitudinally rigid support beams of fixed length"

Following this interpretation, D11a discloses:

A valve prosthesis device (Figure 2, page 1, "Field of the invention"; page 7, line 19-23) suitable for implantation in body ducts, the device comprising:

2. an expandable support frame (Figure 1, **24**)

2.1 comprising a deployable construction

2.1.1 adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and

2.1.2 adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location (page 9, line 14-20),

2.2 the support frame being provided with a plurality of longitudinally rigid support beams (**46/48**) of fixed length; and

3. a valve assembly (**22**, "flexible tubular member", the "valve assembly" including the inserts **72**)

3.1 comprising a flexible conduit having an inlet (Figure 1, lower end of **34**) and an outlet (upper end of **32**),

3.2 made of pliant material ("flexible tubular member") attached to the support beams (insert **72**, which is part of the valve assembly, is connected to post **46/48** via stitchings **76** through bores **80** and **78**) providing collapsible slack portions of the conduit at the outlet (**32**: "leaflet section),

4. whereby when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow (page 11, line 7-11), wherein

5. the support beams are provided with bores (a bore **80** on each post / beam, thus "the support beams are provided with bores") and

6. the valve assembly is stitched to the support beams with thread or fiber through the bores (stitches **76**).

Thus, D11a discloses all features of claim 1 as granted.

This first interpretation follows to some extent appellant 1's claim interpretation in that it assigns the term "support beams" to commissure posts 46/48. It is noted that according to the patent (paragraph [0093]) the "rigid support beams [may be] incorporated with the support stent", such that either the whole frame 24 (including the commissure posts 42) or only its tubular base 40 may be considered the "expandable support frame" as claimed.

Appellant 1 argues that firstly inserts 72 could not be considered part of the valve assembly, there being thus no direct attachment between the valve assembly and the support beams. Secondly, stitching 76 was not a clear and unambiguous disclosure of a stitching with "thread or fiber", as "thread or fiber" implied a textile stitching material.

However, in the very embodiment underlying the subject-matter of auxiliary request 8 (based on which the

patent was maintained by the Opposition Division), the valve is provided with further "attachment means in the shape of long bars" (see Figure 43b and paragraph [0147]). These attachment means are attached to the pericardium, i.e. to the material forming the flexible conduit and thus have to be considered part of the valve assembly. It thus has to be concluded that the term "valve assembly" in the sense of the patent allows the presence of longitudinal attachment means provided on the material making up the leaflets. Therefore, it is justified to consider inserts 72 part of the valve assembly. Inserts 72, and thereby the valve assembly of which they are part, are stitched to the support beams 46/48 with threads 76 through bores 80. There is no requirement in claim 1 of the material making up the leaflets being directly connected to the support beams.

There is furthermore no reason why the term "thread or fiber" in claim 1 should be construed as including only stitches from a textile material. As correctly pointed out by appellant 2, the patent uses the term "thread" in the context of "gold threads" (paragraph [0113], first sentence) and the term "fiber" in the context of "PU, PET or other" fibers (column 10, line 28-31). Given the broad understanding of the term "thread or fiber" in the patent, it can only be concluded that stitches 76 (as well as 74) qualify as "thread or fiber" in the sense of claim 1 as granted.

Therefore, the subject-matter of claim 1 is not new over prior art D11a in the first interpretation.

- 1.2.2 Interpretation (b): the "inserts" **72** are considered to be the "longitudinally rigid support beams of fixed length".

According to the embodiment shown in Figures 8a, b of the patent (paragraph [0105]), such longitudinally rigid support beams may be created from PU by way of mould injection, machining or any other suitable way and subsequently placed on the valve material. This is analogous to inserts 72 of D11a, which are likewise subsequently connected to the valve by stitchings 74. For the reasons discussed in point 1.2.1 above, stitchings 74 result in the valve assembly 22 (in this interpretation not comprising the inserts) being stitched to the support beams with thread or fiber. Furthermore, inserts 72 "prevent the loops from pulling inward again through the axial slot" (page 10, lines 29, 30), a task which inevitably implies a certain rigidity of the material. This rigidity will also make the support beams longitudinally rigid and of fixed length, at least to a degree comparable to the one of the similarly dimensioned PU support beams disclosed in the patent. This is further in accordance with the properties of the material Delrin, which D11a discloses in the context of functionally comparable inserts 166 (page 15, line 23-26; Figure 11, No. 166).

Appellant 1 argues that inserts 72 were not provided with bores and that thus the valve assembly was not stitched to the support beams "...through the bores", as required by the claim.

However, claim 1 is a product claim, not a claim directed to the manufacture of a product or a product by process claim. Features 5 and 6 defining that the support beams "are provided with" and the valve assembly "is stitched to" the support beams are thus not to be interpreted as actions which need to have been performed in a specified order, but as definitions of a property of the finished valve prosthesis device.

Consequently, with respect to the feature "the support beams are provided with bores", it has to be verified in the finished valve assembly whether the support beams have bores or not. D11a, Figure 3 clearly shows stitchings 74 which pass through inserts 72, i.e. the support beams are provided with piercing holes. Similarly, for the claim feature "the valve assembly ... is stitched to the support beams ... with thread or fiber ... through the bores ...", Figure 3 shows the (loops of) valve assembly 70 stitched to the support beams 72 with thread or fiber (see above) through these piercing holes. The characterizing portion would thus be disclosed by D11a if the piercings can be considered "bores".

Appellant 1 has put forward several criteria allegedly being decisive for a hole being a "bore". Firstly, a "bore" had to be formed by a machining process such as, for example, by drilling or laser cutting. In particular, the term implied that material had been removed. This definition is, however, not in accordance with the use of the term in the patent itself: according to paragraph [0105] the rigid support beam 94 (which has "bores", see Figure 8a, 94) is created among others by mold injection, i.e. it is neither created by a machining process, nor is material removed from a blank. Secondly, appellant 1 argued that the lack of the bore canal material was decisive for the definition of a bore: in a "bore" the material of the bore was not present on the element (either because it was removed or because it had never been there), whereas in the case of a suture stitch, it remained either on one site of the element at the exit of the stitching or caused an increase in density of the areas surrounding the stitch canal. The Board does, however, see no basis for this fine distinction. Even if in stitching, some

material remained at the canal exit, still the needle has "bored through" the material. By this boring action, a canal is formed through which the thread is running. There is no reason for not calling this canal a "bore". In this context it is pointed out that the terms "boring through" or "boring in" are also used in the context of boring with a piercing instrument like an awl. This is in accordance with the definition given in BB39, which defines "boring" as being synonymous to making by "piercing or drilling", a bore being a "hole made by boring", which consequently includes a "hole made by piercing". No requirement of the periphery of a bore being necessarily smooth can be derived from these definitions. The Board thus comes to the conclusion that the pierced holes of stitches 74 qualify as "bores" in the sense of claim 1.

D11a thus discloses all features of claim 1 also in the second interpretation.

- 1.2.3 Interpretation (c): posts **42** and "inserts" **72** together are considered to be the "longitudinally rigid support beams of fixed length".

This interpretation is justified because it is in fact the combination of commissure posts 46/48 and inserts 72 which functionally cooperate to support the valve assembly.

For the reasons discussed above the so defined support beams are longitudinally rigid and of fixed length, they are provided with bores (at 74) and the valve assembly is stitched to the support beams with thread or fiber through the bores created by stitches 74.

Thus, also in the third interpretation D11a discloses all features of claim 1.

1.2.4 The subject-matter of claim 1 of the main request is consequently not new over prior art D11a.

2. Auxiliary request 8 - Novelty

2.1 Claim 1 of auxiliary request 8 further defines

1) that the outlet (26) is tapered with respect to the inlet (24) [see point 2.2.1 below] and
2) that the support frame (22) at the outlet is wider in diameter than the pliant material (29) forming the outlet (26) [see point 2.2.2 below].

