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**Datasheet for the decision  
of 11 July 2019**

**Case Number:** T 0845/15 - 3.2.08  
**Application Number:** 04757521.2  
**Publication Number:** 1603493  
**IPC:** A61B17/221, A61F2/95, A61F2/24  
**Language of the proceedings:** EN

**Title of invention:**

MINIMALLY-INVASIVE HEART VALVE WITH CUSP POSITIONERS

**Patent Proprietor:**

Edwards Lifesciences Corporation

**Opponents:**

Isarpatent  
LUDWIG, Gabriele  
Boston Scientific Corporation  
Stolmár, Matthias

**Headword:**

**Relevant legal provisions:**

EPC Art. 100(c), 100(a), 54(3), 54(2), 56  
EPC R. 76(2)(c)

**Keyword:**

Admissibility of opposition

Novelty - (yes)

Inventive step - (yes)

Grounds for opposition - extension of subject-matter (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 0845/15 - 3.2.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.08**  
**of 11 July 2019**

**Appellant 1:** Edwards Lifesciences Corporation  
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**Decision under appeal:**

**Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
23 February 2015 concerning maintenance of the  
European Patent No. 1603493 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 23 February 2015 the Opposition Division decided that European patent No. EP-B-1 603 493 as per the second auxiliary request then on file, and the invention to which it related, met the requirements of the EPC.

II. The patent proprietor (appellant 1) lodged an appeal against that decision.

Likewise, opponent 1 (appellant 2) and opponent 5 (appellant 3) lodged an appeal against said decision.

All appeals were duly filed and reasoned.

III. Oral proceedings before the Board were held on 11 July 2019.

As announced by letter dated 12 June 2019 appellant 3 did not attend. In accordance with Rule 115(2) EPC and Article 15(3) RPBA the oral proceedings were held without that party. Appellant 3 is treated as relying only on its written case.

IV. 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 the patent be maintained as granted, or alternatively on the basis of one of auxiliary requests 1 to 7 filed with letter dated 24 November 2015. Appellant 1 further requested that the opposition of opponent 3 (respondent 2) be rejected as inadmissible.

Appellants 2 and 3 (opponents 1 and 5) requested that the decision under appeal be set aside and the patent be revoked.

Respondents 1 and 2 (opponents 2 and 3) requested that the appeal of appellant 1 (patent proprietor) be dismissed.

V. Claim 1 of the patent as granted reads as follows:

"A collapsible prosthetic heart valve (22), comprising: a collapsible leaflet frame having three cusp regions (30) intermediate three commissure regions (32), the three cusp regions being positioned at an inflow, end of the leaflet frame and circumferentially about a flow axis defined within the leaflet frame, the three commissure regions being positioned at an outflow end of the leaflet frame and circumferentially about the flow axis;

three separate, flexible leaflets (52) attached to the leaflet frame, each leaflet having an arcuate cusp edge opposite a free edge and a pair of commissure edges therebetween, the leaflets being attached around the leaflet frame with the cusp edge of each leaflet extending along one of the cusp regions, and a commissure edge of each leaflet meeting a commissure edge of an adjacent leaflet at one of the commissure regions; and

three cusp positioners (42) rigidly fixed with respect to the leaflet frame and disposed circumferentially about the flow axis, each cusp positioner being located at the outflow end of the leaflet frame and intermediate two of the commissure regions of the leaflet frame."

VI. The auxiliary requests have no bearing on the present decision.

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

D2 US 5,716,417

D5 US 6,425,916

D6 US 5,855,601

D10 EP 1 281 375

D12 WO 03/047468

D14 WO 02/24118

D16 US 6,168,614

D18 WO 01/49213

D19 WO 01/76510

D20 US 5,957,949

VIII. The essential arguments of appellants 2 and 3 and of respondents 1 and 2 (in following referred to as "the opponents") can be summarised as follows:

*Admissibility of the opposition of opponent 3  
(respondent 2)*

In line with Rule 76 (2) (c) EPC opponent 3 had sufficiently substantiated the opposition grounds based on lack of novelty in view of three prior art documents as well as based on lack of inventive step. With regard to the latter, opponent 3 had followed the problem solution approach. The opposition of opponent 3 was thus clearly admissible.

*Article 100(c) EPC*

Claim 1 as granted was based on claim 14 of the PCT application as originally filed. However, claim 14 had

defined the 3 cusp regions to be positioned circumferentially about the flow axis defined "within the support frame", whereas claim 1 as granted referred in this respect to a flow axis defined "within the leaflet frame". Even though - according to paragraph [0070] of the PCT application - the support frame included a leaflet frame, the leaflet frame was a possibly separate part of the support frame, having a flow axis not necessarily identical to the flow axis of the former. The term flow axis had thus undergone a shift in meaning, resulting in subject-matter being claimed which had not been originally disclosed.

*Novelty*

D5 disclosed all the features of granted claim 1, including in particular three separate flexible leaflets attached to the leaflet frame. In this context, it was not clear what the term "separate" was intended to mean. Indeed, in every replacement heart valve the leaflets had to be connected to each other at least at the commissure edges in order to form a functioning valve unit. Thus, even leaflets which had been separate items during manufacture needed to be connected to each other in the claimed finished product, such that the term "separate leaflet" meant nothing more than that the individual leaflets were operating independently in the bloodstream. This was, however, the case in any replacement heart valve and in particular in the stentless porcine valve disclosed in D5, column 5, lines 42-46. Moreover, the term 'preferably' in line 45 disclosed to the skilled person that also other well-known valves were to be used with the frame of D5, such as the ones made from individual separate pericardial leaflets, which were well established in the prior art. D5 thus disclosed - in



addition to all the other claimed features - a heart valve comprising three separate flexible leaflets.

Likewise, the disclosure of document D12 was novelty destroying for granted claim 1. Firstly, the embodiment shown in Figures 43 and 44 disclosed three separate flexible leaflets attached to the leaflet frame. These leaflets had an arcuate cusp edge, at least because the cusp edge - the edge at the bottom of the valve as represented in Figure 43a - followed the curved inner surface of the cylindrical leaflet frame. The arcuate shape of the cusp edge was further represented in Figure 43b as line 565 and in Figure 44a by the arcuate line drawn on the pericardial leaflet 570. Moreover, also the embodiment of Figure 23 comprised three individually operating, i.e. separate leaflets, which - as shown in Figure 23e, 382 - had an arcuate cusp edge. With the cited embodiments comprising also all other claimed features, claim 1 was not novel over D12.

Also document D18 disclosed, in addition to all other claimed features, a valve having three separate flexible leaflets. The valve body was formed by everting the inner graft member and forming a pocket or envelope at the eversion point, further imparting a more cusp like structure by coupling sections of the valve flaps along a longitudinal seam to the inner graft member. As could be seen in Figures 2 and 4 this created three individually operating, i.e. separate flexible leaflets.

As submitted in writing, also the valves disclosed in D16 and D10 were novelty destroying. D16 comprised a porcine valve, see column 5, lines 18 et. seq., which - as discussed for D5 above - comprised 3 separate flexible leaflets. Likewise, D10 disclosed all claimed

features. In particular, the palpating finger elements 31 qualified as cusp positioners disposed circumferentially about the flow axis.

*Inventive step*

Document D5 disclosed a collapsible prosthetic heart valve and was thus a suitable closest prior art. In the opinion of the Board, the subject-matter of claim 1 differed from the disclosure of D5 at least in that the valve comprised three separate flexible leaflets. Such valves were, however, well known in the prior art and mentioned even in the patent specification, paragraphs 3 and 4, as an alternative to a porcine valve.

