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**Datasheet for the decision
of 24 October 2023**

Case Number: T 2820/18 - 3.2.01

Application Number: 15153122.5

Publication Number: 2901966

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

Heart valve

Patent Proprietor:

Edwards Lifesciences CardiAQ LLC

Opponents:

1. Müller-Gürtner, Marco
2. Neovasc Tiara Inc.

Headword:

Relevant legal provisions:

EPC Art. 76(1), 123(2), 83, 87, 54, 56

Keyword:

Divisional application - subject-matter extends beyond content of earlier application (no)

Amendments - extension beyond the content of the application as filed (no)

Sufficiency of disclosure - enabling disclosure (yes)

Priority - identity of invention (no) - validity of priority date (no)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 2820/18 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 24 October 2023

Respondent: Edwards Lifesciences CardiAQ LLC
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
12 November 2018 concerning maintenance of the
European Patent No. 2901966 in amended form.**

Composition of the Board:

Chairman	G. Pricolo
Members:	M. Geisenhofer
	O. Loizou

Summary of Facts and Submissions

- I. The appeals were filed by the patent proprietor (Edwards Lifesciences Corporation) and opponent 2 (Neovasc Tiara Inc.) against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 1 then on file, the patent in suit met the requirements of the EPC.
- II. The opposition division decided that
- the subject-matter of the claims of this request neither extended beyond the content of the application as filed nor beyond the content of the earlier application published as WO 2010/037141 A1;
 - the priority of document
A1 WO 2010/121076 A2
was not valid such that this document did not form prior art for the patent in suit;
 - the subject-matter of the claims of this request was novel over document
A2 US 2008/0071369 A1;
 - the subject-matter of the claims of this request was inventive over a combination of document A2 with the common general knowledge or with any of documents
A4 WO 2004/016149 A2 or
A5 US 2003/01631094 A1;
 - the subject-matter of the claims of this request was also inventive over a combination of document
A6 presentation of J. Brent Ratz:
"CardiAQ Valve Technologies -
Innovations in Heart Valve Therapy"
with the common general knowledge, document A2 or
document
B1 WO 2008/013915 A2.

- III. Oral proceedings were held before the Board.
- (a) The patent proprietor withdrew their appeal and hence became respondent.
 - (b) The remaining appellant (opponent 2) did not participate in these oral proceedings as announced in their letter dated 21 September 2023.
 - (c) Opponent 1 (party as of right) neither participated in the oral proceedings nor filed submissions during the appeal proceedings.
 - (d) The appellant (opponent 2) requested in writing before the oral proceedings that the decision under appeal be set aside and the patent be revoked.
 - (e) The respondent (patent proprietor) requested that the appeal be dismissed, and withdrew all other requests.
- IV. Independent claim 1 of the request maintained by the opposition division reads as follows:
- "A frame (500) for a replacement mitral valve (600) wherein the frame (500) can be expanded from a compacted state to an expanded state and comprises: a first end (538), a second end (539), a foreshortening portion (520) and a non-foreshortening portion (510); wherein the non-foreshortening portion (510) comprises a plurality of longitudinal struts (530) having first and second ends (532, 534) and extending from the first end (538) toward the second end (539) of the frame (500), with the longitudinal struts (530) terminating at a transition (540) from the non-foreshortening portion (510) to the foreshortening portion (520); and a plurality of first anchors (550) extending radially outwardly from the non-foreshortening portion (510) of the frame (500) when the frame (500) is in the expanded state;*

and a plurality of second anchors extending from the foreshortening portion of the frame wherein the frame (500) is expandable to bring the second anchors (570) closer to the first anchors (550) to grasp native mitral annulus therebetween characterized in that the plurality of first anchors (550) comprising a plurality of circumferentially expansible struts (524) that connect to one another at free apices (528) arranged between connected apices (526) at which the struts (524) intersect with the longitudinal struts (530); wherein the plurality of second anchors (570) each extend radially outwardly from the foreshortening (520) portion of the frame (500) and toward the first end (538) of the frame (500) when the frame (500) is in the expanded state; and wherein the frame (500) has a D-shape cross section."

- V. The appellant's arguments can be summarized as follows:
- (a) Claim 1 of the request maintained by the opposition division extended both beyond the content of the earlier application and beyond the application as originally filed.
 - (b) The invention according to claim 1 was not disclosed in the patent in a manner sufficiently clear and complete for a skilled person to carry it out.
 - (c) The subject-matter of claim 1 of the request maintained by the opposition division was not new over A1 and A2.
 - (d) The subject-matter of claim 1 was not inventive when starting either from document A2 or from document A6 as closest prior art.

- VI. The respondent's arguments can be summarized as follows:
- (a) Claim 1 of the request maintained by the opposition division was based on the embodiment shown in figure 11 and described in paragraphs [0100] - [0103] of both the earlier application and the application as originally filed.
 - (b) The skilled person derived sufficiently clear and complete information from the patent in suit allowing to carry out the invention.
 - (c) Document A1 did not form prior art due to its invalid priority from document
A1P US 61/169 367.
 - (d) Document A2 was not novelty destroying since it lacked a D-shape.
 - (e) The subject-matter of claim 1 was neither obvious when starting from document A2 nor when starting from document A6.

Reasons for the Decision

Amendments (Articles 76(1) and 123(2) EPC)

1. The opposition division decided that the subject-matter of claim 1 of the maintained request neither extends beyond the content of the earlier application WO 2010/037141 A1 as filed, nor that of the application as originally filed.
- 1.1 It is undisputed that the amendments to claim 1 of the request maintained by the opposition division are neither based on the claims of the application as originally filed nor on the claims of the earlier application WO 2010/037141 A1 as filed.

- 1.2 The opposition division held that the embodiment shown in figure 11 and further described in paragraphs [0100] - [0103] of the originally filed description provided basis for the subject-matter of claim 1.

The description of the originally filed application is identical to the description of the earlier application WO 2010/037141 A1 such that this argument applies both to the question of amendments with regard to the earlier application and with regard to the application as originally filed.

- 1.3 The appellant disagreed and argued (see statement of grounds of appeal, page 15, first to fifth paragraph) that the embodiment comprised the following features that were inextricably linked to the features defining the claimed frame:

- (a) the foreshortening portion comprises a ring of generally diamond-shaped cells connected to one another at connectors;
- (b) the foreshortening portion connects to the non-foreshortening portion at eyelets;
- (c) the non-foreshortening portion includes three rings of undulating circumferentially expansible struts; and
- (d) the first anchors are formed by struts of the third ring that are extending radially outwardly.

Since these features were omitted, the maintained claim was based on an unallowable intermediate generalisation of what was disclosed in the originally filed description.

- 1.3.2 With regard to feature (a), the Board notes that paragraph [0076] of the description explains that although diamond-shaped cells are used in the embodiments shown in the application, other designs of

the foreshortening portion are possible ("*it is to be understood that other configurations can be employed*").

Contrary to the appellant's argument, the diamond-shaped cells of the foreshortening portion according to feature (a) are hence not inextricably linked to the structure and/or function of the foreshortening portion but other designs could be used.

- 1.3.3 The same applies to feature (c): paragraph [0072] explains that the non-foreshortening portion comprises a plurality of rows or rings, whereby more or fewer rings than the three rings used in the embodiment can be employed to accomplish the purposes of the stent frame.

The three rings are hence not inextricably linked to the function of the non-foreshortening portion.

- 1.3.4 With regard to feature (b), the Board notes that paragraph [101] indeed cites eyelets formed at the second ends of each longitudinal strut where the non-foreshortening portion is connected to the foreshortening portion.

Paragraph [0101] does not mention a function of these eyelets but it is evident that the eyelets do not influence the frame's behaviour during deployment. In particular, the eyelets have no functional or structural relationship with the shortening and non-shortening portions of the frame or the anchors grabbing the annulus of the native valve. Feature (b) is hence not inextricably linked to the features of claim 1 either.

1.3.5 Feature (d) is partly contained in claim 1 since the characterising portion of claim 1 requires the first anchors to comprise circumferentially expansible struts that are connected to one another at free apices, these anchors being arranged between connected apices at which the struts intersect with the longitudinal struts. The circumferentially expansible struts hence build a ring of struts forming together with the longitudinal struts the non-foreshortening portion.

The only omitted information is hence that this ring is the third ring of a plurality of rings.

As set out above with regard to feature (c), it is irrelevant for the function of the non-foreshortening portion whether three rings are present or a number of rings different from three.

1.3.6 None of the features identified by the appellant is hence inextricably linked to the features of claim 1 of the request maintained by the opposition division. Omitting these features is hence allowable.

1.4 The appellant further argues that the D-shape of the frame was not disclosed in the context of the embodiment of figure 11 but only when describing the embodiment of figure 4A/4B in paragraph [0070].

It is to be noted that the embodiment of figure 4A/4B does not have a D-shape but a "*generally circular cross section*" (see paragraph [0070]). However, this passage further explains that "in other embodiments stents can have a non-circular cross section, such as a D-shape". This teaching is not restricted to the embodiment of figure 4A/4B but to any other embodiment including the one of figure 11.

- 1.5 All amendments criticised by the appellant are hence allowable under Articles 76(1) EPC and 123(2) EPC.

Disclosure of invention (Article 83 EPC)

2. The invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

- 2.1 The appellant argued that the patent did not disclose how the D-shape of the claimed frame can be obtained.

- 2.2 A person skilled in the art knows suitable techniques to shape a frame consisting of a wire structure from their common general knowledge: the frame could be brought into the desired D-shape by either deforming individual struts of the wire structure, or by pressing the entire structure onto a mould having the desired D-shape. It is not a requirement for sufficiency of disclosure to explain generally known standard techniques in the patent. Accordingly, the skilled person can carry out the invention in accordance with the claims of the request maintained by the opposition division.

Novelty (Article 54 EPC)

3. The opposition division held that claim 1 of the maintained request is novel over document A2. Document A1 is not relevant for novelty since it does not form part of the prior art.

- 3.1 Document A1 is the publication of a PCT application filed on 15 April 2010 and claiming priority from document A1P which was filed on 15 April 2009.
- 3.1.1 The opposition division came to the conclusion that the priority of A1 is not valid such that the relevant date of A1 is the filing date, i.e. 15 April 2010. This date though is after the relevant date of the patent in suit (irrespective of whether the filing date or the priority date of the patent is the relevant date) such that A1 is not prior art for the patent in suit.
- 3.1.2 The appellant disagreed and argued that all features of claim 1 can be found both in A1P and A1.
- 3.1.3 This is, however, not the correct standard to be applied.

In accordance with Article 87 EPC, an application is only entitled to priority in respect of the same invention as was disclosed in the alleged priority document. The term "the same invention" has to be interpreted narrowly and in a manner equating it to "the same subject-matter" (see Case Law of the Boards of Appeal, II-D-3.1.1).

It hence has to be examined whether the subject-matter disclosed in A1 is also already disclosed in A1P, i.e. whether the information provided by figures 2A and 2B taken in combination with paragraphs [0035] - [0045] referring to these figures is already disclosed in A1P.

- 3.1.4 Figures 2A and 2B of A1 disclose a plurality of details that are not present in the corresponding figure 13 of A1P. Figure 13 is just a rough sketch without any details such as the eyelets between foreshortening and

non-foreshortening portion, the eyelets on the first anchors or the geometry of the curved, first anchors.

A passage describing the particular design of the first anchors similarly to paragraphs [0041] and [0043] of A1 is not present in A1P either.

On the contrary, paragraph [00046] of A1P explains that in Option B the anchors on the non-foreshortening portion only extend downward from the supporting struts, whereas according to paragraph [0041] of A1 the apical anchors 80 flare radially outwardly. The embodiment according to option B of A1P hence cannot provide disclosure for the embodiment shown in figures 2A and 2B of A1.

Option A of A1P in turn only discloses "a small anchor feature" that is attached to the end of the longitudinal strut and not - as required by paragraph [0041] of A1 - at the free apices of the third ring where two circumferential struts meet. The embodiment according to option A of A1P hence cannot provide disclosure for the embodiment shown in figures 2A and 2B of A1 either.

3.1.5 The Board therefore concurs with the opposition division's decision that the embodiment of figures 2A and 2B of A1 is not entitled to the priority of A1P. The relevant date is thus the filing date on 15 April 2010, the embodiment of figures 2A and 2B in document A1 hence do not form prior art for claim 1 of the patent in suit.

3.2 With respect to document A2, which undisputedly forms prior art under Article 54(2) EPC, the opposition division held that the replacement valve of A2 is

neither D-shaped nor suitable for use as a replacement valve of a mitral valve.

- 3.2.1 The appellant disagreed and argued that use for substituting a mitral valve was disclosed in paragraph [0636] of A2, and that the frame shown in figure 8A of A2 had a D-shaped cross-section, whereby this term was to be broadly construed.
- 3.2.2 The Board agrees that paragraph [0636] discloses the use of the replacement valve of A2 for a mitral valve.
- 3.2.3 However, figure 8A shows in the Board's view an irregularly shaped frame but not a D-shaped frame. A D-shaped frame would require an approximately linear flank combined with a curved flank attached to the ends of the linear flank. Such a geometry is not apparent in figure 8A.
- 3.2.4 The subject-matter of claim 1 of the maintained request is hence novel over A2.

Inventive step (Article 56 EPC)

4. The opposition division came in their decision to the conclusion that starting from document A2 as closest prior art, claim 1 is not rendered obvious.
 - 4.1 The appellant disagreed and argued that the skilled person knew both from expert knowledge and from documents A4 and A5 that stent frames could have a D-shape in cross-section. It hence was obvious to use such a D-shape also in A2.

4.2 The Board notes (as explained above with regard to novelty) that A2 discloses in figure 8A a frame having an irregular shape. Using a shape for the frame that does not concur with the the annulus' shape would result in an unnecessary deformation of the replacement valve provoking a reduced lifetime due to an increased wear. Furthermore, a non-coincident shape would promote paravalvular leakage.

4.3 Albeit D-shaped frames are known in the art (e.g. from A4 and A5), the skilled person would not consider replacing the irregularly shaped frame of A2 by a D-shaped frame since the D-shaped frame would not concur with the shape of the annulus of the native valve, at least to a smaller extend compared to the frame used in A2.

Claim 1 is hence not rendered obvious when starting from A2.

5. The opposition division further held that claim 1 is also inventive over a combination of A6 either with the common general knowledge, or with the teaching of A2 or B1.

5.1 It is undisputed that the subject-matter of claim 1 differs from the frame known from document A6 in that it has a D-shape.

It is also undisputed that the first anchors of claim 1 extend from the the circumferentially expansible struts of the non-foreshortening portion whereas they extend in A6 from the end of the longitudinal struts.

5.2 The subject-matter of claim 1 hence differs from the frame known from A6 in that

- (i) the first anchors comprise a plurality of circumferentially expansible struts that connect to one another at free apices arranged between connected apices at which the struts intersect with the longitudinal struts; and
- (ii) the frame has a D-shaped cross section.

5.2.2 With regard to distinguishing feature (i), the appellant argued that no technical effect was mentioned in the patent in suit related to the particular choice of arranging the first anchors at the free apices formed by the circumferentially expansible struts such that this feature did not contribute to an inventive step.

5.2.3 The Board does not agree for the followings reasons:

- (a) The location of attachment of the first anchors must be considered as a technical feature and cannot be disregarded. The place of the anchor's attachment obviously contributes to the mode of operation of the frame and hence has a technical effect: whether the first anchors are attached to the longitudinal struts or to the circumferentially expansible struts will inevitably influence their behaviour during deployment but also their mechanical stiffness.
- (b) The fact that no technical effect is mentioned in the description is not to be confused with the situation where a feature indeed has no effect.
- (c) It is up to the appellant to demonstrate that the subject-matter claimed in the patent in suit is rendered obvious by the prior art. However, as long

as there is no teaching available in the prior art that would indeed teach the skilled person to amend the place of attachment of the first anchors in A6 to comply with feature (i), feature (i) is not rendered obvious.

The appellant does not provide any argument with regard to where such a teaching could be derived but only alleges that feature (i) is not inventive.

The Board hence considers feature (i) to be not rendered obvious.

- 5.2.4 Due to feature (i) alone, claim 1 is inventive. It hence can remain undecided whether the skilled person would replace the circular shape of the stent known from A6 by a D-shape to comply with feature (ii).
- 5.3 The Board hence also follows the opposition division's decision with regard to inventive step.
6. The decision of the opposition division is thus to be confirmed.
7. Since at the oral proceedings, the patent proprietor withdrew its appeal before the decision was announced their appeal fee is to be reimbursed at 25% under Rule 103(4) (a) EPC.

Order

For these reasons it is decided that:

The appeal of the opponent 2 is dismissed.

The Registrar:

The Chairman:



A. Voyé

G. Pricolo

Decision electronically authenticated