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**Datasheet for the decision
of 1 August 2017**

Case Number: T 0633/14 - 3.2.08

Application Number: 06770296.9

Publication Number: 1893132

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:
HEART VALVE PROTHESIS

Patent Proprietor:
Medtronic CV Luxembourg S.à.r.l.

Opponents:
Boston Scientific Corporation
Isarpatent
LUDWIG, Gabriele

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(2)
EPC R. 103(1)(a)
RPBA Art. 12(4)

Keyword:

Decisions cited:

G 0009/92

Catchword:



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Case Number: T 0633/14 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 1 August 2017

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
9 January 2014 concerning maintenance of the
European Patent No. 1893132 in amended form.

Composition of the Board:

Chairwoman P. Acton
Members: C. Herberhold
W. Ungler

Summary of Facts and Submissions

- I. By decision posted on 9 January 2014 the Opposition Division maintained in amended form European patent No. EP-B-1 893 132 as per the 4th auxiliary request then on file.
- II. The appellant (patent proprietor) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. Oral proceedings before the Board took place on 1 August 2017. For the course taken by the proceedings, reference is made to the minutes of the oral proceedings.

As announced by letter dated 28 July 2017, respondents 2 and 3 (opponents 2 and 3) did not attend.

At the end of the oral proceedings, the parties' requests were as follows:

The appellant requested that the decision under appeal be set aside and the patent be maintained as granted (main request), in the alternative that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 4, 4a, 5, 6, 6a and 7 all filed by letter dated 30 June 2017. Furthermore, reimbursement of the appeal fee was requested.

Respondent 1 (opponent 1) requested that the appeal be dismissed.

Respondents 2 and 3 requested in writing that the appeal be dismissed, that the proceedings be stayed until a decision in case G 3/14 was issued, that

auxiliary requests 2, 4 and 6 not be admitted into the proceedings, and that the case be remitted to the Opposition Division if novelty and inventive step of granted claims were to be discussed.

IV. Claim 1 of the main request (corresponding to claim 1 as granted) reads as follows:

"A valve prosthesis (10) comprising:
a self-expanding multi-level frame (12) having a contracted delivery configuration and an expanded deployed configuration, the multi-level frame having levels, in the expanded deployed configuration, of an outflow section (15) with a first nominal diameter (D_o), an inflow section (16) having a second nominal diameter (D_I), and a constriction region (17) having a third diameter (D_c) smaller than the first and second nominal diameters; and
a valve body (14) affixed to the multi-level frame, the valve body comprising a plurality of leaflets (22)
characterised in that
the outflow section (15) is enlarged and has a first nominal diameter (D_o) ranging from 30 mm to 55 mm,
the inflow section (16) is conical and has a second nominal diameter (D_I) smaller than the first nominal diameter and ranging from 19 mm to 34 mm,
the third diameter (D_c) is fixed, and **in that**
the plurality of leaflets (22) is affixed to a skirt (21)."

V. Auxiliary request 1:

Claim 1 of auxiliary request 1 has been amended over claim 1 of the main request as follows:

"A valve prosthesis (10) comprising:
a self-expanding multi-level frame (12) having a
contracted delivery configuration and an expanded
deployed configuration, the multi-level frame having an
asymmetric hourglass shape (feature C_{part}) and having
levels, ..."

Remark: Feature assignment introduced by the Board. It
corresponds in essence to the nomenclature introduced
by the respondent during oral proceedings.

VI. Auxiliary request 2:

Claim 1 of auxiliary request 2 has been amended over
claim 1 of the main request by the introduction of the
following feature:

"wherein the multi-level frame has proximal and distal
ends and a plurality of cell patterns that vary in size
between the proximal and distal ends (feature A)."

VII. Auxiliary request 3:

Claim 1 of auxiliary request 3 combines the amendments
in auxiliary requests 1 and 2.

VIII. Auxiliary request 4:

Claim 1 of auxiliary request 4 is amended over claim 1
of auxiliary request 2 by the introduction of the
following underlined feature:

"wherein the multi-level frame has proximal and distal
ends and a plurality of cell patterns that vary in size
between the proximal and distal ends, defined by
unequal length zigzags (18, 19)."

IX. Auxiliary request 4a:

Claim 1 of auxiliary request 4a differs from claim 1 of auxiliary request 4 in that the following amendments are made:

"the inflow section is adapted to be disposed in the aortic annulus of the patient, the outflow section is adapted to be positioned in the patient's ascending aorta."

X. Auxiliary request 5:

Claim 1 of auxiliary request 5 combines the amendments in claim 1 of auxiliary requests 1, (2) and 4.

XI. Auxiliary request 6:

Claim 1 of auxiliary request 6 is amended over claim 1 of the main request by the introduction of the following underlined feature:

"wherein the frame comprises a plurality of cells having sizes that vary along the length of the prosthesis (feature A), each cell comprising two zigzag structures having unequal-length struts (feature B1), wherein the vertices of the zigzags are coupled together (feature B2)."

XII. Auxiliary request 6a:

Claim 1 of auxiliary request 6a differs from claim 1 of auxiliary request 6 in that the following amendments are made:

"the inflow section is adapted to be disposed in the aortic annulus of the patient, the outflow section is adapted to be positioned in the patient's ascending aorta."

XIII. Auxiliary request 7:

This request corresponds to auxiliary request 4 as maintained by the Opposition Division.

XIV. The essential arguments of the respondents can be summarised as follows:

Non-admissibility of auxiliary requests 2, 4 and 6

Claim 1 of auxiliary requests 2, 4 and 6 did not comprise all the features of claim 1 of auxiliary request 1, in particular the feature according to which the frame expanded to an asymmetric hourglass shape. Hence these requests were not convergent with auxiliary request 1 and were thus inadmissible.

Alleged procedural violation

No arguments have been put forward by the respondents in this respect.

Articles 100(c) and 123(2) EPC

Claim 1 of all requests defined the outflow section to have a first nominal diameter ranging from 30 mm to 55 mm and the inflow section to have a second nominal diameter ranging from 19 mm to 34 mm.

These values were, however, exclusively disclosed on page 14, lines 7 to 9 of the application as filed, in

the context of a particular embodiment. As became evident from the words "permits" and "thus", the specific diameter ranges claimed were explicitly functionally linked to the cell pattern of the specific embodiment as defined on page 12, lines 23 to 29. The functional link between the nominal diameter and the further features of the embodiment was further underlined in the embodiment's detailed description, which put repeated emphasis on the cell pattern as being necessary to ensure the various functionalities of the frame, such as compressibility, expansion characteristics, expanded tri-level hourglass shape, adaptability to the anatomy, etc. Furthermore, the particular diameters claimed were only disclosed for a frame having a tri-level asymmetric hourglass shape (feature C), a shape to which the subject-matter of claim 1 of all requests was not restricted.

Therefore, in order to avoid an unallowable intermediate generalisation, the independent claim needed to enclose the features of the frame according to which A) the plurality of cells has sizes that vary along the length of the prosthesis, B1) each cell comprises two zigzag structures having unequal length struts, B2) wherein the vertices of the zigzags are coupled together, and C), the frame expands to a tri-level asymmetric hourglass shape.

As claim 1 of the main request and auxiliary requests 1-4, 4a, 5, 6 and 6a each missed at least one of features A, B1, B2 and C, none of these requests was allowable.

XV. The essential arguments of the appellant can be summarised as follows:

Admissibility of auxiliary requests 2, 4 and 6

Firstly, there was no absolute requirement for each and every request to incorporate all limitations of all previous requests. Secondly, all requests in the present case purported to focus more accurately on the preferred embodiment of the valve prosthesis disclosed in the application as filed. Therefore they were in the direction of the same inventive idea and thus convergent with auxiliary request 1.

Procedural violation

In item 2.1.3 of the reasons, the Opposition Division had interpreted the adverb "thus" using a dictionary entry. However, that dictionary entry had not been discussed during opposition proceedings, thus depriving the appellant of the possibility to submit a more complete dictionary entry, which provided other definitions of the word. Hence, the appellant's right to be heard was violated and a refund of the appeal fee justified owing to a substantial procedural violation.

Articles 100(c) and 123(2) EPC

When examining whether or not the subject-matter extended beyond the content of the application as filed, the application as a whole and the knowledge of the skilled person had to be taken into account.

In the present case, the description as well as the original claim tree clearly emphasised the expanded deployed configuration as the most important feature of the invention, with the further properties such as cell pattern, flaring of the outflow and inflow sections or details of the valve being of hierarchically lower

importance. Therefore, these further properties could be omitted without extension of subject-matter.

While it was true that for the example from which the claimed diameters were taken, the deployed configuration was a tri-level asymmetric hourglass shape, there was no need to explicitly define that shape in the claim because the claim already provided for an equivalent definition.

As discussed in the description, page 12, lines 9 to 12, and as also accepted by the respondent, the person skilled in the art knew that various cell patterns as well as other parameters could be chosen to reach a particular deployed configuration. When choosing the dimensions for such a deployed configuration, the skilled person would thus not consider the specific cell pattern of the embodiment a necessary feature, but directly refer to the diameters disclosed on page 14, lines 7 to 9 as an independent teaching. The cell pattern described on page 12, lines 23 to 29 was thus a possible but not a necessary feature of the embodiment.

To conclude, the subject-matter of claim 1 of the main request did not extend over the content of the application as filed, even without claiming features A, B1, B2 and C.

The claims of all auxiliary requests comprised the feature of the asymmetric hourglass shape (feature C_{part}) and/or claimed generalisations over the specific pattern of page 12, lines 23 to 29. These were based on the claim set as filed or on the description as a whole and thus allowable.

Reasons for the Decision

1. Admissibility of auxiliary requests 2, 4 and 6

In respondent 2's view, auxiliary requests 2, 4 and 6 should not be admitted into the proceedings because they are not convergent with auxiliary request 1, claim 1 of these requests not comprising the feature "the multi-level frame having an asymmetric hourglass shape" which is comprised in claim 1 of auxiliary request 1.

By filing these requests, the appellant is aiming to overcome the different unallowable intermediate generalisations identified by the Opposition Division. The requests gradually add or partly generalise - in roughly the same way as in the opposition proceedings - the features of the detailed disclosure on page 12, lines 23-29 and page 13, lines 4-8, which were objected to as missing from claim 1 as granted. The Board considers that this behaviour is not inappropriate on the part of a (partly) losing party.

Moreover, the requests have been filed with the grounds of appeal and thus at a very early stage of the appeal proceedings. Hence, the respondents and the Board have had no difficulty in preparing appropriately.

Auxiliary requests 2, 4 and 6 are thus admitted into the proceedings.

2. Request for reimbursement of the appeal fee

The main objection resides in the fact that in interpreting a particular passage comprising the word "thus", the Opposition Division referred to a Merriam-

Webster dictionary entry which had not been discussed during the oral proceedings.

The issue of whether the second sentence (which discloses the parameter ranges) was logically or causally linked with the first sentence (which refers to the "above described cell pattern") was discussed during the oral proceedings (point 2.1 of the minutes), including page 14, lines 7-9, i.e. the particular passages with the word "thus"; this much is undisputed.

Furthermore, in order to come to a decision about extension of subject-matter, the Opposition Division had to interpret the wording of the description and the meaning of the word "thus". After the debate in the oral proceedings, they were entitled to interpret the specification and to argue - without any dictionary support - that the word "thus" logically connected both sentences. Hence, the dictionary entry was only cited in the written decision in support of a conclusion already reached during oral proceedings - after a detailed discussion with the parties regarding the contextual interpretation of the relevant passage.

Therefore, the reference to the Merriam-Webster dictionary in the decision, having only a supporting but not a decisive function, neither leads to a violation of the right to be heard, nor to a substantial procedural violation. Consequently, the request for reimbursement of the appeal fee has to be rejected for that reason alone. Moreover, the requirements for reimbursement of the appeal fee pursuant to Rule 103(1)(a) EPC are also not met because the appeal was not deemed allowable (see below).

3. Articles 100(c) and 123(2) EPC

3.1 Main request

Claim 1 as granted corresponds to claim 1 as filed with the following additional features:

- the outflow section (15) has a first nominal diameter (D₀) ranging from 30 mm to 55 mm,
- the inflow section (16) has a second nominal diameter (D₁) smaller than the first nominal diameter and ranging from 19 mm to 34 mm.
(emphasis added by the Board)

The only support for these parameter ranges is on page 14, lines 3-9 of the published PCT application, which in context read as follows:

"The above-described cell pattern permits each of the inflow and outflow sections of frame 12 to expand to a diameter within a range of deployed diameters, while retaining constriction region 17 at a substantially constant diameter. **Thus, for example, outflow diameter D₀ may range from 30 to 55 mm, while inflow diameter D_I may vary from 19 to 34 mm"**.

Therefore, the particular parameter values are disclosed in a specific textual context, belonging to the embodiment shown in Figure 1. The frame of this embodiment has a particular cell pattern (page 12, lines 23-29) and expands to a particular tri-level asymmetric hourglass shape (page 13, lines 4-8).

3.1.1 The tri-level asymmetric hourglass shape

The appellant agreed that the expanded deployed configuration of the frame was disclosed as a key feature for the particular embodiment from which the specific diameter ranges were derived. They were, however, of the opinion that the claim defined subject-matter equivalent to the tri-level asymmetric hourglass shape disclosed for the embodiment, and that thus there was no need to specifically claim the frame as having an asymmetric hourglass shape.

The claim indeed defines a shape having a conical inflow section, an enlarged outflow section and a constriction region, with the inflow section having a diameter smaller than the outflow section, and with the constriction region having a third diameter smaller than the inflow and outflow sections. The frame thus has a tri-level configuration.

However, the tri-level configuration defined encompasses expanded deployed configurations which exhibit sharp transitions between the levels, i.e. without the smooth transitions between adjacent sections and without the convex-concave shape within the constriction region exhibited by an asymmetric hourglass shape. These transitions and the shape are disclosed as having particular functionalities, such as holding the frame away from the opposing sinus wall in the ascending aorta and directing blood flow through the valve body with little or no turbulence (see page 13, lines 19 to 24 and page 13, line 28 to page 14, line 2). Given the functional and structural relationship between the particular diameters of the inflow and outflow sections and the asymmetric hourglass shape (feature C_{part}) of the frame, the

omission of the feature relating to the asymmetric hourglass shape in the claim gives rise to an unallowable intermediate generalisation.

3.1.2 The cell-pattern

The Board agrees with the Opposition Division in that, in the present context, the word "thus" indicates that the content of the sentence is a consequence of the preceding sentence.

The preceding sentence makes explicit reference to the particular "above described cell pattern" which is defined on page 12, lines 23-29 as follows:

" ..the frame comprises a plurality of cells having sizes that vary along the length of the prosthesis. As indicated by dotted lines a, b and c, each cell comprises two zig-zag structures having unequal-length struts, wherein the vertices of the zigzags are coupled together."

The explicit wording used thus conveys a logical and functional relationship between the features of the cell pattern and the diameter ranges claimed.

The appellant was of the opinion that the description as well as the claim taught the skilled person - who was aware of various ways to manufacture a frame having a particular expanded deployed shape - that it was the expanded deployed configuration which was crucial for the invention while the particular cell pattern was only a possible but not a necessary feature of the embodiment.

It is uncontested that the person skilled in the art at the time of filing was aware of different frame-manufacturing parameter choices in principle available for reaching a certain intended frame-expanded configuration. However, the description of the specific embodiment emphasises in an almost repetitive way - using strong causally linking verbs such as "permits", "enables" or "ensures" - the importance of the particular cell pattern described on page 12, lines 23 to 29 in reaching the intended expanded configuration and its various benefits. It would thus go against the explicit teaching of the document to "jump" - as suggested by the appellant - from the very general mentioning of an expanded deployed configuration on page 12, lines 9 to 12, directly to the specific diameter ranges on page 14, lines 7-9, thereby ignoring two pages of detailed description disclosing how the specific cell pattern and the expanded deployed configuration are functionally interrelated. While the common general knowledge can supplement and enhance a disclosure, it cannot overwrite such an explicit detailed teaching in the application, unless such a teaching was clearly erroneous (which is undisputedly not the case here).

It is further noted that in the embodiment described on pages 12-16, the first mentioning of a frame including "multiple levels, including outflow section, inflow section and constriction region" (page 12, lines 21-23) is immediately followed by the description of the particular cell pattern (page 12, lines 23 to 29). Thus, at least in the description, the particular frame claimed and the cell pattern do not differ in terms of their hierarchy.

Even if the claim tree abstracts the shape from the cell pattern, this is not for the tri-level asymmetric hourglass shape of the embodiment, but for a more general tri-level shape (see point 3.1.1 above).

Neither the description nor the claim tree thus provide a basis for generalising the cell pattern from the one disclosed on page 12, lines 23-29, comprising A) a plurality of cells having sizes that vary along the length of the prosthesis, B1) each cell comprising two zig-zag structures having unequal length struts, wherein B2) the vertices of the zigzags are coupled together.

3.1.3 As claim 1 as granted lacks features A, B1, B2 and the asymmetric hourglass shape (C_{part}), its subject-matter extends beyond the content of the application as filed.

4. Auxiliary requests 1-4, 4a, 5, 6, 6a

Claim 1 of each of these requests undisputedly lacks or generalises in respect of at least one of features A, B1, B2 or the asymmetric hourglass shape (feature C_{part}). Therefore, the auxiliary requests likewise extend beyond the content of the application for the reasons discussed in point 3 above.

5. Auxiliary request 7

This request is the same as auxiliary request 4, which the Opposition Division held as being compliant with the EPC. As only the proprietor has appealed, neither the Board nor the non-appealing respondents (parties to the proceedings as of right under Article 107, second sentence, EPC) may challenge the maintenance of the

patent as amended in accordance with the interlocutory decision (G 9/92, HN 1, OJ 1994, 875).

6. In view of the conclusions reached above, the further procedural requests made by respondents 2 and 3 have become moot.

Order

For these reasons it is decided that:

1. The appeal is dismissed.
2. The request for reimbursement of the appeal fee is refused.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated