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Datasheet for the decision of 31 March 2023

Case Number: T 1593/18 - 3.2.08

Application Number: 11005559.7

Publication Number: 2399550

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
System for replacing a deficient native heart valve

Patent Proprietor:
Edwards Lifesciences PVT, Inc.

Opponents:
Boston Scientific Corporation
Beetz, Rainer
Symetis SA
BIOTRONIK AG
St. Jude Medical, LLC/Abbott Medical GmbH/St. Jude Med UK Ltd/SJM Int, Inc./SJM Coord Center BVBA/ St. Jude Med S.C., Inc./Teschner, Michael

Relevant legal provisions:
RPBA 2020 Art. 12(2)
EPC Art. 56, 76(1), 84, 83

Keyword:

Appeal case directed to facts on which decision was based (yes)
Sufficiency of disclosure - (yes)
Claims - clarity (yes)
Divisional application - added subject-matter (no)
Inventive step - (yes)

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Boards of Appeal

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Case Number: T 1593/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 31 March 2023

Appellant: (Patent Proprietor)	Edwards Lifesciences PVT, Inc. One Edwards Way Irvine, CA 92614 (US)
Representative:	Alt, Michael Bird & Bird LLP Maximiliansplatz 22 80333 München (DE)
Respondent 3: (Opponent 2)	Beetz, Rainer Riemergasse 14 1010 Vienna (AT)
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Representative:	Biotronik Corporate Services SE Corporate Intellectual Property Sieversufer 7-9 12359 Berlin (DE)
Respondent 2: (Opponent 5)	St. Jude Medical, LLC/Abbott Medical GmbH/St. Jude Med UK Ltd/SJM Int, Inc./SJM Coord Center BVBA/ St. Jude Med S.C., Inc./Teschner, Michael One St. Jude Medical Drive/Helfmann-Pk/Banbury Rd St. Jude Med Dr/Da Vincilaan/Bee Cave Rd/Sinclair St. Paul, MN 55117/65760 Eschborn/Stratford CV37 7GX/St. Paul, MN 55117/1935 Zaventem Austin, TX 78746/Westfield, NJ 07090 (US)

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 18 June 2018 revoking European patent No. 2399550 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: G. Buchmann
C. Schmidt
M. Foulger
F. Bostedt

Summary of Facts and Submissions

I. With the decision posted on 18 June 2018, the opposition division revoked the European patent No. 2 399 550.

II. The patent proprietor filed an appeal against this decision.

III. Oral proceedings took place before the Board on 31 March 2023.

IV. At the end of the proceedings, the appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of auxiliary request 1 as filed with letter dated 12 February 2018.

Respondent 1 (Biotronik) and respondent 2 (St Jude Medical) requested that the appeal be dismissed.

Respondent 3 (Rainer Beetz) did not make any submissions during the appeal proceedings.

Respondents 4 and 5 (Boston Scientific Corporation and Symetis SA) withdrew their oppositions with letter of 15 January 2019. They ceased to be parties to the proceedings.

V. Respondents 1 and 3 did not attend the oral proceedings. The proceedings were continued without them according to Rule 115(2) EPC.

VI. In the present decision, reference is made to the following documents.

D3 WO 00/44313 A1

D20a PowerPoint presentation "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case", by Alain Cribier et al. held at the TCT 2002 symposium on September 27, 2002 in Washington, DC;

D29 US 4,172,295 B

VII. Claim 1 of auxiliary request 1 reads as follows.

Additions and ~~deletions~~ compared to claim 1 of the earlier application (WO 03/047468 A1) are indicated. The numbering of the features was added by the Board.

1
A system for cardiac implantation of a valve prosthesis, comprising:
2
a catheter; and
3
a radially expandable valve prosthesis (20) ~~device suitable for implantation in body ducts, the device~~ comprising:
3.1
~~a support stent comprised of a deployable construction~~ an expandable annular support frame (22)
3.1.1
adapted to be initially crimped in a narrow configuration ~~suitable~~ for catheterization through ~~the~~ a body duct to ~~the~~ a target location,

3.1.2

~~the support stent provided with~~ the annular support frame (22) comprising a plurality of longitudinally rigid support beams (23) of fixed length each provided with a plurality of bores,

3.1.3

~~and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state~~ the expandable support frame configured to be expanded to an expanded configuration in the target location; and

3.2

a tricuspid leafed-valve assembly (28) comprising a

3.2.1

~~flexible~~ conduit having an inlet (24) end and an outlet (26),

3.2.2

made of pliant material arranged so as to present collapsible walls at the outlet (26),

