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**Datasheet for the decision
of 15 May 2023**

Case Number: T 2408/19 - 3.2.01

Application Number: 16152466.5

Publication Number: 3045147

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

A REPLACEMENT VALVE

Patent Proprietor:

Symetis SA

Opponent:

St. Jude Medical, LLC/Abbott Med GmbH/St. Jude
Med UK Ltd/SJM Int, Inc./SJM Coord Center BVBA/
St. Jude Med S.C., Inc./Di Bianca, William A.

Headword:

Relevant legal provisions:

EPC Art. 76(1)

RPBA 2020 Art. 12(3), 25(1)

Keyword:

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

Decisions cited:

G 0009/92

Catchword:



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Case Number: T 2408/19 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 15 May 2023

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
5 July 2019 concerning maintenance of the
European Patent No. 3045147 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: V. Vinci
 S. Fernández de Córdoba

Summary of Facts and Submissions

- I. The appeal filed by the opponent is directed against the interlocutory decision of the opposition division to maintain the European patent EP 3 045 147 in amended form.

In its decision the opposition division held that the ground for opposition under Article 100(c) in combination with Article 76(1) EPC was prejudicial to the maintenance of the patent as granted and decided to maintain the patent in amended form according to the auxiliary request 1 filed at the oral proceedings.

The contested patent is based on the European patent application EP 16 152 466.5 filed as a divisional application of the parent application EP 08 806 901.8 published as

E1b: WO 2009/024859 A2.

- II. The appellant (opponent) requested to set aside the interlocutory decision of the opposition division and to revoke the patent in its entirety.

The patent proprietor also filed an appeal and requested, with the statement of grounds of appeal, to set aside the interlocutory decision of the opposition division and to maintain the patent as granted (main request) or, in the alternative, based on one of the auxiliary requests 1 to 6a filed with the statement of grounds of appeal.

- III. With a communication pursuant to Article 15(1) RPBA dated 24 August 2022, the Board informed the parties of

its preliminary, non-binding assessment of the appeal.

With letter dated 16 March 2023 the patent proprietor withdrew their appeal and the request for oral proceedings. No further submissions were made in reply to the communication of the Board.

In view of the final requests of the parties and of the assessment of the case by Board as set out below the appeal could be decided in writing and the oral proceedings scheduled on 27 April 2023 were cancelled.

IV. Claim 1 of the patent as maintained according to the auxiliary request 1 reads as follows:

1. *"A cardiac replacement valve for use within a human body comprising*

2. *a valve component comprising an outer surface covered at least partially with fabric*

A. *wherein the valve component includes at least one suture along a free edge of the valve component*

B. *and at least one suture along an inflow free edge of the valve component and*

3. *a stent component for housing the valve component*

4. *wherein the stent component and valve component are capable of at least a collapsed configuration for delivery, and an expanded configuration after implantation,*

C. *the fabric comprising a skirt (902, 1002) extending below the valve component*

5. *and with a free edge folded over a bottom portion of the stent component*

6. *and sutured to the stent component*

characterized in that

7. *the free edge comprises at least one cut (1008)*

8. *wherein the at least one cut (1008) is oriented in a direction of a longitudinal axis of the stent component."*

In this request dependent claims 2, 4 and 5 as granted have been deleted.

Claim 1 according to the auxiliary request 1 reads as follows:

"A cardiac replacement valve for use within the human body comprising a valve component comprising an outer surface covered at least partially with fabric 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) with a free edge folded over a bottom portion of the stent component and sutured to the stent component, characterized in that the free edge comprises at least one cut (1008), wherein the at least one cut (1008) is oriented in a direction of a longitudinal axis of the stent component."

Claim 1 according to the auxiliary request 2

corresponds to claim 1 of the auxiliary request 1 and further specifies that the skirt *"is extending below the valve component"*.

Claim 1 according to the auxiliary request 3 correspond to claim 1 of the auxiliary request 2 and further specifies that *"the valve component includes at least one suture along an inflow free edge of the valve component"*.

Claim 1 according to the auxiliary request 4 correspond to claim 1 of the request allowed by the opposition division.

Claim 1 according to the auxiliary request 5 correspond to claim 1 of the auxiliary request 2 and specifies that *"the stent component comprises an annular groove, in that the free edge of the skirt is positioned within the annular groove"*.

Claim 1 according to the auxiliary request 6 correspond to claim 1 of the auxiliary request 2 and specifies that the stent component has *"a flared/grooved bottom portion"* and that *"the at least one cut (1008) is made along a free floating edge (1006) of the skirt between sutures of the free edge of the skirt, and wherein the free edge comprises multiple cuts (1008)."*

Claim 1 of the auxiliary requests 1a, 2a, 3a, 4a, 5a and 6a corresponds to claim 1 of the respective auxiliary requests 1 to 6 wherein it has been further specified that the cardiac valve is for use *"in a percutaneous heart valve replacement therapy"*.

Reasons for the Decision

1. By withdrawing their appeal, the patent proprietor is no longer an appealing party and as a respondent is primarily restricted to defend the patent in the form upheld by the opposition division (see G 9/92).
- 1.1 In their reply to the statement of grounds of the appellant (opponent), the patent proprietor submitted that claim 1 of the auxiliary request 4 filed with the statement of grounds of appeal corresponded to claim 1 of the auxiliary request maintained by the opposition division, and that only auxiliary requests 5 to 6a were more restricted. Hence, the requests of the patent proprietor as respondent can only be understood as to maintain the patent in the form upheld by the opposition division (i.e. that the appeal of the opponent be dismissed) or in accordance with one of auxiliary requests 5 to 6a.
- 1.2 However, auxiliary request 4 does not correspond to the patent as upheld because, as stated in the communication of the Board, this request, unlike the auxiliary request considered allowable by the first-instance department, still contains dependent claims 2, 4 and 5 which according to the minutes were discussed at the oral proceedings and considered not compliant with the requirements of Article 76(1) EPC.
- 1.3 In any event, even assuming that all the requests filed with the statement of grounds of appeal by the respondent (patent proprietor) were maintained notwithstanding the withdrawal of the appeal, none of these requests would be admissible or allowable for the reasons given in the communication of the Board dated 24 August 2022 (see points 5 and 6 thereof) which have

not been contested by the respondent. Therefore, the Board has no reasons to deviate from the conclusions presented in the preliminary opinion which are hereby confirmed and read as follows:

Lack of substantiation / Admissibility

2. The Board notes that the auxiliary requests 1 to 6a submitted with the statement of grounds of appeal of the respondent (patent proprietor) correspond to the auxiliary requests filed on 13 March 2019 during the first instance proceedings and renumbered as auxiliary requests 2 to 13 at the end of the oral proceedings following the introduction of the new auxiliary request 1. None of these requests correspond to the new auxiliary request 1 filed at the oral proceedings and allowed by the opposition division. While the content and the alleged basis of the amendments introduced in each one of these requests are duly indicated by the respondent (patent proprietor), the Board is of the opinion that it has not been duly substantiated, as instead required by Article 12(3) RPBA 2020 which pursuant to Article 25(1) RPBA 2020 applies to the present appeal, why they should overcome the objection raised under Article 76(1) EPC against claim 1 of the main request.

Article 76(1) EPC

3. In any case and irrespective of the above admissibility issue, the auxiliary requests 1 to 6a do not meet the requirements of Article 76(1) EPC for the following reasons:

Auxiliary requests 1 to 3a and 5 to 6a

3.1 Claim 1 of each of these auxiliary requests do not contain at least one of the following information disclosed in paragraph [0009] of the parent application Elb together with the feature recited in claim 1 that the fabric *"includes a skirt"*, namely 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", and that

"the skirt extends below the valve component".

3.2 The Board comes to the conclusion that the omission of these features results in an unallowable intermediate generalisation contrary to Article 76(1) EPC.

3.3 In the context of the discussion of claim 1 the main request that contains the same issue, the respondent (patent proprietor) argued in writing that, contrary to the view of the opposition division, the skilled person realized that there was no technical relationship between the sutures disclosed in the 2nd sentence of paragraph [0009] and the remaining features presented in this paragraph, in particular with the skirt-related features of the 2nd, 3rd and 7th sentence. In other words in the respondent's (patent proprietor's) opinion the presence of a skirt did not mandatorily imply the suturing described in the 2nd sentence of paragraph [0009], which could thus be omitted without infringing Article 76(1) EPC. Turning to the omission of the feature that *"the skirt extends below the valve component"*, the respondent (patent proprietor) alleged that the person skilled in the art realized from

paragraph [0005], lines 14 and 15, that any valve component and, consequently, any valve position of the valve within the stent, could be used, thereby concluding that the indication of the positioning of the skirt relative to the valve component was not essential in the context of the 2nd sentence of paragraph [0009]. Finally, the respondent (patent proprietor) alleged that also in the following sentences of paragraph [0009] no specific relationship between the skirt and the valve component or its position within the stent was indicated, whereby the view of the opposition division that this feature could not be omitted without infringing Article 76(1) EPC was not justified.