2.2 It is common ground between the parties that the subject-matter of claim 1 of auxiliary request 8 was not disclosed in the priority document. For this request, D11a thus forms prior art under Article 54(2) EPC.

2.2.1 As to the first feature, D11a, Figure 1 shows the conduit of the valve assembly 22 to be initially in a cylindrical form. In forming loops 70, folds of the leaflet section are pulled through axial slots 54. Similar to dress-making, this creates "darts" or "tucks" in the originally cylindrical form, which inevitably result in the outlet being tapered with respect to the inlet.

2.2.2 With respect to the second feature, the support frame is considered to comprise tubular base 40 and commissure posts 46/48. This is in accordance with the use of the term "support frame" in the patent, which may or may not "incorporate" the longitudinally rigid

support beams (see paragraph [0093] vs. the embodiment shown in Figure 8a, b). The so defined support frame is an essentially tubular structure, which - for insertion - has to fit into a tubular catheter, and which - at the implantation site - is deployed into the annular native valve annulus. In this context, the person skilled in the art would naturally interpret the term "support frame diameter at the outlet" as for any tubular, circular or cylindrical structure, i.e. in the sense of the diameter of the circle defined by the commissure posts distal ends.

According to the claim this diameter has to be compared with the diameter of the "pliant material forming the outlet". The claim language defines the terms "inlet" and "outlet" in the context of the flexible conduit formed, through which the flow is allowed to pass (see features 3.1 and 4). Interpreting the claim in its context, it has thus to be concluded that the "pliant material forming the outlet" is the pliant material defining where the flow is allowed to exit the conduit. This exit of the conduit does not comprise the loops of pliant material 70, but is fully comprised within the outlet end of the support frame 48. Given that the tubular leaflet section is made from pericardium, there will also be no expansion of the conduit outward the boundaries of the circle defined by the commissure posts.

The hatching in Figure 2 mentioned by appellant 1 is rather the result of the inward taper of the conduit at the outflow due to the "darts" or "tucks", than indicative of any slack material. The support frame at the outlet is thus wider in diameter than the pliant material forming the outlet.

Consequently, claim 1 of auxiliary request 8 is not new.

Appellant 1 was of the opinion that before any comparison is made with the prior art disclosure, it was mandatory to establish the correct claim interpretation. For this it was again mandatory to first consult the description and the drawings. With respect to the features additionally claimed in auxiliary request 8 it became clear from paragraph [0147] of the description that they resulted in a permanent clearance distance between the pericardial leaflets and the frame, thereby protecting the pericardium from abrading against the frame. This was not the case in D11a, which thus was not novelty destroying.

However, the permanent clearance between pericardial leaflets and frame is not defined in the claim. It was the patent proprietor who drafted the claim without that feature - although the description esteems it to be "of major importance". In this context, the Board follows the well-established principle in the case law that the description may not be used to read additional features and limitations into the claim (Case Law of the Boards of Appeal, 8th edition 2016, II.A.6.3.4). Furthermore, the claim being consistent in its definition as discussed above, there is no need to seek additional guidance in the description in order to interpret the claim feature. To put it differently, if the creation of a permanent clearance was an essential part of the claimed subject-matter, in particular for distinguishing it from the prior art, the feature should have been explicitly defined in the claim.

3. Remittal to the Opposition Division

After the Board had announced that auxiliary request 8 was not new, both parties requested remittal of the case to the Opposition Division for further prosecution. In this context appellant 2 explained that the need for acceleration had been linked only to the Opposition Division's finding that auxiliary request 8 fulfilled the requirements of the Convention, and that after the Board's conclusions in this respect normal treatment by the Opposition Division was perfectly in order.

In view of the fact that both parties requested remittal, the Board, giving due consideration to the principle of party disposition, decided to remit the case to the Opposition Division for further prosecution.

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 for further prosecution.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated