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Datasheet for the decision of 2 December 2025

Case Number: T 1854/23 - 3.2.02

Application Number: 10835174.3

Publication Number: 2485795

IPC: A61M25/01, A61F2/24, A61M25/02

Language of the proceedings: EN

Title of invention:
PROSTHETIC VALVE FOR REPLACING MITRAL VALVE

Patent Proprietor:
Edwards Lifesciences Corporation

Former Opponent:
Neovasc Tiara Inc.

Relevant legal provisions:
EPC Art. 54(2), 54(3), 56, 83, 84, 123(2)
RPBA 2020 Art. 12(4)

Keyword:

Amendment to case - amendment within meaning of Art. 12(4) RPBA 2020 - amendment admitted (yes)
Novelty - main request (no) - auxiliary request (yes)
Inventive step - auxiliary request (yes)
Amendments - added subject-matter (no)
Claims - clarity (yes)
Sufficiency of disclosure - (yes)

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Beschwerdekammern

Boards of Appeal

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Case Number: T 1854/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 2 December 2025

Appellant: (Patent Proprietor)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
Representative:	Eisenführ Speiser Patentanwälte Rechtsanwälte PartGmbB Postfach 31 02 60 80102 München (DE)
Former Respondent: (Former Opponent)	Neovasc Tiara Inc. 2135 - 13700 Mayfield Pl Richmond, BC V6V 2E4 (CA)
Representative:	WBH Wachenhausen Patentanwälte PartG mbB Müllerstraße 40 80469 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 August 2023 concerning maintenance of the European Patent No. 2485795 in amended form.**

Composition of the Board:

Chairman	D. Ceccarelli
Members:	S. Dennler
	Y. Podbielski

Summary of Facts and Submissions

I. The patent proprietor filed an appeal against the opposition division's interlocutory decision to maintain the patent in amended form.

II. In its decision, the opposition division found the subject-matter of claim 1 as granted to lack novelty over both D1 and D14. While D1 is prior art under Article 54(2) EPC, the opposition division regarded D14 as prior art under Article 54(3) EPC, since it considered that none of the priorities claimed by the patent, including the priority of P2, were validly claimed.

D1, D14 and P2 are the following documents:

D1 WO 2008/035337 A2
D14 WO 2011/057087 A1
P2 US application No. 61/287,099

The decision also refers to the following documents:

P4 US application No. 61/258,331
D11 WO 2009/045338 A1
D12 US 2009/0216312 A1
D13 US 2007/0142906 A1
D15 WO 2012/011108 A2
D20 DE 10 2006 052 564 B3

III. The appellant (the 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, as amended on the basis of one of

auxiliary requests 1 to 4 filed with the statement of grounds of appeal.

IV. By letter of 30 August 2024, the former respondent (the former opponent) withdrew its opposition without replying to the statement of grounds of appeal.

V. The Board summoned the appellant to oral proceedings and, in its communication under Article 15(1) RPBA, indicated its preliminary opinion that, unlike the main request and auxiliary requests 1 and 2, auxiliary request 3 was allowable. The Board added that it was therefore inclined to set aside the decision under appeal and to remit the case to the opposition division with the order to maintain the patent as amended on the basis of the claims of auxiliary request 3 and a description to be adapted thereto.

VI. By letter of 22 August 2025, the appellant withdrew its request for oral proceedings on the condition that the Board would maintain the patent as indicated in its communication.

VII. The Board subsequently cancelled the oral proceedings.

VIII. Claim 1 of the **main request** (claim 1 as granted) reads as follows (with the feature numbering used in the decision under appeal):

F1 *A prosthetic valve (100) for implanting at the native mitral valve region of the heart, the native mitral valve (2) having a native annulus (8) and native valve leaflets (10, 12), the prosthetic valve comprising:*

F1.1 *a tubular main body (122) comprising a lumen and configured for placement within the native*

annulus (8), the main body being radially compressible to a radially compressed state for delivery into the heart and self-expandable from the compressed state to a radially expanded state; and

F1.2 *a valve structure (104) coupled to the inner surface of the main body, the valve structure (104) comprising a plurality of valve leaflets (106) that form a one-way valve in the lumen,*

F1.3 *the valve structure sutured to the main body;* ***characterized by***

F1.4 *at least two ventricular anchors (126)*

F1.4.1 *extending from a ventricular end (130) of the main body (122) and*

F1.4.2 *disposed outside of the main body for securing the prosthetic valve to the anterior and posterior native mitral valve leaflets (10, 12),*

F1.4.3 *wherein the ventricular anchors (126) are configured to capture the native mitral valve leaflets (10, 12) between the ventricular anchors (126) and an outer surface of the tubular main body (122); and*

F1.5 *an atrial sealing member (124) extending radially outwardly from an atrial end (132) of the main body (122), the atrial sealing member (124) blocks blood from flowing beyond the atrial end (132) of the main body on the outside of the main body when the prosthetic valve (100) is implanted.*

IX. Claim 1 of **auxiliary request 1** differs from claim 1 as granted in that feature F1.1 has been amended as follows:

F1.1 *a frame (102) comprising a tubular main body (122), which forms an open-ended tube and comprises~~ing~~ a lumen and is configured for placement within the native annulus (8), the main body being radially compressible to a radially compressed state for delivery into the heart and self-expandable from the compressed state to a radially expanded state; and*

In addition, the expression "characterized by" has been amended to "characterized ~~by~~ in that the frame (102) further comprises".

X. Claim 1 of **auxiliary request 2** differs from claim 1 as granted in that feature F1.5 has been amended as follows:

F1.5 *an atrial sealing member (124) extending radially outwardly from an atrial end (132) of the main body (122), the atrial sealing member(124) has an outer rim (140) that is sized and shaped to contact the atrial side of the native annulus and tissue of the left atrium when the frame is implanted, and blocks blood from flowing beyond the atrial end (132) of the main body on the outside of the main body when the prosthetic valve (100) is implanted.*

XI. Claim 1 of **auxiliary request 3** differs from claim 1 as granted in that feature F1.5 has been amended as follows:

F1.5 *an atrial sealing member (124) extending radially outwardly from an atrial end (132) of the main body (122), the atrial sealing*

member(124) includes a sealing layer (142) comprising polyester material that is impervious to the flow of blood and blocks blood from flowing beyond the atrial end (132) of the main body on the outside of the main body when the prosthetic valve (100) is implanted.

The remaining claims of auxiliary request 3, claims 2 to 14, are dependent claims.

XII. The appellant's arguments relevant for the present decision are dealt with in detail in the reasons for the decision.

Reasons for the Decision

1. Subject-matter of the patent

1.1 The patent relates to a prosthetic heart valve suitable for implantation, typically by a minimally invasive technique, at the native mitral valve region of the heart.

Figure 5, reproduced below, illustrates an example of such a valve, and Figure 23 shows it in the implanted state. Paragraphs [0024]-[0029] of the specification describe this valve.

1.2 As defined in claim 1 as granted, the valve comprises a tubular main body (122) comprising a lumen and configured for placement within the native annulus (8) of the mitral valve, the main body being radially compressible to a radially compressed state for delivery into the heart and self-expandable from the compressed state to a radially expanded state; and a

valve structure coupled to the inner surface of the main body and comprising a plurality of valve leaflets (106) that form a one-way valve in the lumen.

FIG. 5

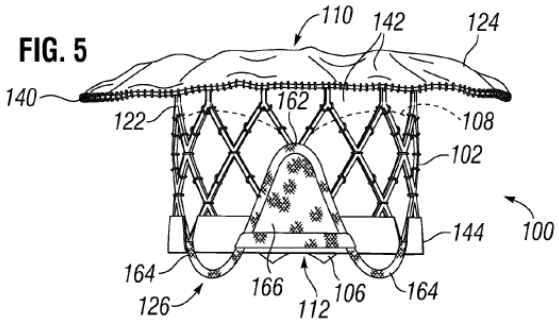
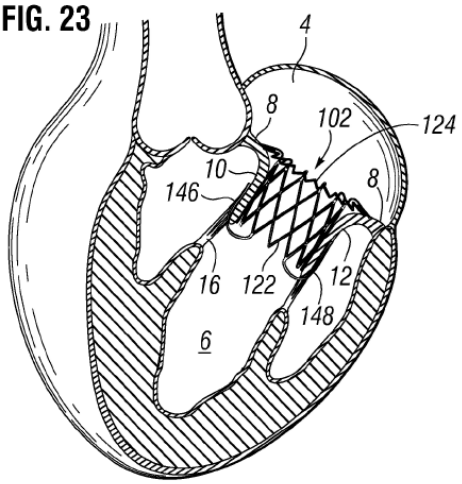


FIG. 23



1.3 Compared to the relatively round and rigid aortic annulus, the mitral valve annulus (8) is more compliant and undergoes dynamic conformational changes throughout the cardiac cycle.

Accordingly, the claimed valve is not designed to rely primarily on a pressure- or friction-fit between the outer surface of the main body and the inner surface of the mitral annulus for retention. Instead, it is intended to be secured by at least two ventricular anchors (126) which extend outwardly from a ventricular end of the main body for capturing the native mitral valve leaflets (10, 12) between them and the outer surface of the tubular main body (as described in paragraph [0028]).

In addition, the valve comprises an atrial sealing member (124) extending radially outwardly from an atrial end of the main body. This atrial sealing member is intended to form a fully annular contact area, or

seal, with the native tissue on the atrial side of the mitral annulus, thereby preventing blood from leaking through any gaps between the main body and the native leaflets or annulus that might otherwise arise from the main body sitting loosely within the mitral valve (as described in paragraph [0029]).

2. Main request

2.1 Novelty in view of D14

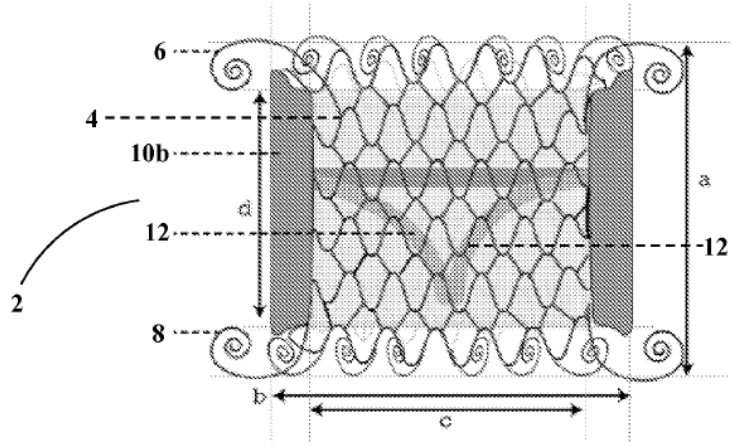
2.1.1 As set out below, D14 discloses the subject-matter of claim 1 as granted and is, as far as this subject-matter is concerned, prior art under Article 54(3) EPC. Consequently, the subject-matter of claim 1 as granted is not novel over D14.

2.1.2 As submitted by the appellant itself (see point C) 1. of the statement of grounds of appeal), the person skilled in the art would be aware that it is unrealistic, in the context of a prosthetic heart valve, to assume - as the opposition division did in the decision under appeal (see Reasons 14) - that "there is no blood flow at all" along the outside of the valve once implanted in the heart. They would therefore recognise that, contrary to the opposition division's interpretation, "blocking" blood from flowing along the implanted valve, as defined in feature F1.5, only means that blood flow is obstructed, i.e. partially blocked.

2.1.3 The appellant disputed the disclosure of feature F1.5 in D14 on the ground that, if the opposition division's interpretation were correct, the same interpretation would likewise have to be applied to D14. Since, as set

out above, that interpretation is incorrect, the appellant's argument is not convincing.

In fact, as acknowledged by the appellant (see point C) 2.2 a) of the statement of grounds of appeal), the webbing which is disposed at the upper anchoring flange 6 of the prosthetic mitral valve 2 disclosed in Figure 1 of D14, reproduced below (see also paragraph [0080] of D14), is described as "assist[ing] with [...] sealing[] of the prosthesis at the implantation site". This necessarily implies a partial obstruction of blood flow along the outside of the implanted valve and therefore corresponds to the meaning of "blocking" in feature F1.5 as correctly interpreted.



Therefore, the upper anchoring flange with this webbing anticipates feature F1.5.

The appellant did not contest, and the Board agrees, that D14 also discloses the other features of claim 1 as granted (see Figure 1), as considered by the opposition division (see Reasons 15.1-15.2).

Therefore, D14 discloses the subject-matter of claim 1 as granted.

2.1.4 D14, which was published on 12 May 2011, i.e. after the filing date of the contested patent (3 December 2010), does not form part of the state of the art pursuant Article 54(2) EPC. However, subject-matter disclosed in D14 is comprised in the state of the art relevant for the patent under Article 54(3) EPC to the extent that such subject-matter has an effective date earlier than that of the relevant subject-matter of the patent.

The appellant asserted that the effective date of the disclosure of D14 was, in general, its filing date (see point C) 2.1 of the statement of grounds of appeal). The Board disagrees. Contrary to the appellant's assertion, the subject-matter of D14 relied upon for the novelty-objection against claim 1 as granted (see point 2.1.3 above) does not derive its effective date from the filing date of D14. Rather, D14 claims priority of P4, and this priority claim is valid for the disclosure in question. In particular, Figures 1-4 of D14 are identical to those of P4 and paragraph [0080] of D14 is identical to paragraph [0028] of P4. The effective date of this relevant subject-matter is therefore the filing date of P4 (5 November 2009), which is earlier than the filing date of P2 (16 December 2009) and, more generally, of all the priorities claimed by the contested patent.

Accordingly, regardless of whether the claimed priorities of the contested patent - including that of P2 - are valid for the subject-matter of claim 1 as granted, D14 still constitutes prior art under Article 54(3) EPC for that claim. This view was indicated in the communication under Article 15(1) RPBA and was not challenged by the appellant in its submission of 22 August 2025.

2.1.5 It follows that the subject-matter of claim 1 as granted is not novel over D14. For this reason alone, the patent in suit cannot be maintained as granted.

2.2 Novelty in view of D1

As argued by the appellant (see point C) 3.2 of the statement of grounds of appeal), the opposition division's interpretation of D1 is incorrect. Consequently, the other novelty objection to claim 1 as granted raised in the decision under appeal in view of that document is without merit.

Indeed, contrary to the opposition division's view, the person skilled in the art would not consider the three distal diverging struts 30 of the inner support structure 12 (visible in Figures 1 and 2B of D1, reproduced below) to form a tubular body having a lumen. At most, the throat section 36 of the proximal skirt 32 could be regarded as forming such a tubular main body having a lumen, with the struts 30 extending out of and distally from this body (see page 75, lines 8-10 of D1). The valve structure 104 coupled to the struts 30 is located outside of the throat section 36 and is not coupled to the inner surface of the main body. Moreover, leaflets of the valve structure do not form a valve in the lumen of the tubular main body. Thus, D1 does not disclose features F1.1 and F1.2.

FIG. 1

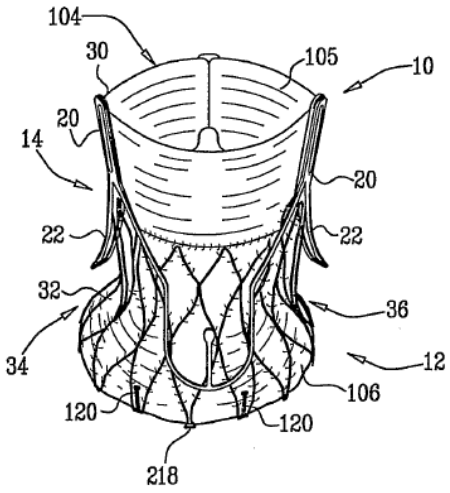
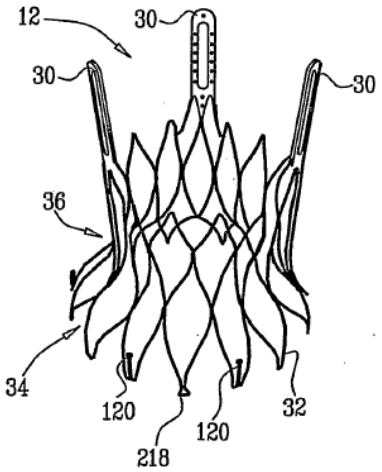


FIG. 2B



For this reason alone, the subject-matter of claim 1 as granted is novel in view of D1.

3. Admittance of auxiliary requests 1 to 3

Auxiliary requests 1 to 3 were filed for the first time with the statement of grounds of appeal. Their admittance is therefore at the Board's discretion, pursuant to Article 12(4) RPBA.

Apart from the minor correction of a typographic error in dependent claim 4, these requests define various amendments to claim 1 as granted that address the novelty objections in view of D1 and D14 raised in the decision under appeal. These amendments are straightforward and do not give rise to any new issues beyond those already discussed in the decision under appeal.

In the exercise of its discretion, the Board therefore decides to admit auxiliary requests 1 to 3.

4. Auxiliary requests 1 and 2

The features added to claim 1 in auxiliary requests 1 and 2 are also disclosed in D14 (for example, see Figure 1). The appellant did not argue otherwise. As the appellant explained (see points D) 1. and of 2. of the statement of grounds of appeal), these additional features were intended to distinguish the subject-matter of claim 1 as granted from the disclosure of D1 in case the Board considered that D1 anticipated the subject-matter of claim 1 as granted, but D14 did not.

For this reason, auxiliary requests 1 and 2 are not allowable either.

5. Auxiliary request 3

5.1 Compared to claim 1 as granted, claim 1 of auxiliary request 3 comprises the additional feature that "the atrial sealing member (124) includes a sealing layer (142) comprising polyester material that is impervious to the flow of blood".

5.2 The Board is satisfied that this additional feature is disclosed in paragraphs [096] and [099] of the application as originally filed, as argued by the appellant. As derivable from the decision under appeal, the opposition division had no concerns with added subject-matter, clarity or sufficiency of disclosure which may apply to auxiliary request 3. The former respondent, which withdrew its opposition without replying to the statement of grounds of appeal, did not provide any arguments to the contrary, and the Board also sees no reason to conclude otherwise.

5.3 Novelty and inventive step

5.3.1 D14

As argued by the appellant and concluded by the opposition division (see Reasons 17), D14 does not disclose that the atrial sealing member includes a sealing layer comprising polyester material that is impervious to the flow of blood.. Therefore, the subject-matter of claim 1 of auxiliary request 3 is novel in view of D14.

As D14 can at most be prior art under Article 54(3) EPC (see point 2.1.4 above), it cannot be considered for inventive step.

5.3.2 D1

As the subject-matter of claim 1 of auxiliary request 3 is more limited than that of claim 1 as granted, it likewise differs from the valve disclosed in D1 by at least features 1.1 and 1.2, and is therefore also novel in view of that document.

In contrast to D14, D1, which is prior art under Article 54(2) EPC, is also relevant for assessing inventive step.

Implementing features 1.1 and 1.2 in the valve of D1 would have required, *inter alia*, extending the throat section 36 to incorporate the three strut supports 30, in contrast to the teaching of D1 that the struts extend out of the proximal skirt 32 including the throat section (see page 75, lines 8 to 10). However, the Board sees no incentive in the cited prior art for

the person skilled in the art to make such a modification in an obvious way.

5.3.3 Further evidence

In the decision under appeal, the opposition division also considered D11 to D13, D15 and D20 when assessing novelty and inventive step of claim 1 of the request that it ultimately found allowable. As derivable from the decision, the opposition division did not consider that these documents were prejudicial to novelty or inventive step of that claim. The Board sees no reason to conclude otherwise as far as claim 1 of auxiliary request 3 is concerned. The former respondent, which withdrew its opposition without replying to the statement of grounds of appeal, did not provide any arguments to the contrary either.

5.4 The Board therefore concludes that the claims of auxiliary request 3 meet the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent with the claims of auxiliary request 3 filed with the statement of grounds of appeal, and a description to be adapted thereto.

The Registrar: The Chairman:

A. Chavinier-Tomsic D. Ceccarelli

Decision electronically authenticated