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**Datasheet for the decision  
of 14 December 2023**

**Case Number:** T 0361/22 - 3.2.01

**Application Number:** 15804003.0

**Publication Number:** 3151784

**IPC:** A61F2/24

**Language of the proceedings:** EN

**Title of invention:**

PROSTHETIC VALVE FOR REPLACING A MITRAL VALVE

**Patent Proprietor:**

Edwards Lifesciences Corporation

**Opponent:**

Neovasc Tiara Inc.

**Headword:**

**Relevant legal provisions:**

EPC Art. 123(2)  
RPBA 2020 Art. 12(4)

**Keyword:**

Amendments - extension beyond the content of the application  
as filed (yes) - unallowable intermediate generalisation

**Decisions cited:**

G 0004/93

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 0361/22 - 3.2.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.01**  
**of 14 December 2023**

**Appellant:** Edwards Lifesciences Corporation  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
26 November 2021 concerning maintenance of the  
European Patent No. 3151784 in amended form.**

**Composition of the Board:**

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

## **Summary of Facts and Submissions**

I. Appeals were filed by the patent proprietor and the opponent against the interlocutory decision of the opposition division to maintain the European patent N° 3151784 in amended form.

II. In its decision the opposition division found that the ground for opposition under Article 100(c) in combination with Article 123(2) EPC was prejudicial to the maintenance of the patent as granted and decided to maintain the patent in amended form according to the auxiliary request 1 filed during oral proceedings.

III. With a communication pursuant to Article 15(1) RPBA dated 25 September 2023 the Board informed the parties of its preliminary, non-binding assessment of the case.

With letter dated 8 November 2023 the opponent withdrew their appeal and informed the Board that they would not attend the oral proceedings.

Oral proceedings pursuant to Article 116 EPC were held before the Board on 14 December 2023 per video-conference in absence of the opponent, now party of right to the proceedings.

IV. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or, in the alternative, that the patent be maintained on the basis of the auxiliary requests 1 and 1a filed on 09 November 2022, or on the basis of the auxiliary requests 2 and 3 filed with the statement of grounds of appeal, the auxiliary request 3 corresponding to the request

allowed by the opposition division, or on the basis of any of the auxiliary requests 4 to 15 filed on 22 August 2022.

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

F1 *"A prosthetic device for implanting at a native mitral or tricuspid valve region of the heart, the native valve region having a native valve annulus and native leaflets, the prosthetic device comprising:"*

F2 *a main body (108,208) configured for placement within the native valve annulus,*

F2.1 *the main body having a lumen extending between an atrial end (110,210) and a ventricular end (112,212);*

F3 *an atrial cap (114,214) that extends radially outwardly from the atrial end (110,210);*

F4 *and a plurality of ventricular anchors (116,216) spaced angularly around a circumference of the main body (108,208),*

F4.1 *each ventricular anchor (116,216) having a proximal end portion (122,222)*

F4.1.1 *connected to the main body (108,208) proximate the ventricular end (112,212)*

4.1.2 *at only a single location on the main body,*

F4.2 *an intermediate portion (124,224)*

F4.2.1 *extending away from the atrial end (110,210)*

F4.2.2 and then back toward the atrial end (110,210) so as to define a first bend,

F4.3 and a distal end portion (116,226) extending from the intermediate portion,

F4.3.1 the distal end portion (116,226) comprising a first section (252), a second section (254), and a second bend between the first (252) and the second section (254),

F4.3.2 the first section (252) extending from the intermediate (124,224) portion in a direction toward the atrial end (110,210) and radially away from the main body (108,208),

characterized in that

F5 the distal end portion (126,226) of each ventricular anchor (116,216) comprises an atraumatic head portion (128,228)

F5.1 that is wider in a circumferential direction of the main body (108,208) than the intermediate portion (124,224) of the respective ventricular anchor (116,216).

Independent claim 1 according to the auxiliary request 1 is identical to claim 1 of the main request.

Compared with independent claim 1 as granted, independent claim 1 of auxiliary requests 1a and 2 contains the following additional feature:

F6 "the atraumatic head portion (128, 228) is curved to form a rounded portion facing the atrial end (110,

210) "

## Reasons for the Decision

### Main request - Patent as granted

#### Article 123(2) EPC - Amendments

1. The Board confirms the findings of the opposition division that the ground for opposition pursuant to Article 100(c) in combination with Article 123(2) EPC is prejudicial to the maintenance of the patent as granted.

1.1 Independent claim 1 as granted includes the following additional features introduced in independent claim 1 as filed during the examination proceedings:

F5 *"the distal end portion (126, 226) of each ventricular anchor (116, 216) comprises an atraumatic head portion (128, 228) "*

F5.1 *"that is wider in a circumferential direction of the main body (108, 208) than the intermediate portion (124, 224) of the respective ventricular anchor (116, 216)."*

1.2 In the decision under appeal the opposition division came to the conclusion that the introduction in independent claim 1 as granted of features F5 and F5.1 above without additionally specifying the curved form and the orientation of the head portions of the ventricular anchors as well as the provision of openings or open areas therein, as shown in Figures 7 to 10 and described in paragraphs [106] and [109] of

the originally filed application on which the amendments to claim 1 were supposedly based, resulted in an unallowable intermediate generalisation of a specific embodiment infringing Article 123(2) EPC. This conclusion is contested by the appellant (patent proprietor) with their appeal.

1.3 Regarding feature F5 the appellant (patent proprietor) convincingly put forward that the head portions of the distal end portions of the ventricular anchors of the prosthetic device at stake were described throughout the originally filed description as terminating in atraumatic curved end portions. In this respect reference was made to paragraph [0090] of the A-Publication describing the distal head portions (128) of the ventricular anchors (116) of the the embodiments in Figures 4 and 5 as well as to paragraphs [0106] and [0109] describing the distal head portions (228) of the ventricular anchors (216) of the alternative embodiments in Figures 7 to 10. In view of the above, the Board concludes that the claimed atraumatic functionality of the head portions of the ventricular anchors introduced in claim 1 can be directly and unambiguously derived verbatim from the original application documents.

1.4 Regarding feature F5.1 the appellant (patent proprietor) did not contest that the introduced limitation was not disclosed verbatim in the originally filed application documents. However, the appellant (patent proprietor) maintained that, contrary to the opposition division's view, the claimed dimensioning requiring atraumatic head portions wich are wider than the respective intermediate portions of the ventricular anchors was not only derivable from the Figures, in particular from Figures 7 and 10, but it was inherently



derivable from the fact that the head portions of the distal end portions were qualified throughout the whole originally filed application as being "*atraumatic*", or "*curved*" or "*rounded*" as now specified in feature F5. The appellant (patent proprietor) argued that since in all the embodiments described in the originally filed application, with the mere exception of the schematic and hence non-conclusive representation given in Figures 1A, 1B and 2, the head portions of the ventricular anchors had all in common a shape fulfilling the dimensional limitation imposed by feature F5.1, the objected omission in independent claim 1 of the curved design of the head portions disclosed verbatim in paragraphs [0106] and [0109] of the A-Publication resulted in an allowable intermediate generalisation directly and unambiguously supported by the content of the application as originally filed which therefore did not infringe Article 123(2) EPC. Regarding the objected omission of the information that the head portions of the ventricular anchors had openings or openings areas through which ventricular tissue and/or native valve annulus tissue can protrude as disclosed in paragraphs [0090], [0106] and [0109], the appellant (patent proprietor) argued that this feature was not presented as mandatory, but rather as a mere possible design option among several alternative head portion designs as listed in paragraph [090], to which also paragraphs [0106] and [0109] explicitly referred to. In support of this allegation the appellant (patent proprietor) argued that a "*cup shaped*" head portion as suggested in paragraph [0090] did not have any opening. Moreover, contrary to the allegedly unsubstantiated finding of the opposition division, it was argued that features F5 and F5.1 introduced in claim 1 were not inextricably linked to the remaining structural features of the head portion

disclosed in paragraphs [0106] and [0109] and shown in the associated figures, whereby these features could be omitted without infringing Article 123(2) EPC. In this regard the appellant (patent proprietor) explained that the openings were not mandatorily required for securing the prosthetic device to the native valve annulus location. This could be derived from paragraphs [0122] and [0123] read in combination with Figures 16D and 20 according to which at least some of the head portions of the ventricular anchors, after installation of the device, were not in contact with the native valve annulus and/or adjacent tissue because, as well known, the shape and dimension of the native valve annulus varied from individual to individual. It was thus argued that the person skilled in the art realized that the claimed device could perfectly work and be correctly secured in position in the native valve annulus also without providing openings at the head portions of the ventricular anchors. The appellant (patent proprietor) thus concluded that curve-shaped design of the head portions and the provision of openings or opening areas were not inextricably linked to the other structural features introduced in claim 1 on the basis of the information presented in paragraphs [0106] and [0109] and Figures 7-10 whereby, contrary to the findings of the opposition division, their omission in the independent claim did not result in an unallowable intermediate generalisation infringing Article 123(2) EPC.

1.5 The arguments of the appellant (patent proprietor) are not convincing for the following reasons:

Firstly, contrary to the view of the appellant (patent proprietor), the dimensional relationship between the head portion and the intermediate portion of the

ventricular anchor expressed in feature F5.1 is not inherently derivable from the term "*atraumatic*" which qualifies the shape of the head portion according to antecedent feature F5. In fact, as convincingly argued by the opponent (respondent) in their reply to the statement of grounds of appeal of the appellant (patent proprietor), "*atraumatic head portion*" simply means that the head portion is designed in such a way, for example as a smooth profile without sharp edges, to minimise trauma upon contact with the native tissue of the native valve annulus. However, to achieve this functionality, it is not mandatorily required that the head portion must be wider compared with the respective intermediate portion of the ventricular anchor. For example, a semi-spherical shaped head portion having the same radial dimension as the intermediate portion underneath is also "*atraumatic*" within the meaning of the contested patent. It follows that the only possible support for the limitation expressed in feature F5.1 is indeed represented by the figures and in particular by the embodiments presented in Figures 7 and 10 as correctly stated by the opposition division. However, the description of these figures does not contain any pointer selectively drawing the attention of the person skilled in the art looking at these figures to the dimensional relationship between the head portion and the intermediate portion of the ventricular anchor represented therein in such a way to consider this dimensioning a purposive and originally disclosed feature of the invention. Therefore, the person skilled in the art does not find in the originally filed disclosure any direct and unambiguous hint to extract the dimensional relationship recited in feature F5.1 from the specific embodiments shown in Figures 7 and 10 and to introduce it in claim 1 in isolation, i.e. without also mentioning the disclosed atraumatic curved

shape of the head portions and the openings associated therewith which are consistently presented in combination in all the embodiments of the invention. Further, the Board does not share the view of the appellant (patent proprietor) that the openings are not inextricably linked to the other structural features of the head portion disclosed in paragraphs [0106] and [0109] and shown in Figures 7 to 10 of the originally filed application, in particular to the curved atraumatic shape of the head portion. Firstly, the Board observes that according to all the relevant embodiments presented in the figures the head portions of the ventricular anchors are curved and provided with openings or open areas. This is also the case with all the alternative designs suggested in paragraph [090] of the A-Publication, namely *"a closed shape, a circle, an oval shape, a teardrop shape, a cupped shape, a coil, a spiral, or a serpentine"*, this alternative designs also applying to the embodiments in Figures 7 to 10 (see last sentence of paragraphs [0106] and [0109]). Regarding the alternative *"cupped shape"* listed in paragraph [0063] and discussed by the appellant (patent proprietor) in support of their view that openings are not mandatorily required, the Board observes that while a cup is indeed closed at its bottom end, it also inherently presents an opening/opened surface at the opposite end. The opening of a cup-shaped head portion also allows for the native tissue of the valve annulus or of the region adjacent thereto to penetrate into the cup and fill it in such a way to provide the same anchoring functionality as the openings of the ring- or horse-shoe shaped head portions presented in all the figures. Furthermore, the Board is convinced that the person skilled in the art, reading the contested patent as whole, realizes that the technical problem to be solved by the claimed prosthetic device and in

particular by the design of the ventricular anchors is to secure the prosthetic device within the native valve annulus without causing damage to the native tissue at the area of contact. According to the original disclosure this purpose is achieved on one side by selecting a curved/rounded and hence atraumatic profile for the head portions and on the other side by providing the head portions with openings through which the valve and /or annulus native tissue can protrude thereby creating secure anchoring points. The fact alleged by the appellant (patent proprietor) that under certain circumstances some of the anchors may not come into contact with the native valve annulus does not imply for the person skilled in the art that the openings can be completely omitted because, if not all, at least a certain number of anchors are required and come into contact with the native valve annulus along at least a part thereof, thereby contributing to the anchoring of the device.

- 1.6 In view of all above the Board confirms the view of the opposition division that the omission in claim 1 as granted of the curved shape of the head portion (feature F6 of the patent as maintained) as well as the provision of openings within the head portion (feature F7 of the patent as maintained) leads to an unallowable intermediate generalisation infringing Article 123(2) EPC.

#### **Auxiliary Request 1**

##### Article 123(2) EPC

2. Independent claim 1 of the new auxiliary request 1, in which granted claim 13 has been deleted, is identical to claim 1 as granted and therefore does not meet the

requirements of Article 123(2) EPC for the same reason presented in respect of the main request.

**Auxiliary Requests 1a and 2**

3. Independent claims 1 of these auxiliary requests are identical. In the auxiliary request 2 dependent claim 13 has been deleted. Compared to claim 1 as granted, claim 1 contains the additional limitation that:

*F6 "the atraumatic head portion (128, 228) is curved to form a rounded portion facing the atrial end (110, 210"*

wordily based on claim 7 as filed and granted.

Admissibility

- 3.1 These requests were filed as auxiliary requests 1 and 2 for the first time with the statement of grounds of appeal of the appellant (patent proprietor). Their admissibility into the appeal proceedings was contested by the respondent (opponent) with their reply.
- 3.2 After having considered the circumstances of the first instance proceedings recalled by the appellant (patent proprietor), in particular the fact that the preliminary assessment of Article 123(2) EPC of the opposition division was reversed at the oral proceedings (see point 4.1 of the minutes), and that the opposition division after rejecting the main request under Article 123(2) EPC clearly expressed the view that the omission of the features reciting the curved shape of the head portion (feature F6 introduced in claim 1 of these requests) and the provision of the openings (feature F7 of claim 1 of the patent as maintained), resulted in an unallowable intermediate

generalisation infringing Article 123(2) EPC (see point 5. of the minutes), the Board considered that there were no specific procedural circumstances that would have prompted the appellant (patent proprietor) to submit at the first instance oral proceedings present auxiliary requests 1a or 2, i.e. a request containing an amended independent claim based on claim 1 as granted and additionally containing feature F6 only. In view of the above and in exercise of the discretion provided by Article 12(4) RPBA 2020 the Board thus decided to admit the auxiliary requests 1a and 2 into the appeal proceedings.

#### Article 123(2) EPC: Amendments

- 3.3 However, in accordance with the assessment of the opposition division, since the independent claim 1 of these auxiliary requests still lacks the feature that the head portion has one or more openings through which the native annulus tissue can protrude (feature F7 of claim 1 as maintained), these auxiliary requests do not meet the requirements of Article 123(2) EPC for the same reasons presented in the respect of the main request.

#### **Auxiliary Request 3 - Patent as maintained**

4. This auxiliary request corresponds to the version of the patent as maintained by the opposition division. As a consequence of the withdrawal of the appeal of the opponent, the maintenance of the patent as amended in accordance with the interlocutory decision cannot be challenged (G 4/93).

### **Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:



A. Voyé

G. Pricolo

Decision electronically authenticated