3.2.3

wherein the valve assembly (28) is made of pericardium,

3.2.4

and ~~attached to the support beams providing collapsible slack portions of the conduit at the outlet~~ wherein the attachment of the valve assembly (28) to the frame (22) is facilitated by the support beams (23) to which the valve assembly is stitched with thread or fiber through the bores of the support beams (23);

4

wherein when flow is allowed to pass through the valve prosthesis (20) ~~device~~ from ~~the~~ an inlet to ~~the~~ an outlet the valve assembly (28) is kept in an open position,

5

whereas a reverse flow is prevented as the collapsible ~~slack portions~~ walls of the valve assembly (28)

collapse inwardly for providing blockage to the reverse flow,

6

and wherein the outlet (26) is tapered with respect to the inlet (24).

VIII. The arguments of the appellant can be summarised as follows.

Admittance of auxiliary request 1

Auxiliary request 1 had been filed during opposition proceedings and was dealt with in the impugned decision. Therefore, it had to be admitted into the proceedings.

Sufficiency of disclosure - Article 83 EPC

In order to carry out the invention according to claim 1, the person skilled in the art could select a suitable catheter from existing catheters without undue burden.

Clarity - Article 84 EPC

A skilled reader of the claim would understand Feature 6 according to which "the outlet (26) is tapered with respect to the inlet (24)" in the way it was intended, namely that the diameter of the outlet was smaller than the diameter of the inlet.

Amendments - Article 76(1) EPC

Feature 2 was based on page 2 of the earlier application.
Feature 3.1.2 was mainly based on claim 1 or claim 42

of the earlier application.
Feature 6 was based on claim 68 of the earlier application.

Inventive Step - Article 56 EPC

At least Feature 6 according to which "the outlet (26) is tapered with respect to the inlet (24)" involved an inventive step.

IX. The arguments of the respondents can be summarised as follows.

Admittance of auxiliary request 1

Auxiliary request 1 should not be admitted because claim 1 contained features added from the description which had neither been searched nor examined.

Sufficiency of disclosure - Article 83 EPC

The patent did not contain sufficient information for carrying out a catheter suitable for a self-expandable valve prosthesis according to claim 1.

Clarity - Article 84 EPC

Feature 6 according to which "the outlet (26) is tapered with respect to the inlet (24)" lacked clarity.

Amendments - Article 76(1) EPC

Features 2, 3.1.2 and 6 contained subject-matter which extended beyond the disclosure of the earlier application.

Inventive Step - Article 56 EPC

The subject-matter of claim 1 did not involve an inventive step starting from D3 in combination with either the common general knowledge or with D29.

Reasons for the Decision

1. Admittance of auxiliary request 1

Respondent 2 requested that auxiliary request 1 not be admitted. Claim 1 contained features added from the description. These features had neither been searched nor examined. This was in contrast to G 1/84 according to which, "the opposition procedure is not designed to be, and is not to be misused as, an extension of examination procedure" (G 1/84, point 9).

However, auxiliary request 1 was filed during the opposition proceedings before the final date set by the opposition division according to Rule 116(1) EPC and was admitted by the opposition division. Additionally, the impugned decision was based, among others, on auxiliary request 1.

Therefore, auxiliary request 1 is part of the appeal proceedings according to Article 12(2) RPBA 2007.

The fact that a feature was taken from the description cannot be seen per se as a reason for not admitting a request, not even when taking G 1/84, point 9 into consideration, which does not relate to the topic of admittance.

2. Sufficiency of disclosure - Article 83 EPC

Respondent 2 raised an objection according to which the patent did not contain sufficient information for carrying out a catheter suitable for a self-expandable valve prosthesis. Such a catheter was not explicitly described in the patent.

Such catheters were, however, well known in the art for many years before the priority date of the patent. Additionally, it is not necessary for all the details of an invention to be specifically described in order for a disclosure to be sufficient. In the present case, there are no requirements specified for the catheter except that it must be suitable for implantation of a self-expandable heart valve prosthesis. The person skilled in the art is capable of selecting a suitable catheter from existing catheters without undue burden.

Therefore, the invention specified in claim 1 of auxiliary request 1 is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

3. Clarity - Article 84 EPC

Respondent 2 argued that the Feature 6, according to which "the outlet (26) is tapered with respect to the inlet (24)", was not clear within the meaning of Article 84 EPC. The inlet and the outlet were two-dimensional entities which could not be "tapered". This property was only applicable to three-dimensional bodies, for example the introducing tube shown in figure 26c, or the conduit of the valve assembly ("tapered tube" mentioned on page 44, first full paragraph). Therefore, the reader of claim 1 would not

understand what was meant by said feature.

The claim does not however define the inlet and/or the outlet itself as being tapered. In contrast, it requires the outlet to be tapered with respect to the inlet. Even if this wording could be seen as being uncommon, the claim is to be interpreted in a manner as it would be understood by the person skilled in the art. Taking into account the wording of the whole claim, in particular Feature 3.2.1, according to which the inlet and the outlet form part of a conduit, the Board considers that the skilled person would understand that the conduit has a tapered shape between the inlet and the outlet.

Respondent 2 further argued that it was not defined in which state of the prosthetic valve the taper should be present.

Since the conduit of the valve assembly is made from pliable material, it is self-evident that this definition is valid for the conduit in its most expanded state.

Therefore, the subject-matter of claim 1 fulfils the requirements of Article 84 EPC.

4. Amendments - Article 76(1) EPC

4.1 Feature 6, which was added to claim 1 in auxiliary request 1, is disclosed verbatim in claim 68 of the earlier application. Claim 68 depends on claim 42 which specifies the valve prosthesis in general terms.

Respondent 2 argued that the tapered shape was only achieved by the "long bars 561 that are attached to the

pericardium in an angular way" described on page 44, first full paragraph. The omission of this technical context in the amended claim represented an intermediate generalisation of the original disclosure.

The Board considers that page 44 describes a method of producing a preferred embodiment of the tapered conduit. The tapered shape in general terms is already disclosed in claim 68 of the earlier application.

Therefore, Feature 6 does not contravene Article 76(1) EPC.

4.2 Respondent 2 argued that the catheter (Feature 2) was not originally disclosed by the earlier application in the general sense as claimed. Claim 1 encompassed catheters which were suitable for both self-expanding and balloon-expandable support frames. Only page 2 of both the earlier and divisional application mentioned a catheter in general. This part of the description, however, was already part of the general description of the priority document which only encompassed balloon-expandable support frames and balloon catheters. Therefore, it could only refer to catheters for balloon-expandable support frames. The embodiments having a self-expandable support frame had been added only in the earlier application. The addition of these embodiments in the detailed description did not however change the meaning of said passage in the general description concerning the catheter.

The Board notes that for assessment of the conformity with Article 76(1) EPC, it is only necessary to compare the content of the divisional application with the disclosure of the earlier application. The priority document is of no relevance in this respect. Regarding

the earlier application as originally filed, the Board considers that the general description of the invention must be taken as referring to all embodiments of the invention mentioned in the detailed description, i.e. both self-expandable and balloon-expandable support frames.

Therefore, the earlier application as originally filed discloses on page 2 a catheter in general terms which is suitable for implantation of all the described embodiments of valve prostheses, self-expandable and balloon-expandable, which is the same as required in Feature 2 of claim 1.

It follows that Feature 2 does not contravene Article 76(1) EPC.

4.3 A further objection of respondent 2 was that Feature 3.1.2, according to which "the annular support frame (22) compris[es] a plurality of longitudinally rigid support beams (23) of fixed length each provided with a plurality of bores", was not disclosed in the earlier application in these general terms. The feature should not only specify that the beams are of a fixed length but that the beams should additionally at least be defined as having the same length as the frame.

However, the part of the feature comprising the beams of fixed length was already present in claims 1 and 42 of the earlier application, which did not address the length of the beams. Concerning the part of the feature specifying the bores, respondent 2 did not present any convincing argument as to why the presence of the bores was linked to the fact that the beams had the same length as the support frame. Therefore, the plurality of bores can be added to the claim independently from

the length of the beams without violating Article 76(1) EPC.

It follows that Feature 3.1.2 does not contravene Article 76(1) EPC.

5. Inventive Step - Article 56 EPC

5.1 Starting from D3

Respondent 2 raised an objection that the subject-matter of claim 1 was not inventive with respect to D3 in combination with common general knowledge or in combination with D29.