According to the patent specification column 3, lines 18 to 21, a particular advantage of the present invention and its valve design was an increase in long-term efficacy of the valve, ensuring its integrity and durability once implanted. When looking for increasing long-term efficacy of the valve, while ensuring its integrity and durability once implanted, the person skilled in the art would consult document D19, which, see page 2, lines 18-20 related to this very problem. The skilled person would thus strive to use the D19 valve attachments, which uncontestedly relied on three separate flexible leaflets being attached to the leaflet frame. This would lead in an obvious way to three separate flexible leaflets either directly sutured onto the leaflet frame of D5 or to the leaflet frame of D5 being slightly modified towards a leaflet carrying structure as known from D19. The necessary techniques for such a modification, i.e. for connecting separate valve leaflets to a stent like structure, were well established in the prior art. Due to the elasticity of the wire frame such connections were not

prone to failure but indeed very resistant to tear. In both cases such an obvious modification resulted in a valve prosthesis falling under the scope of claim 1.

A separate leaflet design was equally known from D14, Figure 2, such that the subject-matter claimed was also obvious with respect to the teaching of D5 being combined with the teaching of D14.

Furthermore, the subject-matter was not inventive starting from D19 as closest prior art. D19 disclosed a collapsible prosthetic heart valve having all features claimed, apart from the three cusp positioners, which had the function, see paragraph [0046] of the patent, to stabilize the valve at the implantation site. The problem to be solved was thus to improve anchoring at the implantation site. A solution for this problem was disclosed in document D6, Figure 7 which suggested the provision of barb elements on the wire frame. Adding such elements on the posts, Figure 7, No. 148 of the wireframe of D19 would result in cusp positioners as claimed. In this context, the person skilled in the art would provide the barbs at such a length that they were located at the outflow end in order to improve anchoring.

Thus claim 1 did not involve an inventive step.

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

*Admissibility of the opposition of opponent 3  
(respondent 2)*

The opposition of respondent 2 had to be rejected as inadmissible because it did not sufficiently indicate

the facts and evidence presented in support of the grounds of opposition, contrary to what was required by Rule 76 EPC. Respondent 3 had only provided the literal claim wording with a few notes as to the location of disclosure of a feature, which were however far from complete or had made only coarse reference to some drawings, without any explanation which would allow to infer the structural feature the drawing allegedly disclosed. With regard to inventive step, opponent 3 had refrained from exercising the problem solution approach. The writ of respondent 2 was thus incomplete and did not fulfil the requirements for a sufficient substantiation according to Rule 76 EPC.

*Article 100(c) EPC*

It was the leaflets and their position which defined the flow axis. The leaflets were held in the leaflet frame, such that the flow axis defined within the support frame (which included the leaflet frame) was identical to the flow axis defined within the leaflet frame.

The subject-matter of claim 1 did thus not extend over the application as originally filed.

*Novelty*

Apart from several further differentiating features, D5 did not disclose that the collapsible prosthetic heart valve comprised three separate flexible leaflets attached to the leaflet frame. Said feature required three separate flexible leaflets individually connected to the leaflet frame. This was different from the stentless tissue valves or tri-leaflet stentless porcine valves disclosed as preferable in D5, column 5,

lines 42-46. These valves comprised a part of the donor aorta or other tube like structure holding the leaflets, which consequently were not separate. That these valves were disclosed as "preferably" did in no way imply a clear and unambiguous disclosure of using with the D5 prosthesis any other valve design, such as the one comprising three separate flexible leaflets.

Thus, already for that reason the subject-matter of claim 1 was novel over the disclosure of D5.

D12, Figure 23 did likewise not disclose a valve having three separate flexible leaflets. On the contrary, all three leaflets 378 were part of a single composite fabric 375 formed into a tubular shape, see Figure 23d, in order to form a tubular valve, which was subsequently attached to the support frame, see Figure 23e. This further resulted in cusp regions which were not positioned at the inflow end but somewhere in the middle portion of the valve. The subject-matter of claim 1 was thus novel over the embodiment shown in Figures 23.

With respect to the embodiment depicted in D12, Figures 43 and 44, it was true that it comprised three separate flexible leaflets. However, these leaflets were rectangular, see Figure 43b, and did not have an arcuate edge. In this context, the term arcuate edge had to be interpreted as a feature characterizing the leaflet no matter whether it was built into the prosthesis or not. Indeed, in a valve held in a cylindrical frame basically every free and cusp edge was to a certain extent bent. Considering such a bend an "arcuate cusp edge" in the sense of the claim would deprive the feature of any meaning. Hence, it was not the one the skilled person would apply. With respect to

line No. 565 represented in Figure 43b, it could be derived from Figure 43a that it indicated the resulting free edge of the leaflet on the outflow end of the valve once the elements 565 were in parallel and connected to the posts. Figure 44a did show the leaflets connected to the zigzag lines of the stent in a clearly not arcuate way, whereas the arcuate line depicted above the zig-zag line belonged to additional re-enforcing PET pieces, see Figure 44b, 571. The respective lines mentioned by the opponents had thus nothing to do with the cusp edge. To conclude, the embodiment of Figures 43 and 44 did not have leaflets having an arcuate cusp edge opposite a free edge. The subject-matter of claim 1 was therefore also novel over this embodiment.

D18 disclosed on pages 15 and 16 that the valve flaps were created by either everting the inner graft member toward the central longitudinal axis of the stent body or by passing through the outer graft member through to the luminal surface of the stent body. The valve flaps were thus all still connected to either the inner or outer graft member and did not qualify as separate flexible leaflets.

As discussed before with respect to D5, the leaflets of a porcine valve as used in D16 were connected to each other by the tubular aortic part of the graft. They could thus not be seen as separate in the sense of the claim.

As to D10, even if elements 31 were considered to be cusp positioners, they were not located at the outflow end of the leaflet frame.

The subject-matter of claim 1 as granted was thus novel over the valves disclosed in D18, D10 and D16.

*Inventive step*

D5 was neither a suitable starting point, nor would the person skilled in the art combine its teaching with the teaching of D19 or D14. However, even if one accepted that the skilled person would try to provide the D5 valve with a separate leaflet valve design according to D19, it was far from obvious how this should be done. The arcuate cusp edge only coincided with the wireframe of D5 at distinct separate points. It was therefore unclear how a sealing connection to the frame could be effectuated. Furthermore, the distinct separate connection points resulted in points of high stress in the material. Indeed D19 as well as D14 disclosed arcuate supporting frame members to which the arcuate end of the valve was connected and which had an important role in distributing stresses. The person skilled in the art would thus not apply the valve leaflets directly onto the wireframe of D5. Instead they would try to incorporate the D19 or D14 supporting structures into the D5 wireframe. However, the D14 structure was not suitable to be collapsed. As to the D19 structure, this amounted to nothing less than a complete redesign of the leaflet frame, a task by far exceeding what could be expected from the skilled person as a routine modification.

With respect to it being obvious to provide anchoring barbs as disclosed in D6, Figure 7 onto the frame of D19, Figure 7, these would either not be "intermediate two of the commissure regions of the leaflet frame" or not be at the outflow end. A prolonged version of the barbs, such as envisaged by the opponents in order to

improve anchorage, would indeed make the valve unsuitable for its purpose. Barbs of such a length would impede valve implantation, endanger the sensitive pericardial leaflets and not even improve anchorage.

Therefore, neither starting from D5 nor from D19 was the subject-matter of claim 1 obvious.

### **Reasons for the Decision**

1. Admissibility of the opposition of opponent 3 (now respondent 2)

The notice of opposition covers two grounds of opposition: lack of novelty and lack of inventive step.

Lack of novelty is argued based on three prior art documents ("D2", which corresponds to D16 of the present nomenclature; "D3", a family member of present D5; and "D4", which is called D18 in appeal).

For all three documents, reference is made to one or two figures of the respective disclosure (replicated in the notice), with an indication which claim feature is considered to be disclosed by which reference sign or in which part of the drawing.

Furthermore, an inventive step objection is raised, based on a combination of "D5" (= D19 in the present appeal) and "D6" (called D20 in appeal). From the context it is indeed clear that the closest prior art is "D5" (D19 in the present nomenclature). This is confirmed by the replication of Figure 7 of said document on page 8. A difference is identified and an objective problem formulated (page 9, point 2).



"D6" (now D20) is introduced as a solution to the identified problem. The document does, however, not comprise a Figure 7 as the one replicated on page 9 of the notice of opposition (and page 11 of the reply dated 24 July 2015).

Still, it resorts from point B.I of the notice (see in particular page 4, first paragraph) that a key argument of opponent 3 is based on "a cusp positioner [being possibly] ... almost everything which is arranged at the outflow end of the leaflet frame and intermediate two of the commissure regions of the leaflet frame".

Thus, in the notice of opposition two grounds of opposition have been identified. With respect to these, several documents ("evidence") have been cited, further providing the facts ("D2", "D3" and "D4" are novelty destroying; the subject-matter is not inventive over a combination of "D5" and "D6") and including arguments in support of the alleged facts ("feature x is shown in reference y of drawing z").

This information allows the opposition division and the proprietor to form an opinion whether the raised grounds of opposition are persuasive or not.

The Opposition Division was thus correct to consider the opposition of opponent 3 admissible.

2. Article 100(c) EPC

Claim 1 as granted is based on claim 14 of the PCT application as filed, which does, however, not refer to an axis "of the support frame", but to a "flow axis defined within the support frame". The point of reference is thus the axis of the blood flow, not the

axis of the frame. With the axis of the blood flow being defined by the valve leaflets, the flow axis defined within the leaflet frame is identical to the flow axis defined within the support frame of which the leaflet frame is a part. As to appellant 1's argument that the leaflet frame was possibly separate from the support frame, each having a different flow axis, there is no disclosure of such an embodiment in the application as filed. Indeed, in all embodiments, the leaflet frame is an integral part of the support frame, both being oriented concentrically around a single axis identical to the flow axis.

There is thus no extension of subject-matter.

### 3. Novelty

#### 3.1 D5

Document D5 discloses a collapsible leaflet frame (Figure 10) having posts 32 which support a valve portion 38, which performs the functions of the patient's malfunctioning native valve (D5, column 5, lines 42-48). Preferably, the valve portion 38 is a stentless tissue valve such as a tri-leaflet stentless porcine valve. Such stentless valves typically comprise a tube or annulus-like structure holding the leaflets. It is the tube or annulus like structure which is attached to the leaflet frame. In this context D5 refers to a valve portion 38 having a base 41 which is secured to the support structure 26 with sutures. Because the leaflets in such a stentless tissue valve are part of or held in the tube or annulus-like structure, they do not qualify as separate, flexible leaflets attached to the leaflet frame. For the skilled person there is a clear difference recognizable on the

finished prosthetic heart valve between valves comprising separate, flexible leaflets attached to the leaflet frame (such as e.g. in the patent; D12, Figure 43 or D14) and valves in which a complete three-leaflet valve (such as a porcine valve) is attached to the leaflet frame (such as in D5). The Board thus cannot follow the opponents' argument that the term "separate leaflet" indicated nothing more than individual leaflets operating independently in the blood stream.

The opposition division argued (point 2.2.3 of the impugned decision) that three separate, flexible leaflets attached to the leaflet frame were disclosed in Figure 11 and column 5, lines 44-48. However, although Figure 11 shows three leaflets, it cannot be derived therefrom that these are "separate leaflets attached to the leaflet frame". Indeed, as discussed above, the passage in column 5, lines 44-48 refers to a stentless tissue valve such as a tri-leaflet stentless porcine valve having a base (which holds the leaflets) with the base being secured to the support structure.

Therefore, the subject-matter of claim 1 is novel over the disclosure of document D5.

### 3.2 D12

#### 3.2.1 The embodiment of Figure 23

Figures 23a-e illustrate the manufacture of the prosthetic valve of that embodiment. A composite fabric is created, which is then cut along a stitching line (Figure 23c, 373) leaving enough material to later suture the valve assembly to the support construction. It is then formed to a tubular shape and stitched 374. As can be appreciated in Figure 23d, this results in a

tube or annulus-like structure (at the bottom part of Figure 23d) holding the leaflets which is then sutured to the frame (Figure 23e, 379). The embodiment of Figures 23a-e thus does not have three separate flexible leaflets attached to the leaflet frame.

### 3.2.2 The embodiments of Figures 43, 44

This embodiment has separate flexible leaflets attached to the leaflet frame (Figure 43a). However, the leaflets are rectangular and not arcuate (see Figure 43b). The opponents have argued that line 565 represented the arcuate cusp edge. However, Figure 43a, which comprises the same reference sign, clarifies that reference 565 refers to the bulged-in free upper edge (which is the lower edge in Figure 43b). This bulged-in free edge is formed when the angled attachment means 561 are sutured in parallel to the posts (see page 44, second paragraph). Conversely, the dashed straight upper line in Figure 43b indicates that the cusp edge is sutured to the cylindrical stent in the transversal plane. While it is true that this straight suture line follows the perimeter of the circular stent lumen, the person skilled in the art would not understand such a leaflet as having an arcuate cusp edge.

Further reference has been made to Figure 44a which allegedly also showed an arcuate cusp edge. That embodiment comprises additional pieces of PET used for sealing and protecting the pericardium (see the paragraph bridging pages 44 and 45). As can be derived from Figure 44b, the leaflet and the PET piece are together attached to the stent by bottom attachment suture 577. This suture follows the bottom zigzag ring of the stent, the attachment being analogous to the Figure 43 embodiment. Conversely, the upper suture

connects only the PET pieces to the frame. Consequently, the arcuate line shown in Figure 44a corresponds to the upper edge of the PET piece and not to an arcuate cusp edge of the separate flexible valve leaflet.

Therefore, the embodiments of Figures 43, 44 do not disclose leaflets having an arcuate cusp edge opposite a free edge.

3.3 To conclude, the subject-matter of claim 1 is novel over the disclosure of document D12.

3.4 D18

D18 discloses (page 15, lines 12-20) a valve prosthesis with a valve body formed by everting an inner graft member toward the central longitudinal axis of the stent body, such that a pocket or envelope is formed at the eversion point. Alternatively, portions of the outer graft member may be passed through to the luminal surface of the stent body thereby becoming the inner graft member and everted to form the valve body. Sections of the valve flaps are preferably coupled along a longitudinal seam to the inner graft member and the outer graft member at points equidistant from the valve arms in order to impart a more cusp-like structure to the valve flaps (page 16, lines 13-15).

The so formed valve leaflets are thus an integral part of a tubular structure (the inner and outer grafts) and - for the reasons already discussed with respect to D5 above (see point 3.1) - do not qualify as three separate flexible leaflets attached to the frame.

3.5 D16

The valve element 6 used in D16 is a biological porcine valve, removed from a slaughtered pig of 100kg (D16, column 5, lines 18, 19), i.e. a classical porcine valve, such as the one referred to in D5. For the reasons explained in point 3.1 above, its leaflets are part of and held in a tubular part of the donor aorta. They thus do likewise not qualify as separate, flexible leaflets.

3.6 D10

The heart valve disclosed in D10 essentially comprises three parts: palpating finger elements (Figure 3, No. 31: "éléments palpeurs"), a cylindrical stent graft (treillis cylindrique: No. 20) and a valve element (No. 2). Appellant 3 has argued that the palpating finger elements (31) did form "cusp positioners" in the sense of claim 1. Even if this were the case, these elements would not be located at the outflow end of the leaflet frame. As can be appreciated in Figure 3, which shows the valve in the implanted state, elements 31 are located at the end closer to the ventricle (which is to the left in Figure 3). The location of the ventricle and thus the inflow end of the prosthesis can be clearly and unambiguously derived from the location of the natural valve (50) and the location of the coronary ostia (52) in Figure 3. As the natural valve is more proximal to the ventricle than the coronary ostia, the ventricle needs to be on the left and the left end of the prosthesis is the inflow opening. Therefore, even if elements 30, 31 qualified as cusp positioners, they would be on the inflow end and not on the outflow end as claimed.

Thus, claim 1 is novel over the disclosure of document D10.

4. Inventive step

4.1 D5 as closest prior art, in combination with D19 or D14

D5 does at least not show three separate flexible leaflets. For the sake of the argument, the Board follows the opponents in that flexible leaflets may have the effect of an increase in durability and in that document D19 addresses durability and associates it with a separate leaflet design. However, even if one assumed that the person skilled in the art was motivated to change the design of the D5 valve into a separate leaflet one, it is not obvious how to put that aim into practice. The opponents have argued that one could simply suture the individual leaflets to the wireframe (windings 31) of the D5 valve. However, this would result in only a few, separate suture attachment points in the tissue, which would indeed be subject to high local stress endangering the integrity of the separate valve leaflets. The opponents have argued that the flexibility of the frame would dampen the stress and that such single suture connections were well established in the art. There has, however, been no supporting evidence in this respect. With the alleged common general knowledge being put in doubt by appellant 1, it would have been upon the opponents to provide evidence. Furthermore, such a single suture point attachment would also be against the teaching of documents D19 and D14, which both disclose the arcuate edges of the flexible leaflets to be held and supported along their entire length by an arcuate wire / frame element.

It was further argued that the person skilled in the art would then simply integrate said arcuate supporting frame element in the stent structure of D5. However, as to D14, this supporting element is not disclosed as being collapsible. As to the supporting arcuate element disclosed in D19, this is not an isolated element but is supported by the cusp posts (Figure 7, No. 148), which again are held in tubular member 140. It is by no means obvious how to integrate these elements of D19 into or merge them with the wireframe of D5. This is a task which amounts to a full reconstruction of the D5 leaflet frame and which by far surpasses modifications routinely performed by the person skilled in the art.

#### 4.2 D19 + D6

The opponents have further argued that the person skilled in the art would be incited to provide the D19 frame with barb like structures such as disclosed in D6, Figure 7, which would be connected to the posts 148 (see D19, Figure 7). These would then, however, not be located at the outflow end of the leaflet frame. In this context the Board cannot follow the argument that the person skilled in the art would not only provide these barbs on posts 148 but furthermore would as a routine modification prolong them up to the outflow end. This is a modification for which the person skilled in the art has no reason at all and which would not even improve anchorage in the adjacent tissue but would rather lead - due to the resulting length of the barb elements - to an unpredictable flex behaviour, impeding valve insertion and endangering leaflet integrity.



Thus even combining the teachings of D19 and D6 does not lead to a subject-matter falling under the definition of claim 1.

4.3 D2, D16, D18 or D14 as closest prior art

These documents had only been discussed in the written proceedings.

Documents D2 and D14 disclose valves which are to be inserted surgically and which do not have a "collapsible leaflet frame". The frame of these valves would need to be fully redesigned. Consequently, these documents do not form a promising springboard for the invention which is in the field of minimally invasively inserted cardiac valves.

Starting from D16 or D18 the situation is analogous to what has been discussed above with respect to D5 as closest prior art. Even if the person skilled in the art were prompted to replace the porcine valve or the valve made up from everted or inverted inner or outer liners held in the D16/D18 frame by a three separate flexible leaflets design, there would be either problems in attaching the leaflets to the frame or the necessity of a complete redesign of the metallic frame. Both are far from obvious.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated