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**Datasheet for the decision
of 27 September 2023**

Case Number: T 2674/19 - 3.2.01

Application Number: 15201540.0

Publication Number: 3025681

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

COLLABSIBLE AND RE-EXPANDABLE PROSTHETIC HEART VALVE CUFF
DESIGNS AND COMPLEMENTARY TECHNOLOGICAL APPLICATIONS

Patent Proprietor:

St. Jude Medical, LLC

Opponents:

Boston Scientific Corporation
Symetis SA
Edwards Lifesciences Corporation
BIOTRONIK AG

Headword:

Relevant legal provisions:

EPC Art. 54

Keyword:

Novelty - (no)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2674/19 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 27 September 2023

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
16 September 2019 concerning maintenance of the
European Patent No. 3025681 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: M. Geisenhofer
A. Jimenez

Summary of Facts and Submissions

I. Appeals were filed by the patent proprietor, opponent 1 and opponent 3 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. In particular, the opposition division decided that

(a) the subject-matter of the main request (patent as granted) extended beyond the content of the earlier application PCT/US2009/004094; and

(b) the subject-matter of auxiliary request 1 *inter alia* was novel over document

E4 US 2007/0073387 A1.

III. Oral proceedings were held before the Board.

(a) Opponent 4 did not attend the oral proceedings as announced with letter dated 7 July 2023.

(b) During oral proceedings, the appellant-patent proprietor withdrew their appeal such that they had the party status of respondent. At the same time, they withdrew all requests on file other than auxiliary request 4a corresponding to the version found allowable by the opposition division.

(c) The appellants (opponents 1 and 3) both requested that the decision under appeal be set aside and the patent be revoked.

(d) The respondent (patent proprietor) requested that the appeals be dismissed.

IV. Independent claim 1 of auxiliary request 4a reads as follows:

"A prosthetic heart valve, comprising:

(a) a stent including a generally tubular annulus region (30) having a proximal-to-distal axis, the stent extending in a distal longitudinal direction from a proximal end to a distal end, the stent having a radially collapsed condition for mounting on a delivery device and a radially expanded condition when the stent is implanted;

(b) one or more prosthetic valve elements (70) mounted to the stent, the one or more prosthetic valve elements being collapsible and expandable along with the stent, the one or more prosthetic valve elements being arranged to allow flow of blood in an antegrade direction when the stent is in the expanded condition; and

(c) characterized by a cuff (285) including a first wall and at least one second wall radially outward of the first wall and radially outward of the stent, the first and second walls cooperatively defining one or more pockets outside of the annulus region, each such pocket having one of the at least one second wall and an open side for entry of blood into the pocket (220) when the stent is in the expanded condition, the each open side being disposed adjacent the proximal end of the stent, the at least one opening and facing in a first axial direction toward the distal end of the stent, and each such pocket having a closed side facing in a second axial direction towards the proximal end of the stent, wherein the second axial direction is opposite to the

first axial direction, so that when the stent is implanted, retrograde blood flow around the outside of the stent can bias the at least one second wall outwardly into engagement with native tissue."

- V. The appellants argued *inter alia* that the subject-matter of claim 1 was not novel over the embodiment shown in figures 19A - 19D of E4.
- VI. The respondent alleged that the subject-matter of claim 1 was novel over E4 since E4 neither disclosed a pocket having a closed side, nor that retrograde blood flow could bias the second wall outwardly into engagement with native tissue, nor that the sealing member was coupled to the support structure in such a way as to prevent blood from passing between the sealing member and the support structure.

Reasons for the Decision

Auxiliary request 4a

1. Auxiliary request 4a corresponds to the request upheld by the opposition division.

Novelty over E4

2. The opposition division held that the subject-matter of claim 1 was novel over E4.
- 2.1 It is undisputed between the parties that E4 discloses a prosthetic heart valve, comprising:
- a stent (32) including a generally tubular annulus region having a proximal-to-distal axis, the stent extending in a distal longitudinal direction from a

proximal end to a distal end (see figure 19D), the stent having a radially collapsed condition for mounting on a delivery device and a radially expanded condition when the stent is implanted (see figures 18C and 18D showing the two states);

- one or more prosthetic valve elements (130) mounted to the stent, the one or more prosthetic valve elements being collapsible and expandable along with the stent (see paragraph [0186]), the one or more prosthetic valve elements being arranged to allow flow of blood in an antegrade direction when the stent is in the expanded condition (function of each and every heart valve, hence implicit also in E4); and
- a cuff (512) including a first wall (518) and at least one second wall (519) radially outward of the first wall and radially outward of the stent, the first and second walls cooperatively defining a pocket outside of the annulus region (see figure 19B and 19C).

The pocket has an open side for entry of blood into the pocket when the stent is in the expanded condition whereby the open side is disposed adjacent the proximal end of the stent and facing in a first axial direction toward the distal end of the stent (see figure 19C and paragraphs [0206] and [0207]).

- 2.2 In the opposition division's view (which is shared by the respondent) E4 does not disclose that retrograde blood flow around the outside of the stent can bias the second wall (i. e. the wall referred to as "sealing member" in E4) into engagement with native tissue. The outwards deflection of the sealing member could also occur due to the inherent material property of the sealing member (see grounds for the decision on page

19, last entire paragraph and paragraph bridging pages 19 and 20).

The Board does not agree. It is clearly and unambiguously disclosed in paragraph [0207] of E4 that a systolic blood flow (situation shown in figure 19B) causes the sealing member (512) to lie adjacent to the outer surface (514) of the support structure, whereas diastolic blood flow (situation shown in figure 19C) deflects the sealing member outwards away from the support structure such that it seals the region between the valve and surrounding native tissue.

The pocket formed by the sealing member of E4 is only accessible by a blood flow around the outside of the stent as described in paragraph [0026]. In the situation of diastolic blood flow, a leakage blood flows through this gap between the valve and the surrounding tissue and is in general referred to as a "retrograde blood flow".

Independently from a possible additional pre-tensioning of the sealing member as an alternative reason for the sealing member's outwardly directed deflection, this retrograde blood flow will in any case enter the pocket formed by the sealing member and bias the flexible sealing member (i. e. the second wall in the sense of claim 1 of the patent in suit) outwardly into engagement with native tissue. Albeit this effect is not explicitly described in E4, it is an inevitable result due to the retrograde blood flow entering the pocket formed by the sealing member and the sealing member being flexible.

2.3 The respondent further alleged that the sealing member is coupled to the support structure, but it is not

described in E4 that this connection prevents blood from passing between the sealing member and the support structure such that the pocket formed in E4 is not a closed pocket. Furthermore, the edge where the sealing member is attached to the support structure cannot be considered to be a side of the pocket since this would require an additional wall forming a bottom of the pocket between sealing member and support structure.

The Board again does not agree. As set out in paragraph [0206], the sealing member serves "*to promote sealing between the valve support structure 32 and the adjacent vascular tissue wall*". It is hence excluded that blood may pass through the pocket formed by the sealing member but it is implicitly disclosed in E4 that the pocket must be closed at its proximal side to achieve the effect described in [0206].

The closed edge where the sealing member is connected to the support structure is furthermore a closed side of the pocket since a closed side - contrary to the respondent's argument - does not necessarily require a separate bottom wall in addition to the side walls of the pocket. A tube pinched at one side has a closed side albeit it is not closed by a separate wall.

2.4 The Board hence concludes that contrary to the respondent's arguments, the pocket disclosed in E4 has a closed side facing in a second axial direction towards the proximal end of the stent, wherein the second axial direction is opposite to the first axial direction, so that when the stent is implanted, retrograde blood flow around the outside of the stent can bias the second wall outwardly into engagement with native tissue.

- 2.5 Contrary to the opposition division's decision, the subject-matter of claim 1 is thus known from E4 and hence does not comply with the requirements of Article 54 EPC.
3. The respondent withdrew all other requests filed with their statement of grounds of appeal such that no further requests are on file.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



A. Voyé

G. Pricolo

Decision electronically authenticated