3.4 The arguments submitted by the respondent (patent proprietor) are not convincing:

3.5 The Board concurs with the view of the opposition division as expressed in the context of the discussion of claim 1 of the main request and with the appellant (opponent) that according to paragraph [0009], in the event that the valve component includes a skirt (see expression "where the fabric includes a skirt" on line 15 of this paragraph), as in fact required by claim 1, "*one suture along a free edge of the valve component and at least one suture along an inflow free edge of the valve component*" are provided (see lines 14-15). Therefore, the person skilled in the art reading the whole sentence on lines 14-16 of paragraph [0009] can only directly and ambiguously derive that the skirt is presented in combination with the specific double suture described therein which cannot thus be omitted. Moreover, as further observed by the opposition division and the appellant (opponent), the skirt is disclosed only "*with the extension below the valve*

component" (see also claim 8 of the parent application). Finally, contrary to the view of the respondent (patent proprietor), the above discussed generalisation with respect to the information disclosed in paragraph [0009] of the parent application Eb1 introduced in claim 1 is not supported by the information presented in claims 8, 11 and 12 of the original parent application either, because these claims, beside the formulations introduced in claim 1 as granted, contain further features which are also omitted.

Auxiliary requests 4 and 4a

- 3.6 Regarding the auxiliary requests 4, the Board notes that independent claim 1 corresponds to independent claim 1 of the request allowed by the opposition division. The same applies to claim 1 of the auxiliary request 4a that additionally specifies that the cardiac replacement valve is for use "*in a percutaneous heart valve replacement therapy*". However, these requests (as the higher ranking requests 1 to 3a and the lower ranking request 6 and 6a) still contains dependent claims 2, 4 and 5 which according to the minutes were discussed at the oral proceedings and considered not to comply with the requirements of Article 76(1) EPC. No arguments in response to this negative assessment have been submitted by the respondent (patent proprietor). Therefore, the Board does not see any reason to deviate from the conclusion of the first-instance department that the auxiliary request 4 on file does not meet the requirements of Article 76(1) EPC. In addition, as it will be explained below, the Board is of the opinion that claim 1 of these auxiliary requests, contrary to the view of the opposition division, does not still comply with the requirements of Article 76(1) EPC.

Patent as maintained - Appeal of the Opponent

4. The respondent (patent proprietor) did not provide any comment in response to the communication of the Board dated 24 August 2022 according to which the patent as maintained (auxiliary request 1 filed at the first-instance oral proceedings) did not appear to meet the requirements of Article 76(1) EPC. The Board has thus no reasons to deviate from its preliminary conclusions which are hereby confirmed and read as follows:

Article 76(1) EPC

5. The appeal of the appellant (opponent) is directed against the decision of the opposition division to maintain the patent in amended form according to the new auxiliary request 1 filed at the opposition oral proceedings and in particular against the positive assessment of Article 76(1) EPC.
- 5.1 Contrary to the conclusion of the opposition division the Board considers that the patent as maintained does not meet the requirements of Article 76(1) EPC.
- 5.2 The appellant (opponent) contested, among others, the view of the opposition division that the subject-matter of the amended claim 1 is directly and unambiguously derivable from paragraphs [0005] and [0009] in combination with claims 8, 11 and 12 of the parent application Elb, and that thus complied with the requirements of Article 76(1) EPC.
- 5.3 The Board does not follow the arguments of the opposition division and of the respondent (patent proprietor) for the following reasons:

The appellant (opponent) in their statement of grounds of appeal put correctly forward that in accordance with settled case law of the boards of appeal a general listing in the description of multiple optional features without any clear interrelation to one another cannot form the basis for a specific embodiment that combines only some of the features of the list while omits others. This is the case of the contested patent in the version as maintained by the opposition division. Paragraphs [0005] and [0009] of the parent application Elb contain indeed, among others, a very large list of optional technical features of a stent valve and of a valve component respectively which are introduced by generic expressions like "*in some embodiments*", "*may include*" and "*alternatively or additionally*". Contrary to the view of the respondent (patent proprietor), features 2, 5 and 6 to 8 and A, B and C of claim 1 as maintained are presented in paragraph [0009] either as optional (see features 2, 5, 7, A, B and C) or are mentioned in the same sentence in combination with a preceding optional feature (see features 6 and 8). The Board, in disagreement with the conclusion of the opposition division and the view of the respondent (patent proprietor), shares the opinion of the appellant (opponent) that there is nothing in the parent application, be the description or the cited claims 8, 11 and 12, that directly and unambiguously suggests which ones, among the several optional features listed in paragraph [0009] should, according to the teaching of the contested patent, be included in claim 1 as maintained and which ones omitted.

5.4 Therefore, irrespective of the assessment of the further issues raised by the appellant (opponent) under Article 76(1) EPC in respect of claim 1 as maintained,

the Board concludes that, contrary to the assessment of the opposition division, the combination recited in claim 1, while solving the issues raised under point 3.1 above, is still not directly and unambiguously derivable from the parent application Elb, thereby infringing Article 76(1) EPC.

5.5 This conclusion applies for the same reasons to claim 1 of the auxiliary request 4a.

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. Vottner

G. Pricolo

Decision electronically authenticated