

**Internal distribution code:**

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

**Datasheet for the decision  
of 29 August 2024**

**Case Number:** T 1177/22 - 3.2.01

**Application Number:** 15783951.5

**Publication Number:** 3142607

**IPC:** A61F2/24, A61F2/95

**Language of the proceedings:** EN

**Title of invention:**  
PROSTHETIC HEART VALVE

**Patent Proprietor:**  
Edwards Lifesciences Corporation

**Opponent:**  
Abbott Cardiovascular Systems Inc.

**Headword:**

**Relevant legal provisions:**  
EPC Art. 83, 52(1), 54, 56, 100(a), 100(b)

**Keyword:**  
Sufficiency of disclosure - main request (yes)  
Novelty - main request (yes)  
Inventive step - main request (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0

Case Number: T 1177/22 - 3.2.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.01**  
**of 29 August 2024**

**Appellant:** Abbott Cardiovascular Systems Inc.  
(Opponent) 3200 Lakeside Drive  
Santa Clara, CA 95054 (US)

**Representative:** Gill Jennings & Every LLP  
The Broadgate Tower  
20 Primrose Street  
London EC2A 2ES (GB)

**Respondent:** Edwards Lifesciences Corporation  
(Patent Proprietor) One Edwards Way  
Irvine, CA 92614 (US)

**Representative:** Thum, Bernhard  
Thum & Partner  
Thum Mötsch Weickert  
Patentanwälte PartG mbB  
Siebertstr. 6  
81675 München (DE)

**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 4 March 2022  
rejecting the opposition filed against European  
patent No. 3142607 pursuant to Article 101(2)  
EPC.**

**Composition of the Board:**

**Chairman** G. Pricolo  
**Members:** V. Vinci  
A. Jimenez

## **Summary of Facts and Submissions**

I. The appeal filed by the appellant (opponent) is directed against the decision of the opposition division rejecting the opposition against European patent No. 3 142 607.

In its decision the opposition division held that none of the grounds of opposition raised by the appellant (opponent) pursuant to Article 100(a) in association with Articles 54 and 56 EPC and to Article 100(b) in association with Article 83 EPC were prejudicial to the maintenance of the patent as granted. In particular, the opposition division found that the subject-matter of claim 1 as granted was novel and involved an inventive step within the meaning of Articles 52(1), 54 and 56 EPC in view of the following prior art documents:

D2: JP 2005-185529

D2a: Machine translation of D2

D4: US 6 814 754

D7: AU 2011 253834

D12: US 2012/123529

II. With the communication according to Article 15(1) RPBA dated 18 June 2024, the Board informed the parties of its preliminary assessment of the case according to which the appeal was likely to be dismissed.

With letter dated 2 July 2024 the appellant (opponent) withdrew their request for oral proceedings.

The oral proceedings scheduled on 21 October 2024 were

then cancelled.

III. The parties' final requests are the following:

The appellant (opponent) requests that the decision of the opposition division be set aside and that the patent be revoked.

The respondent (patent proprietor) requests that the appeal of the appellant (opponent) be dismissed or, in the alternative, that the patent be maintained in amended form on the basis of one of the auxiliary requests 1 to 17 filed with the reply to the statement of grounds of appeal of the appellant (opponent).

IV. Independent claim 1 of the patent as granted reads as follows (labelling of the features according to the decision under appeal):

1.1 *An implantable prosthetic valve (10) comprising:*

1.2 *an annular frame (12) comprising an inflow end (15) and an outflow end (19) and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame (12) defining an axial direction extending from the inflow end (15) to the outflow end (19);*

1.3 *a leaflet structure (14) positioned within the frame (12) and secured thereto; and*

1.4 *an annular outer skirt (18) positioned around an outer surface of the frame (12), wherein the outer skirt (18) comprises:*

1.5 *an inflow edge (160) secured to the frame (12) at a first location,*

1.6 an outflow edge (162) secured to the frame (12) at a second location; and

1.7 an intermediate portion between the inflow edge and the outflow edge that comprises slack that buckles radially outwards from the inflow and outflow edges (160,162) of the annular outer skirt (18) when the valve (10) is in the expanded configuration;

characterized in that

1.8a the outer skirt further comprises:

(a) a fabric (170) that is stiffer in the axial direction (172) of the valve (10) compared to a circumferential direction (173) to enhance the radial outward buckling of the slack; and/or

1.8b a self-expandable fabric (230) comprising fibers made of shape memory material having a shape memory set to enhance the radially outward buckling of the slack of the outer skirt (18).

## **Reasons for the Decision**

1. After the communication of the Board pursuant to Article 15(1) RPBA expressing the preliminary assessment of the appeal of the Board the parties did not make any further submissions. Therefore, the Board has no reasons to deviate from the its preliminary conclusions which are herewith confirmed and read as follows:

### **Article 100(b) in association with Article 83 EPC**

2. The ground for opposition pursuant to Article 100(b) in association with Article 83 EPC is not prejudicial to the maintenance of the patent as granted as correctly decided by the opposition division in the decision under appeal.

- 2.1 With the statements of grounds of appeal, the appellant (opponent) maintained following objections raised during the first instance proceedings:

#### Term "slack" in features Fl. 7, Fl. 8a and Fl.8b

- 2.2 The appellant (opponent) essentially alleged that paragraph [0055] of the contested patent referred to by the opposition division and the respondent (patent proprietor) in their argumentation did not contain any definition of the term "slack". This term had thus to be read with its generally accepted meaning, namely as something *"loose or not under tension or not taut"*. However, it was argued that this generally accepted interpretation contradicted the functionality required by feature F1.7 according to which the slack *"buckles radially outwards from the inflow and outflow edges of the annular skirt when the valve is in the expanded*

*configuration*". In the appellant's (opponent's) view, this functionality could only be achieved if the intermediate portion of the outer skirt did not buckle, i.e. if it did not form a slack. It was thus concluded that the person skilled in the art confronted with this contradiction was not be able to carry out the invention as claimed without undue burden.

- 2.2.1 The Board does not agree and follows the view of the opposition division and the respondent (patent proprietor) that paragraph [0055] read in combination with Figures 2, 3, 42 and 43 clearly teaches the person skilled in the art that while the annular frame (12) prevents inwardly buckling of the annular outer skirt (18), the latter must be secured to the frame (12) in such a way that there is an excess of material between its secured inflow and outflow edges as it can be clearly appreciated in Figures 1 to 3, 42 and 43. Therefore, as correctly concluded by the opposition division, the person skilled in the art reading feature F1.7 in the light of the description and with the support of the figures has no difficulties to provide an annular outer skirt with an intermediate portion dimensioned and secured to the frame (12) in such a way to form a slack that buckles radially outwards as required by feature F1.7 of claim 1 as granted.

Alleged overly broad scope of the claim 1

- 2.3 With their statement of grounds of appeal the appellant (opponent) argued that the person skilled in the art was not able without undue burden to carry out all embodiments falling within the scope of claim 1 because the fact that there were features which could be included or omitted in the claim caused serious

difficulties when putting the invention into practice.

- 2.3.1 The Board, in accordance with the findings of the opposition division and the arguments provided by the respondent (patent proprietor) with their reply takes the view that this objection is not justified for the following reasons:

Omission of "*foreshortening*" of the frame

- 2.3.2 The Board cannot see how the fact that claim 1 does not mention foreshortening of the frame would prevent the person skilled in the art to carry out feature F1.7. How the expansion of valve from the radially collapsed configuration shown in FIG. 49 to the radially expanded state shown in FIG. 51 takes place is described in paragraph [077] and the Board has no doubt that a person skilled in the art would be able - based on this information - to design a frame suitable to provide the required functionality in such a way to allow foreshortening of the frame during expansion.

"*Fabric*" according to feature F1.8a

- 2.3.3 The appellant (opponent) argued that feature 1.8a was too broad formulated to enable the skilled person to "*obtain substantially all embodiments falling within the ambit of claim 1*". In this respect it was also pointed out that it was not sufficient to provide a single example of fabric capable to enhance the radial outward buckling of the slack according to feature F1.8a in order to comply with the requirements of Article 83 EPC.

- 2.3.4 However, as convincingly pointed out by the respondent (patent proprietor), claim 1 defines specific

structural features capable to "*enhance the radial outward buckling*", namely, according to the first alternative of the invention, by providing "*a fabric that is stiffer in the axial direction of the valve compared to a circumferential direction*". Furthermore, the patent specification provides in paragraphs [0056] to [0059] detailed information regarding how different (and hence not only one) kind of fabrics that are stiffer in the axial direction according to feature F1.8a can be implemented. Therefore, the allegation of the appellant (opponent) that the patent describes "*no other way*" to manufacture a fabric with the functionality expressed in feature F1.8a is moot. As correctly observed by the respondent (patent proprietor) compliance with Article 83 EPC does not require that the patent describes any possible embodiment falling within the scope of the invention as claimed, but rather that the person skilled in the art, using the information contained in the patent and in the light of common general knowledge is able to put the invention in practice. This is clearly the case in view of the teachings of paragraphs [0056] to [0059] which describe in details several embodiments of a fabric meeting the requirements of feature F1.8a.

Omission of the "*inner skirt*" in claim 1

2.3.5 The appellant (opponent) alleged that "*the inner skirt*" was presented in the application as an essential feature of the invention. As this allegedly essential feature was omitted in claim 1 the person skilled in the art was not able to carry out the invention.

2.3.6 Also this argument is not convincing:

Even considering the inner skirt as an essential

feature, its omission results at most in a lack of clarity under Article 84 EPC rather than in a lack of disclosure pursuant to Article 83 EPC.

**Article 100(a) in association with Article 54 EPC**

3. The ground for opposition pursuant to Article 100(a) in association with Article 54 EPC is not prejudicial to the maintenance of the patent as granted as correctly decided by the opposition division.

3.1 The appellant (opponent) contested the conclusion of the opposition division according to which the subject-matter of claim 1 as granted according to the first embodiment defined in claim 1 as granted is novel over document D12. In particular the appellant (opponent) was of the opinion that the only distinguishing feature of the first alternative indicated by the opposition division, namely feature F1.8a, was directly and unambiguously derivable from this prior art document. The appellant (opponent) essentially criticized the allegedly narrow interpretation of the opposition division of feature F1.8a according to which stiffness was an inherent characteristic of the fabric. The appellant (opponent) argued that the opposition division did not duly take into account that the stiffness also depended on the shape and dimension of the piece of the material at issue, i.e. that the stiffness of a portion of a uniform fabric decreased proportionally with the length of said portion. Based on this consideration, the appellant (opponent) alleged that D12 described in paragraph [0084] a material used for the outer skirt the stiffness of which decreased with the length. It was thus concluded that as Figure 41 of D12 showed an outer skirt having a circumferential length which was much longer than the

axial length, feature F1.8a was disclosed in this prior art document. This reading of document D12 is not convincing for the following reasons:

- 3.1.1 The Board concurs with the opposition division and the respondent (patent proprietor) that the stiffness of a material, in the present case of a fabric, is generally considered by the person skilled in the art as an intrinsic property of a material itself which does not rely on the specific geometric shape or dimension into which an element made of this material is cut. As a matter of fact D12 does not provide any information regarding the stiffness of the material used for the outer skirt of the valve disclosed therein and even less discloses a relationship between its stiffness in axial and circumferential directions whatsoever. Therefore, in accordance with the conclusion of the opposition division, the Board cannot see how feature F1.8a can be directly and unambiguously derived from the technical information contained in D12.
- 3.1.2 As no further novelty attacks are submitted, the Board confirms the assessment of the opposition division that the subject-matter of claim 1 as granted is novel over the prior art within the meaning of Articles 52(1) and 54 EPC.

**Article 100(a) in association with Article 56 EPC**

4. The ground for opposition pursuant to Article 100(a) in association with Article 56 EPC is not prejudicial to the maintenance of the patent as granted as correctly stated by the opposition division in the decision under appeal.

4.1 The appellant (opponent) maintained that - contrary to the findings of the opposition division - the subject-matter of claim 1 as granted was rendered obvious by the combination of D12 with D2 or D4 (alternative of claim 1 comprising features F1.8a) or with D7 (alternative of claim 1 comprising feature F1.8b).

4.2 It is common ground that the technical problem to be solved by the distinguishing features F1.8a or F1.8b characterizing the two alternative embodiments recited in claim 1 is to implement the implantable prosthetic valve of D12 in such a way as to reduce perivalvular leakage.

4.3 None of the lines of arguments submitted by the appellant (opponent) in support of their objection of lack of inventive step is convincing for the following reasons:

D12 + D4 (against the first alternative of claim 1)

4.4 The appellant (opponent) essentially criticized the view of the opposition division that a combination of D12 with the structurally different device disclosed in D4 was not obvious and therefore disregarded by the person skilled in the art.

4.4.1 However, the Board shares the view of the the opposition division and the respondent (patent proprietor) that the person skilled in the art aiming to reduce perivalvular leakage of the valve of D12 would not consider the teaching of D4 that indeed deals with a quite different kind of medical device, namely a stent-graft, which is structurally and functionally very remote to a cardiac valve provided with an outer skirt and which undergoes a different dynamics.

Irrespective of that, the Board in accordance with the opposition division and the respondent (patent proprietor) and contrary to the allegations of the appellant (opponent) does not see in D4 any disclosure of an outer skirt, let alone of an outer skirt made of a fabric with the characteristics defined in feature F1.8a. Therefore, the combination of D12 with D4, even if considered by the person skilled in the art, does not render obvious the first alternative defined in claim 1 of the patent as granted.

D12 + D2/D2b (against the first alternative of claim 1)

4.5 The appellant (opponent) argued that the technical problem of reducing perivalvular leakage underlying the contested patent - contrary to the view of the opposition division - was implicitly derivable from paragraph [0004] of D2. Thus the person skilled in the art was motivated to introduce the teaching of D2 in the valve of D12 thereby arriving without inventive step to the subject-matter of claim 1. This line of arguments cannot convince:

4.5.1 The Board concurs with the opposition division and the respondent (patent proprietor) that the reasoning of the appellant (opponent) is based on hindsight. Document D2 relates to artificial cardiovascular vessels and fails to disclose an outer skirt, an intermediate fabric portion having slack and the idea of reducing perivalvular leakage by enhancing an outward buckling of slack. Therefore, the Board - contrary to the appellant's (opponent's) allegation - cannot see why the person skilled in the art should extract the material disclosed in D2 in isolation from the technical context of this prior art document and

use it to replace the fabric of the outer skirt of the valve disclosed in D12. Furthermore, as correctly observed by the opposition division and the respondent (patent proprietor) by referring to paragraph [0052], D2 teaches away from enhancing slack that buckles radially outwards. In view of all the above this combination of pieces of evidence proposed by the appellant (opponent) cannot lead in an obvious manner to the subject-matter of claim 1 as granted.

D12 + D7 (against the second alternative of claim 1)

4.6 The appellant (opponent) contested the view of the opposition division that the structural differences between the valve of D12 and the cuff of D7 spoke against a combination of these prior art documents which in their opinion led to a valve comprising all the features of claim 1 as granted. Also this line of arguments is not convincing:

4.6.1 The Board shares the view of the opposition division and the respondent (patent proprietor) that the skilled person, starting from D12 and aiming to solve the technical problem associated to the perivalvular leakage - contrary to the allegation of the appellant (opponent) - has no motivation to adopt the shape memory material of the self-expanding cuff used in the method of D7 for the annular outer skirt of the valve of D12 . As convincingly observed by the respondent (patent proprietor) in their reply, the arrangement used in the method of D7 is on the one hand conceptually and structurally different from that of an implantable prosthetic valve and, on the other hand, it does not even comprise components structurally and functionally corresponding to the main components of the valve of D12. Therefore, the person skilled in the

art does not have any motivation to look in document D7 for a solution to the technical problem of the reduction of perivalvular leakage of the valve of D12.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

G. Pricolo

Decision electronically authenticated