D3 discloses:
1
A system for cardiac implantation of a valve prosthesis (see pages 22-23 and Figure 17C), comprising:
2
a catheter (page 23, line 9); and
3
a radially expandable valve prosthesis comprising:
3.1
an expandable annular support frame (90)
3.1.1
adapted to be initially crimped in a narrow configuration for catheterization through a body duct to a target location (page 23, lines 1-2),
(3.1.2)
the annular support frame (90) comprising a plurality of longitudinally rigid support beams (struts 92) of fixed length (page 23, lines 17-18) ~~each provided with a plurality of bores,~~

3.1.3
the expandable support frame configured to be expanded to an expanded configuration in the target location (page 23, lines 2-4); and
3.2
a tricuspid leafed-valve assembly (80) comprising a
3.2.1
conduit (81) having an inlet end and an outlet,
3.2.2
made of pliant material arranged so as to present collapsible walls at the outlet,
~~**3.2.3**~~
~~wherein the valve assembly (28) is made of pericardium,~~
(3.2.4)
and wherein the attachment of the valve assembly (80) to the frame (90) is facilitated by the support beams (92) to which the valve assembly is stitched with thread or fiber ~~through the bores of the support beams~~;
4
wherein when flow is allowed to pass through the valve prosthesis from an inlet to an outlet the valve assembly is kept in an open position,
5
whereas a reverse flow is prevented as the collapsible walls of the valve assembly collapse inwardly for providing blockage to the reverse flow.

It is common ground that D3 does not disclose
- Feature 3.2.3 concerning the valve assembly being made from pericardium and
- Features 3.1.2 and 3.2.4, concerning the bores in the support beams and fixation of the valve assembly by stitching through the bores.

For the purpose of the present decision there was no need to establish whether or not these features

contribute to an inventive step.

It was disputed between the parties whether D3 also implicitly disclosed Feature 6 according to which "the outlet (26) is tapered with respect to the inlet (24)."

According to respondent 2, the valve leaflets had to contact each other along straight coaptation lines in order to close the valve properly. The length of the two straight coaptation lines extending from one commissure post over the centre of the valve to another commissure post, was geometrically shorter than the circular arc formed by the support frame between the two commissure posts. Therefore, it was inevitable that the outlet of the conduit made of pliant material had a smaller circumference than the inlet which was completely attached to the frame. From that, respondent 2 concluded that D3 implicitly disclosed feature 6.

In order to provide a sufficient closure of the valve, it does not go without saying that the upper edges of the valve leaflets must contact each other along straight lines. On the contrary, it is possible that the leaflets form a wavy contact line. Reference is made, for example, to page 5 of D20a which shows a valve prosthesis having such a geometry.

It is correct that Figure 17C of D3 shows a "tissue valve" having straight contact lines. But this is not a direct and unambiguous disclosure of the geometry because the figure is schematic, and it is possible that the lines were drawn straight to facilitate the drawing of the figure.

Therefore, D3 does not disclose that the outlet of the conduit of the valve assembly is tapered with respect

to the inlet (Feature 6).

5.2 For the above reasons, the subject-matter of claim 1 differs from the disclosure of D3 at least by Feature 6.

This feature has the technical effect of preventing the leaflets from contacting the support frame in their open position. This avoids damage to the leaflets.

5.3 Inventive Step in view of common general knowledge

Respondent 2 argued that the person skilled in the art would prefer straight coaptation lines over undulated coaptation lines of the leaflets in order to avoid valve leakage. The appellant provided, however, no evidence that there was a well known correlation between the shape of the coaptation lines and a possible leakage of the valve.

Therefore, when starting from D3, the common general knowledge does not suggest that the prosthetic valve is provided with a valve assembly in which "the outlet (26) is tapered with respect to the inlet (24)."

For these reasons, the subject-matter of claim 1 of auxiliary request 1 involves an inventive step over D3 in combination with the common general knowledge.

5.4 Inventive step in view of D29

D29 discloses (column 4-5) a surgically implanted heart valve. It comprises a stent (2) made from e.g. titanium (column 4, line 51) which has three posts (6) with sewing holes (32, 34, 36). Leaflets of bovine pericardium (column 5, line 2) are stitched to the

posts through the bores (column 5, lines 21-23).

The prosthesis of D29 does not comprise a support frame which may contact the valve leaflets when being open. Therefore, D29 cannot provide any teaching of how to avoid such a contact.

For this reason, the subject-matter of claim 1 of auxiliary request 1 involves an inventive step over D3 in combination with D29.

6. Claim 1 of auxiliary request 1 fulfils the requirements of the EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent on the basis of claims 1 to 15 of auxiliary request 1, filed with letter dated 12 February 2018 and a description to be adapted.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated