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**Datasheet for the decision
of 8 August 2025**

Case Number: T 0724 / 23 - 3.2.02

Application Number: 16783861.4

Publication Number: 3285690

IPC: A61F2/24, A61B17/04

Language of the proceedings: EN

Title of invention:

PERCUTANEOUS MITRAL VALVE REPLACEMENT DEVICE

Patent Proprietor:

Edwards Lifesciences Corporation

Opponent:

Tendyne Holdings, Inc.

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

Prohibition of reformatio in peius - subject-matter of claim 1
open for review

Amendments - added subject-matter (yes)

Decisions cited:

G 0009/92, G 0004/93, T 0856/92, T 0149/02, T 0168/04,
T 0659/07, T 1713/08, T 0722/10, T 0428/12, T 1626/11



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0724/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 8 August 2025

Appellant: Edwards Lifesciences Corporation
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
8 February 2023 concerning maintenance of the
European Patent No. 3285690 in amended form.

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Dennler
S. Ruhwinkel

Summary of Facts and Submissions

- I. The patent proprietor filed an appeal against the opposition division's interlocutory decision to maintain the contested patent as amended in accordance with auxiliary request 1.
- II. In its decision, the opposition division had concluded that claim 1 of the patent as granted did not contain added subject-matter in breach of Article 123(2) EPC, but that dependent claims 5 to 7 did. Consequently, the patent could not be maintained as granted.

Auxiliary request 1, which the opposition division found allowable, is identical to the patent as granted, except for the deletion of claims 5 to 7.
- III. The **appellant (patent proprietor)** requested that the decision under appeal be set aside and that the patent be maintained as granted.
- IV. The **respondent (opponent)** requested that the appeal be dismissed.
- V. Oral proceedings were held before the Board on 8 August 2025, at the end of which the present decision was announced.
- VI. **Claim 1 as granted** reads as follows (the feature numbering is that used in the decision under appeal):

M1 "*A prosthetic valve assembly (300; 500; 800) for replacing a native heart valve comprising:*

M2 *a radially expandable and compressible support structure (302; 502; 802),*

M2.1 *the support structure (302; 502; 802) comprising an annular frame (308; 510; 812) having a lumen extending from an inflow end (506; 808) to an outflow end (508),*

M2.2 *the support structure (302; 502; 802) further comprising an annular sealing member (330; 512) extending radially inwardly into the lumen of the frame (308; 510; 812) and having an inner peripheral portion defining an orifice (332; 514); and*

M3 *a radially expandable and compressible valve component (304; 504; 804),*

M3.1 *the valve component (304; 504; 804) comprising an annular frame (322; 546; 820) and a valve structure (326; 548) supported inside of the frame (322; 546; 820) for permitting the flow of blood through the valve component (304; 504; 804) in one direction and blocking the flow of blood in the opposite direction;*

M3.2 *wherein the valve component (304; 504; 804) is configured to expand within the orifice (332; 514) of the sealing member (330; 512) and*

M3.3 *engage the inner peripheral portion of the sealing member (330; 512) when radially expanded*

M3.4 *so that the valve component (304; 504; 804) is suspended within the support structure (302; 502; 802)."*

VII. **Claim 5 as granted** reads as follows:

"The prosthetic valve assembly of any preceding claim, wherein the sealing member (512) comprises a first end wall (534) defining a first orifice, a second wall

(536) axially spaced from the first end wall (534) and defining a second orifice, and a tubular, inner sleeve (532) extending from the first orifice of the first end wall (534) to the second orifice of the second end wall (536), and wherein the valve component (504) is configured to be deployed within the inner sleeve (532)."

Claims 6 and 7 as granted both depend on claim 5.

VIII. The **appellant's arguments**, where relevant to the present decision, can be summarised as follows.

Prohibition of reformatio in peius; extent of the Board's review

In the decision under appeal, the opposition division had concluded that claim 1 as granted did not contain added subject-matter in breach of Article 123(2) EPC. As the patent proprietor was the sole appellant, the principle of prohibition of *reformatio in peius* barred the Board from reopening and deciding upon this question. This prevented the Board from considering feature M3.4 in the context of claim 1 as granted to the detriment of the appellant.

Added subject-matter

In any event, neither claim 1 as granted nor claims 5 to 7 as granted contained added subject-matter. The opposition division's finding, in the decision under appeal, that claims 5 to 7 as granted contained added subject-matter resulted from a misinterpretation of the term "suspended".

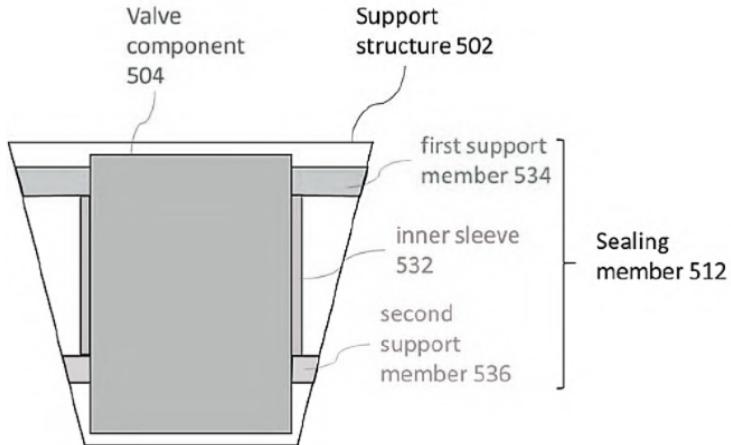
The person skilled in the art would understand the term "suspended" as used both in feature M3.4 of claim 1 as granted and in the application as originally filed (paragraph [0106]) to have its usual meaning, namely that the valve component was "hanging" within the support structure through its engagement with the sealing member, without "support from below", i.e. that the valve component was secured within the support structure without any part sitting in its hypothetical path of movement out of the support structure.

This teaching was not only embodied in the series of embodiments disclosed in the application as originally filed in relation to Figures 7 to 25 ("embodiments E1") - as the opposition division had correctly considered in the decision under appeal - but also in the other series of embodiments disclosed in relation to Figures 26 to 33 ("embodiments E2"), which also comprised a valve component that was suspended within the support structure.

In embodiments E1, the valve component 304 was expanded within the orifice 332 of the sealing member 330 to form a press fit with the sealing member 330 sufficient to secure and suspend the valve component 304 within the support structure 302 (see Figure 25).

In embodiments E2, the sealing member 512 comprised a first support member 534, a second support member 536 and a tubular, inner sleeve 532 extending between them. As could be seen in the cross-sectional sketch on page 18 of the statement of grounds of appeal, reproduced below in black and white, the valve component 504 was deployed within and engaged the inner sleeve of the sealing member 512. Therefore, the valve component was also suspended within the support

structure 502, just as in embodiments E1. This was the case even though the term "suspended" was not explicitly used in the original application when describing embodiments E2.



It followed that claims 5 to 7 as granted, which were directed at embodiments E2, did not contain added subject-matter.

In any event, paragraph [0106], which explicitly used the term "suspended" and from which the wording of feature M3.4 was derived, did not establish an inextricable link between the suspension of the valve component 304 and a gap between the frames 308 and 322 over the entire height of the frame 322. The person skilled in the art would infer from that paragraph, in particular given the expression "for example", that such a gap was optional, and indeed no such gap was visible in Figure 25. The fact that such a gap was only specified in original claims 5 and 8 provided a basis for omitting it from claim 1 as granted. In any case, claim 1 as granted also implied the presence of such a gap.

Therefore, the fact that the claims as granted did not explicitly recite such a gap did not amount to an unallowable intermediate generalisation.

IX. The **respondent's arguments**, where relevant to the present decision, can be summarised as follows.

Prohibition of reformatio in peius; extent of the Board's review

The principle of prohibition of *reformatio in peius* did not prevent the Board from considering the feature "suspended" in the context of claim 1 as granted when assessing whether claims 5 to 7 contained added subject-matter. On the contrary, this consideration was in fact required, since claims 5 to 7 as granted depended on claim 1 as granted.

Added subject-matter

The term "suspended" was only found in the application as originally filed in paragraph [0106], which related specifically to the embodiments E1. The person skilled in the art would realise from this paragraph - simply from the use of quotation marks around the word "suspended" - that this term had a special meaning, different from the usual meaning put forward by the appellant.

Indeed, already from the very first sentences of paragraph [0106], the "suspension" of the valve component within the support structure in these embodiments was associated with the fact that the outer diameter of the fully expanded valve component was smaller than the inner diameter of the fully expanded support structure, in other words with the presence of a gap between the frames of these two components over the entire height of the valve component's frame. This allowed the valve component in these embodiments to

"float" within the support structure - another term used in paragraph [0106] to describe this arrangement.

The application as originally filed did not explicitly or implicitly disclose that such a "suspension" or "floating" of the valve component was also achieved in the other embodiments E2, to which claims 5 to 7 as granted were directed. Therefore, as these claims included feature M3.4 through their dependence on claim 1 as granted, they contained added subject-matter.

In any event, feature M3.4 only defined the suspension of the valve component as being caused by its engagement with the sealing member once expanded. Claims 5 to 7 as granted - like claim 1 as granted - did not explicitly or implicitly define a gap between the valve component and the support structure over the entire height of the valve component's frame; nor did they specify any corresponding requirements for the outer and inner diameters of these components. However, according to paragraph [0106], it was this that caused the valve component to be "suspended" within the support structure. Due to this omission, the subject-matter of claims 5 to 7 as granted constituted an unallowable intermediate generalisation of the original disclosure, in breach of Article 123(2) EPC.

Reasons for the Decision

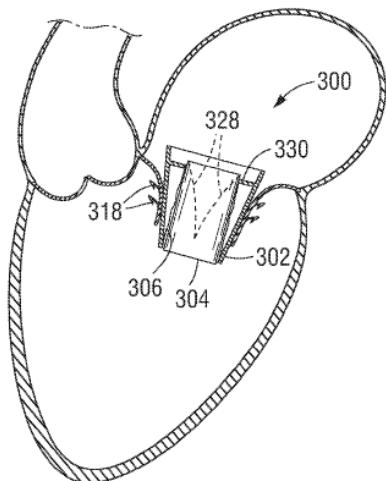
1. Subject-matter of the contested patent

1.1 The contested patent relates to a prosthetic valve assembly, in particular for replacing a native mitral valve, as defined in claim 1 as granted (feature M1; see paragraphs [0005], [0006], [0009] and [0010]).

1.2 As shown for example in Figure 25, reproduced below, this valve assembly comprises:

- (a) a radially expandable and compressible support structure (302) comprising an annular frame (308) having a lumen, and an annular sealing member (330) extending radially inwardly into the lumen and having an inner peripheral portion defining an orifice (features M2 to M2.2);
- (b) a radially expandable and compressible valve component (304) supported with the support structure, and comprising an annular frame (322) and a valve structure (326) with one or more leaflets (328) supported inside the frame (features M3 and M3.1).

FIG. 25



1.3 Claim 1 as granted specifies that the valve component is configured to expand within the orifice of the sealing member (feature M3.2) and engage the inner peripheral portion of the sealing member when radially expanded (feature M3.3) "so that the valve component is suspended within the support structure" (feature M3.4).

Feature M3.4 was added to claim 1 as originally filed during the examination phase. The term "suspended" only appears in paragraph [0081] of the patent specification and paragraph [0106] of the description as originally filed.

1.4 Claim 5 as granted depends on claim 1 and specifies that the sealing member comprises a first end wall defining a first orifice, a second wall axially spaced from the first end wall and defining a second orifice, and a tubular, inner sleeve which extends from the first to the second orifice and within which the valve component is configured to be deployed.

A sealing member with these features is described in relation to Figures 26 to 33 of the contested patent.

2. Patent as granted - added subject-matter

2.1 The parties disagree as to whether claims 5 to 7 as granted contain added subject-matter in breach of Article 123(2) EPC, as held by the opposition division in the decision under appeal.

2.2 It is common ground that, apart from the addition of feature M3.4 to claim 1 and the inclusion of reference signs, claims 1 and 5 to 7 as granted are identical to claims 1 and 8 to 10 as originally filed, respectively.

Claims 5 to 7 as granted depend on claim 1 as granted. By defining a particular construction of the sealing member and specifying how the valve component is deployed within it, claims 5 to 7 as granted further specify the engagement of the valve component with the sealing member defined by features M3.2 to M3.4 in claim 1 as granted.

Therefore, a central issue in this appeal is to assess the effect of the addition of feature M3.4 to claim 1 on the subject-matter of claims 5 to 7 as granted.

For this purpose, it is necessary to consider how the person skilled in the art would interpret feature M3.4, and in particular the term "suspended", both in the claims as granted and in the application as originally filed, and on the basis of this to determine whether claims 5 to 7 as granted present the person skilled in the art with new information that was not originally disclosed.

2.3 *Prohibition of reformatio in peius; extent of the Board's review*

2.3.1 The appellant argued that the Board was not empowered to consider feature M3.4: the opposition division had found this feature to comply with Article 123(2) EPC in the decision under appeal, and the patent proprietor was the sole appellant. Therefore, the principle of prohibition of *reformatio in peius* barred the Board from reopening and deciding upon this question.

The Board disagrees, for the following reasons.

2.3.2 The doctrine of prohibition of *reformatio in peius* means that if the patent proprietor is the sole appellant against an interlocutory decision maintaining a patent in amended form, neither the Board of Appeal nor the non-appealing opponent may challenge the maintenance of the patent as amended in accordance with the interlocutory decision, so as to prevent a sole appellant from being placed in a worse position than it was in as a result of the contested decision (see

G 9/92 and G 4/93; Case Law of the Boards of Appeal ("CLB"), 11th edition 2025, V.A.3.1 and V.A.3.1.4).

In the present case, it follows from the principle of prohibition of *reformatio in peius* that the Board's consideration of feature M3.4 cannot prevent the contested patent from being maintained in the form found allowable by the opposition division (i.e. on the basis of auxiliary request 1), which contained claim 1 as granted in unamended form.

However, it is established case law of the boards of appeal that the prohibition of *reformatio in peius* relates solely to the legal effect of an appealed decision and cannot be construed to apply separately to each point or issue decided, and particularly not to the reasoning leading to the impugned decision (see CLB, V.A.3.1.1). Therefore, the Board is not precluded from applying its own consideration of feature M3.4 when examining dependent claims 5 to 7 of the patent as granted, which were found to be unallowable by the opposition division. In fact, it is inconceivable to assess claims 5 to 7 without considering feature M3.4, which is recited in claim 1, on which claims 5 to 7 depend. The appellant will not be placed in a worse position than it was in as a result of the contested decision even if, as set out below, the Board comes to the conclusion that the main request (patent as granted) is not allowable due to feature M3.4 in claim 1 and that the appeal must therefore be dismissed, thus maintaining unchanged the legal effect of the appealed decision.

The appellant's argument that national courts could be influenced to its detriment by the reasoning given in the Board's decision is not convincing either. The *ratio decidendi* of the decisions of the boards of appeal are not binding on national courts, which have judicial independence in their decisions.

2.3.3 These conclusions are in line with the established case law of the boards of appeal, in particular with decision T 659/07, which was cited by the appellant during the oral proceedings before the Board.

In decision T 659/07, the relevant board held that if the patent proprietor was the sole appellant, the patent *as maintained* by the opposition division could not be objected to by the board, either at the request of the respondent (opponent) or *ex officio*, even if the patent *as maintained* would otherwise have to be revoked on the ground that a feature present in both claim 1 *as granted* and claim 1 *as maintained* introduced added subject-matter contrary to Article 123(2) EPC (see Reasons point 5.6). However, that board did not consider itself precluded from assessing the feature in question again on appeal, finding that by virtue of this feature claim 1 *as granted* contravened the requirements of Article 123(2) EPC and concluding that the main request was therefore not allowable (see Reasons point 3.1). This corresponds to the present case: here too, the Board is prevented from revoking the patent *as maintained* by the opposition division (i.e. including claim 1 *as granted* but with dependent claims 5 to 7 *as granted* deleted), but not barred from finding that claims 5 to 7 *as granted*, which depend on claim 1, comprise added subject-matter in breach of Article 123(2) EPC by virtue of feature M3.4 in claim 1.

The appellant also referred to decision T 1626/11. In decision T 1626/11 (see Reasons point 1.1), the first ten claims of the main request were identical in wording to those of the second auxiliary request, which the opposition division had found to comply with the EPC. The board deciding on that case followed the earlier decisions T 856/92 and T 149/02 and concluded that, where the proprietor was the sole appellant, the entire set of claims considered by the opposition division to be EPC-compliant could no longer be examined by the board if it was part of another set of claims containing *additional* (*parallel*) claims, provided that the additional claims did not change the understanding of the claims. Thus, decision T 1626/11 concerned independent sets of claims. Similarly, the other decisions referred to in decision T 1626/11 under point 1.1.3, namely T 856/92 (see Reasons point 2.), T 149/02 (see Reasons point 2.), T 168/04 (see Reasons point 2.), T 1713/08 (see Reasons points 3 and 4.), T 722/10 (see Reasons point 2.) and T 428/12 (see Reasons point 2.2), also concerned constellations of independent claims. However, the present case clearly deviates from such constellations, since claims 5 to 7 are not *additional/independent* claims but are *dependent* on claim 1, so claim 1 cannot be disregarded when assessing dependent claims 5 to 7.

Therefore, the principle of prohibition of *reformatio in peius* does not bar the Board from considering the feature "suspended", and more generally feature M3.4, in the context of claim 1 as granted.

2.4 *Disclosure of "suspended" in the application as originally filed*

It is common ground that, in the application as originally filed, the term "suspended", and more generally the feature that the valve component is "suspended" within the support structure, is only disclosed explicitly in paragraph [0106]. This paragraph belongs to the section of the original application relating to a series of embodiments of a valve assembly 300 disclosed in relation to Figures 7 to 25 ("embodiments E1"), of which the paragraph describes particular embodiments (see first sentence).

The Board agrees with the respondent that, simply from the use of quotation marks around the term "suspended" in paragraph [0106], the person skilled in the art would realise that this term has a special meaning in the context of the original disclosure, different from the meaning put forward by the appellant. This is further suggested by the use of the synonym "floating", also in quotation marks, which indicates that the "suspension" of the valve component differs from its being secured within the support structure without any part sitting in its hypothetical path of movement out of the support structure, as asserted by the appellant.

Indeed, in the first two sentences of paragraph [0106], the "suspension" or "floating" of the valve component 304 within the support structure 302 is presented as resulting from the outer diameter of the fully expanded valve component being smaller than the inner diameter of the fully expanded support structure. This relationship between the outer diameter of the inner component (the valve component) and the inner diameter of the outer component (the support structure) creates

a radially and axially extending gap between the frames of the two components over the entire height of the valve component's frame, as described in the next sentence of the paragraph. Contrary to the appellant's argument, the phrase "for example" does not describe this gap as a possible example of how such a "suspension" can be concretely realised, but merely makes the point that the gap is particularly visible in Figures 12, 13 and 25, among others. The appellant's assertion that no such gap is visible in Figure 25, in contradiction of this explicit statement, is unconvincing, this figure clearly being of a schematic nature.

The person skilled in the art would therefore understand from paragraph [0106] that the "suspension" or "floating" of the valve component 304 within the support structure 302 described for these embodiments is inextricably linked to the presence of such a gap.

As mentioned in the Board's communication under Article 15(1) RPBA (see point 2.3.5), an annular sealing member 330 is not described until paragraph [0108], i.e. after the description in paragraph [0106] of the "suspension" of the valve component within the support structure with reference to the frame diameters and the gap. Therefore, the person skilled in the art would infer that, in the embodiments E1 in which the valve component is "suspended", the sealing member 330 merely secures the valve component 304 within the support structure 302 while achieving the aforementioned gap. However, contrary to the appellant's argument, the person skilled in the art would realise that it is not the mere engagement with the sealing member 330 that allows the valve component to be "suspended" within the support structure.

2.5 *Interpretation of feature M3.4 in the claims as granted*

The parties agree, as does the Board, that the term "so that" in feature M3.4 of claim 1 as granted expresses a causal relationship, i.e. the person skilled in the art would infer from the wording of claim 1 as granted that the valve component is suspended within the support structure by virtue of its engagement with the inner peripheral portion of the sealing member after the valve component has been radially expanded upon deployment.

Contrary to the appellant's argument and the opposition division's view in the decision under appeal (see Reasons 2.1.4.3), a gap between the frames of the valve component and support structure over the entire height of the valve component's frame does not implicitly follow from the wording of claim 1 as granted. As stated above, claim 1 as granted merely attributes the suspension of the valve component to its engagement with the sealing member. However, the wording of claim 1 as granted does not rule out the possibility that the valve component might additionally engage the support structure at some other location, with the consequence that there would be no gap extending between the frames of the two components over the entire height of the valve component's frame. This is in particular the case if the term "suspended" in feature M3.4 of claim 1 as granted is interpreted as put forward by the appellant.

The further specification of the sealing member as defined in claims 5 to 7 as granted does not paint a different picture. None of these claims defines a gap between the frames of the valve component and support

structure over the entire height of the valve component's frame - or a corresponding requirement for the diameters of these components. Furthermore, the feature that the valve component is configured to be deployed within the tubular, inner sleeve does not rule out the possibility that the valve component is in contact with the support structure outside the sealing member, either, as can be derived from the cross-sectional sketch on page 18 of the statement of grounds of appeal, reproduced above.

2.6 Conclusion

It is common ground that claims 5 to 7 as granted are directed to the series of embodiments disclosed in relation to Figures 26 to 33 ("embodiments E2").

Even if it is conceded, to the benefit of the appellant, that the disclosure of the "suspension" of the valve component in paragraph [0106] of the original application in relation to particular embodiments E1 also applies to the embodiments E2 - which the respondent disputes - it follows from the considerations above that the omission from claims 5 to 7 of a gap between the frames of the valve component and support structure over the entire height of the valve component's frame - or a corresponding requirement for the diameters of these components - constitutes an intermediate generalisation of the original disclosure, in breach of Article 123(2) EPC.

Contrary to the appellant's argument, it is irrelevant that a gap over the entire height of the valve component's frame is defined in dependent claims 5 and 8 as originally filed. The question is not whether the particular sealing member defined in claim 5 as

granted can be specified without also specifying such a gap, but rather whether the "suspension" of the valve component as defined by feature M3.4, which claims 5 to 7 include through their dependence on claim 1 as granted, was originally disclosed independently of the presence of such a gap (or a corresponding requirement for the diameters of the frame).

Since claims 5 to 7 as granted do not comply with Article 123(2) EPC, the patent cannot be maintained as granted, as concluded by the opposition division in the decision under appeal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

G. Magouliotis

The Chairman:

M. Alvazzi Delfrate



Decision electronically authenticated