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**Datasheet for the decision
of 13 October 2023**

Case Number: T 2402/18 - 3.2.01

Application Number: 15169678.8

Publication Number: 2949292

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

REPLACEMENT VALVE

Patent Proprietor:

Symetis SA

Opponents:

1. Edwards Lifesciences Corporation
2. 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

Headword:

Relevant legal provisions:

EPC Art. 76(1)

Keyword:

Divisional application - subject-matter extends beyond content of earlier application (yes)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 2402/18 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 13 October 2023

Respondent:
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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
31 August 2018 concerning maintenance of the
European Patent No. 2949292 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. Appeals were filed by the patent proprietor and both opponents (opponent 1 and 2) against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 1, the patent in suit met the requirements of the EPC.
- II. The opposition division *inter alia* decided that the subject-matter of the single claim of this request did neither extend beyond the content of the application as filed nor beyond the content of the earlier application PCT/IB22008/002180 ("parent application", published as WO 2009/024859 A2).
- III. The patent proprietor (Symetis SA) and opponent 1 (Edwards Lifesciences Corporation) withdrew their appeals with letters dated 17 January 2019 and 17 August 2023, such that opponent 2 (St. Jude Medical LLC et al.) remained the sole appellant.

The patent proprietor further clarified with letter dated 12 October 2023 that they withdrew all requests filed with their statement of grounds of appeal, and only maintained their request that the appeal of opponent 2 be dismissed.

- IV. Oral proceedings were held before the Board.
- (a) The appellant (opponent 2) requested that the decision under appeal be set aside and the patent be revoked.

(b) The respondent (patent proprietor) did not attend the oral proceedings as announced with their letter dated 7 September 2023.

V. The sole claim of the request deemed patentable by the opposition division in their interlocutory decision reads as follows:

*"A replacement valve for use within a human body comprising
a valve component comprising an outer surface, at least a portion thereof being covered with fabric, wherein the valve component includes at least one suture along a free edge of the valve component and at least one suture along an inflow free edge of the valve component and
a stent component for housing the valve component; wherein the stent component and valve component are capable of at least a collapsed configuration for delivery, and an expanded configuration after implantation, the fabric comprising a skirt (902, 1002),
characterized in that
at least a portion of the fibers of the fabric are oriented +/-45 degrees with respect to a longitudinal axis of the valve component and wherein the skirt extends below the valve component, and
wherein the skirt comprises a free edge which is folded over a bottom portion of the stent component and sutured to the stent component."*

VI. In their statement of grounds of appeal the appellant submitted, *inter alia*, that the claim as maintained by the opposition division was unallowable amended over the parent application (Article 76(1) EPC).

In particular, contrary to the view taken by the opposition division, claims 8 and 9 in connection with paragraphs [0005], [0009], [0042] and [0043] of the parent application provided neither a basis for generalising the feature of the valve component comprising at least one suture along the trimmed aortic sinus to read "suture along a free edge of the valve component", nor for reducing the amount of fabric covering substantially the entire valve component to only a portion thereof.

In fact, paragraphs [0005] and [0009] were an arbitrary listing of optional features that were not at all interrelated and could not form the basis for any specific embodiment linking two or more of the features recited.

- VII. In reply to this objection the respondent essentially submitted that starting from claim 8, the Opposition Division correctly recognized that paragraphs [0005] and [0009] represented a generalisation to other valve types and, thus, offered a basis for at least the omission of the valve-related features in claim 8.

Reasons for the Decision

1. The single claim of the request maintained by the opposition division extends beyond the content of the earlier application PCT/IB22008/002180 (published as WO 2009/024859 A2) as originally filed, contrary to Article 76(1) EPC.
- 1.1 The opposition division held that the subject-matter of the claim represented an allowable generalisation of claims 8 and 9 in view of the disclosure in paragraphs [0005] and [0009] of the earlier application (see reasons for the decision, page 13, forth paragraph - end of page 13).
- 1.2 The earlier application WO 2009/024859 A2 provides in figures 9 and 10 disclosure for an embodiment of a replacement valve. This embodiment is further specified in paragraphs [0042] and [0043] of the originally filed description.
 - 1.2.1 According to these passages, the disclosed valve is provided with a fabric reinforcement that covers substantially the entire outer surface of the valve down to the skirt (line 19). A continuous suture is provided along the trimmed aortic sinus that serves, together with a continuous suture along the perimeter of the inflow margin to increase seal integrity (lines 20-23). The fibers of the fabric are oriented about +/- 45 degrees with respect to a longitudinal axis of the valve component (line 27).
 - 1.2.2 This corresponds to what is claimed in originally filed claims 8 and 9 of the earlier application: claim 8 recites that the valve component is substantially

entirely covered with fabric and comprises at least one suture along the trimmed aortic sinus and claim 9 (dependent on 8) that substantially all the fibers of the fabric are oriented about +/- 45 degrees with respect to a longitudinal axis of the valve component.

- 1.3 In the claim as maintained by the opposition division, however, the suture "*along the trimmed aortic sinus*" was replaced by a suture "*along a free edge of the valve component*", hence omitting the information on the geometry of the free edge of the valve component being a sinus.

Furthermore, the claim maintained by the opposition division required the fabric to only cover a portion of the outer surface of the valve component instead of substantially the entire surface.

- 1.3.1 As set out in paragraph [0042] as originally filed, the suture along the free edge of the valve component serves to increase seal integrity which also depends on the geometry of the free edge of the valve component. The geometry of the valve component following a sinus hence is inextricably linked to the function of the suture and therefore cannot be omitted without generalizing the definition of the valve component in an unallowable way.

- 1.3.2 The fabric in turn prevents wearing of the valve due to contact with the stent as also set out in paragraph [0041]. A fabric that covers only a part of the outer surface of the valve component thus cannot provide the effect of avoiding contact between valve component and stent to the same extent than a fabric covering substantially the entire valve component.

1.4 The respondent, as also the opposition division, argued that paragraphs [0005] and [0009] provided a basis for generalising the valve type and thus the geometry of the free edge of the valve component. Paragraph [0009] further provided a basis for reducing the portion of the valve component covered by fabric.

1.4.1 The Board does not agree for the following reasons:

(a) It is true that paragraph [0009] discloses several features of claim 1, in particular the feature that at least a portion of the fibers of the fabric are oriented +/-45 degrees with respect to a longitudinal axis of the valve component, and the features added to claim 1 as granted, namely the features designated A, B, C in the decision under appeal (see pages 11 and 12). It is also true that this paragraph does not mention the feature that the valve component comprises at least one suture along the trimmed aortic sinus.

(b) Paragraph [0009], however, does not disclose all the features of claim 1 in combination. On the contrary

- the feature that at least a portion of the outer surface of the valve component is covered with fabric ("In some embodiments, the valve component..."),
- the feature that the valve component includes at least one suture along a free edge of the valve component and at least one suture along an inflow free edge of the valve component (feature A) (due to the use of the verb "may": "the valve component may include...") and
- the feature that at least a portion of the fibers of the fabric are oriented +/-45 degrees with

respect to a longitudinal axis of the valve component ("In some embodiments, substantially all or at least a portion of the fibers...") are individually disclosed as optional but there is no indication that these individual features might be combined within one and the same embodiment.

(c) Paragraph [0005] is irrelevant in this context as it does not mention these features at all.

1.4.2 Hence the only basis for the features' combination of claim 1 is to be found in claims 8 and 9 of the earlier application and the related embodiment disclosed in the description and figures 9 and 10, where, however, both the feature that the valve component comprises at least one suture along the trimmed aortic sinus and the feature that the fabric covers substantially the entire surface of the valve component are present.

1.5 There is thus no basis in the earlier application for omitting these features and as a consequence the claim introduces new technical information over the content of the earlier application, namely that the above-mentioned features can be omitted.

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