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**Datasheet for the decision
of 18 June 2024**

Case Number: T 0385/22 - 3.2.01

Application Number: 11153114.1

Publication Number: 2484309

IPC: A61F2/24, A61F2/02

Language of the proceedings: EN

Title of invention:
Heart valve prosthesis

Patent Proprietor:
Gabbay, Shlomo

Opponent:
Abbott Cardiovascular Systems Inc.

Headword:

Relevant legal provisions:
EPC Art. 123(2), 112(1)(a)
RPBA 2020 Art. 13(2)

Keyword:

Amendments - extension beyond the content of the application
as filed (yes)

Amendment after summons - exceptional circumstances (no)

Referral to the Enlarged Board of Appeal - (no)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 0385/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 18 June 2024

Appellant: Abbott Cardiovascular Systems Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 13 December
2021 rejecting the opposition filed against
European patent No. 2484309 pursuant to Article
101(2) EPC.**

Composition of the Board:

Chairman G. Pricolo
Members: V. Vinci
O. Loizou

Summary of Facts and Submissions

- I. The appeal was filed by the appellant (opponent) against the decision of the opposition division rejecting the opposition filed against the European patent N°2 484 309.

In its decision the Opposition Division found that the grounds for opposition raised by the opponent under Articles 100(a) in combination with Articles 54 and 56 EPC, Article 100(b) in combination with Article 83 EPC and Article 100(c) in combination with Article 123(2) EPC did not prejudice the maintenance of the patent as granted and hence rejected the opposition.

- II. With a communication according to Article 15(1) RPBA dated 3 April 2024 the Board informed the parties of its preliminary, non-binding assessment of the case.

Oral proceedings took place before the Board on 18 June 2024 by videoconference.

- III. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked. The appellant also requested that the following questions be referred to the Enlarged Board of Appeal:

1. In the claims of a granted European Patent, is it admissible in opposition and appeal proceedings for assessing if claim amendments carried out during examination proceedings before grant of the patent comply with the requirements of Art. 123(2) EPC to interpret a term which in itself has a clear technical meaning and which refers to a first part of the claimed

subject-matter in a manner that this same term refers to a second part of the claimed subject-matter which is different from the first part?

2. If the answer to question 1 is "yes", is it admissible to consider the description when interpreting the term to refer to the second part or must the claim alone be considered to identify that a first appearance of the term refers to the first part and a second appearance of the same term refers to the second part?

3. If the answer to question 1 is "yes", does this answer also apply to a scenario in which the term appears multiple times in a single claim, and is it admissible to interpret the multiple appearances of the term differently such that the same term refers to different parts of the claimed subject-matter in a single claim?

4. If the answer to question 1 is "no", does an amendment to a claim according to which the term refers to the second part of the claimed subject-matter while the term is originally disclosed only as referring to the first part of the claimed subject-matter infringe the requirements of Art. 123(2) EPC?

A pending request of the appellant (opponent) for reimbursement of the appeal fee due to a substantial procedural violation allegedly occurred during the opposition proceedings was withdrawn in the course of the oral proceedings.

The respondent (patent proprietor) requested that the appeal be dismissed (main request) or, in the alternative, that the patent be maintained in amended

form according to one of the auxiliary requests 1a to 1e and 2 to 10 filed with their reply, or auxiliary request 11 received during oral proceedings (see annex 3 to the minutes).

IV. Independent claim 1 as granted reads as follows (labelling of the features according to the decision under appeal):

F0 *"A heart valve prosthesis comprising:*

F1 a supported valve (16) comprising a biological valve portion (76) mounted within a support structure (12), the supported valve being configured to provide for substantially unidirectional flow of blood through the supported valve,

F1.1 the supported valve having inflow (78) and outflow (80) ends that are spaced axially apart from each other; and

F2 a fixation support member (14,174) comprising inflow (40,173) and outflow (42, 175) portions,

F2.1 the inflow portion of the fixation support member extending from a radially inner contact surface (44, 176, 180) of the fixation support member radially outwardly and axially in a direction of the inflow end of the supported valve,

F2.2 the outflow portion of the fixation support member extending from the radially inner contact surface radially outwardly and axially in a direction away from the inflow portion of the fixation support member,

F2.3 the radially inner contact surface being attached

to a radially outer surface of the supported valve adjacent the inflow end of the supported valve, F3 the supported valve and the fixation support member being deformable between a reduced cross-sectional dimension and an expanded cross-sectional dimension thereof, whereby implantation of the heart valve prosthesis is facilitated,

F4 wherein the fixation support member further comprises a flexible and deformable annular support (10)

F4.1 which includes an inflow portion (20), an outflow portion (22), and an annular opening extending through the support (10) corresponding to a radially inner extent (28) thereof,

F5 the fixation support member having a substantially V-shaped cross-sectional configuration for a longitudinal cross-section taken axially through the prosthesis in its expanded cross-sectional dimension,

F5.1 such that the radially inner contact surface of the fixation support member defines an apex and each of the inflow and outflow portions of the fixation support member define legs of the V-shaped cross-sectional configuration, characterised in that

F6 the annular support (10) is a continuous monolithic structure having a substantially V-shaped cross-sectional configuration for a longitudinal cross-section taken axially through the prosthesis in its expanded cross-sectional dimension,

F6.1 said structure consisting in a zigzag arrangement of support features (24,26), in which the support

features alternate between extending in the inflow and outflow directions along a circumferential path corresponding to the radially inner extent (28) of the support structure.

Independent claim 1 of each one of the auxiliary requests 1a, 1b, 1c, 1e, 8, 9 and 10 contains the same limitation stated in feature F6 of claim 1 as granted. that *"the annular support (10) is a continuous monolithic structure having a substantially V-shaped cross-sectional configuration for a longitudinal cross-section taken axially through the prosthesis in its expanded cross-sectional dimension"*.

In independent claim 1 of each one of the auxiliary requests 1d, 2, 3, 7 the term *"prosthesis"* in feature F6 of claim 1 as granted has been replaced by *"annular support"*.

In independent claim 1 of the auxiliary request 4 feature F6 of claim 1 as granted has been reworded to read *"the annular support (10) is a continuous monolithic structure having a substantially V-shaped cross-sectional configuration for an axial longitudinal cross-section taken radially outwardly through one side of the annular support in its expanded cross-sectional dimension"*.

In independent claim 1 of the auxiliary requests 5 and 6 feature F6 has been reworded to read that the annular support (10) is a continuous monolithic structure, wherein the inflow features and the outflow features of the annular support define *"a substantially V-shaped cross-sectional configuration for the annular support along an axial longitudinal cross-section taken radially outwardly through one side of the annular*

support in its expanded cross-sectional dimension."

Independent claim 1 according to the auxiliary request 11 filed at the oral proceedings is identical to claim 1 as granted and contain the additional feature that:

"the fixation support structure (10) provides a generally hourglass shape in which it has a substantially V-shaped cross-sectional configuration for a longitudinal cross-section taken radially outwardly through one side of the fixation support structure (10) in its expanded configuration."

Reasons for the Decision

MAIN REQUEST - PATENT AS GRANTED

1. Contrary to the findings of the Opposition Division, the Board finds that the subject-matter of independent claim 1 as granted does not meet the requirements of Article 123(2) EPC.
 - 1.1 The positive assessment of compliance with the requirements of Article 123(2) EPC of the Opposition Division was contested by the appellant (opponent) with their appeal.

Feature F6

- 1.2 Among the several objections raised under Article 123(2) EPC, the appellant (opponent) maintained that

there was no basis in the originally filed application for feature F6 introduced in claim 1 and requiring that

"the annular support (10) is a continuous monolithic structure having a substantially V-shaped cross-sectional configuration for a longitudinal cross-section taken axially through the prosthesis in its expanded cross-sectional dimension".

The appellant (opponent) put forward that Figure 5 indicated by the Opposition Division and the respondent (patent proprietor) as basis for the disputed amendment did not show the annular support, let alone an annular support which was V-shaped in cross-section. Furthermore, it was pointed out that the wording adopted in the claim could not be derived from paragraphs [0024] and [0025] of the application as originally filed which did not mention the *"annular support"*.

1.3 The respondent (patent proprietor) replied that feature F6 was clearly derivable from Figure 5 which - apart from the omission of the reference (10) - showed in broken and bold lines the legs the portions of the annular support resulting in cross-section in the claimed V-shaped configuration. In the respondent's (patent proprietor's) view, the disputed feature could also be directly and unambiguously derived from Figure 1 as filed. Finally, it was argued that the wording of feature F6 was literally disclosed in dependent claim 2 as filed.

1.4 The Board does not agree with the findings of the opposition division and the reasoning of the respondent (patent proprietor) and follows the arguments of the

appellant (opponent):

- 1.5 The Board observes that the cited paragraphs [0024] and [0025] refer to a "*fixation support structure*" and not to the "*annular support*" recited in feature F6 claim 1. Therefore, no clear and unambiguous basis for the wording of feature F6 can be found in these passages of the original application. Regarding Figure 5, the Board agrees that the bold line identified by the respondent (appellant) on the left part of the section of the valve represented in this figure and allegedly forming the first leg of the claimed V-shaped configuration is indeed located on a vertical cross-sectional plane passing through the central axis of prosthesis. However, the second portion which in the respondent's (patent proprietor's) view should form the second leg of the claimed V-shaped configuration in cross section is represented in Figure 5 in broken lines which means that this portion does not lie on the same vertical cross-sectional plane of the first portion of the leg. Therefore, feature F6 cannot be read in Figure 5. Regarding the information allegedly derivable from Figure 1, the Board follows the view of the appellant (opponent) that it is not possible to obtain a V-shaped cross-sectional configuration for the annular support 10 formed by a zigzag arrangement of support features. In fact for any longitudinal cross-section taken through the prosthesis, it is merely possible to obtain intersection points on the intersecting plane and this because none of the zig-zag shaped support features (24,26) lie with both of its legs fully on the same vertical cross-sectional plane. Regarding the alleged support for feature F6 in claim 2, the Board - in agreement with the appellant (opponent) - observes that claim 2 does not disclose an annular support having in combination a continuous monolithic structure and a

substantially V-shaped cross-sectional configuration.

- 1.6 In conclusion, the Board takes the view that feature F6 of claim 1 as granted is not directly and unambiguously derivable from the originally filed application. Therefore the ground for opposition pursuant to Article 100(c) in combination with Article 123(2) EPC is prejudicial to the maintenance of the patent as granted.

Auxiliary Requests 1a-1e and 2 to 10

2. The Board observes that each one of the auxiliary requests 1a to 1e and 2 to 10 suffers from the same issue under Article 123(2) EPC raised above against the main request, whereby these auxiliary requests are not allowable for the same reasons. This conclusion was also acknowledged by the respondent (patent proprietor) during oral proceedings.

Auxiliary Request 11

Admissibility

3. Auxiliary request 11 was filed by the respondent (patent proprietor) for the first time during the oral proceedings before the Board. Its admittance, which was contested by the appellant (opponent), is at the discretion of the Board which has to be exercised in accordance with the provisions of Article 13(2) RPBA.
- 3.1 The respondent (patent proprietor) alleged that the objection regarding feature F6 was raised by the appellant (opponent) for the first time at the oral proceedings and therefore the submission of the new auxiliary request 11 was a justified reaction to this

new and unexpected procedural situation. Furthermore, it was explained that they were surprised by the unexpected change of opinion of the Board at the oral proceedings that - contrary to the assessment expressed in the communication according to Article 15(1) RPBA dated 3 April 2024 - came to the conclusion that the subject-matter of claim 1 as granted did not meet the requirements of Article 123(2) EPC.

- 3.2 The reasons provided by the respondent (patent proprietor) for filing the new auxiliary request 11 at the oral proceedings are not convincing:

Firstly, contrary to the allegation of the respondent (patent proprietor) and as pointed out by the appellant (opponent), feature F6 of claim 1 as granted was objected under Article 123(2) EPC already with the notice of opposition (see point 3.5). This objection was then maintained with the statement of grounds of appeal (see page 17) of the appellant (opponent). Furthermore, according to established case law of the Boards of Appeal, a change of opinion compared with the preliminary assessment expressed by the Board in the communication according to Article 15(1) RPBA does not amount to "*exceptional circumstances*" within the meaning of Article 13(2) RPBA justifying the admittance of an amendment to the party case at this late stage of the proceedings. For these reasons, the Board decided to exercise its discretion and did not admit the auxiliary request 11 in the appeal proceedings under Article 13(2) RPBA.

Request for a Referral to the Enlarged Board of Appeal

4. The questions proposed by the appellant (opponent) for the referral to the Enlarged Board of Appeal concerning

the possibility to construe a claim in the light of the description in order to assess compliance Article 123(2) EPC were filed in view of the disputed interpretation of feature F6.1 of claim 1 as granted provided by the opposition division in the context of the examination of compliance with Article 123(2) EPC. However, the fact that the Board concluded that feature F6 is not directly and unambiguously derivable from the originally filed application is sufficient to decide the case irrespective of the interpretation of feature F6.1. This circumstance renders the request for a referral to the Enlarged Board of Appeal of the questions filed by the appellant (opponent) obsolete and not necessary. Therefore it is refused.

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:



H. Jenney

G. Pricolo

Decision electronically authenticated