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**Datasheet for the decision
of 25 March 2022**

Case Number: T 2091/17 - 3.2.08

Application Number: 11805348.7

Publication Number: 2651335

IPC: A61F2/24, A61F2/95

Language of the proceedings: EN

Title of invention:

SYSTEMS AND METHODS FOR POSITIONING A HEART VALVE USING VISUAL
MARKERS

Patent Proprietor:

Medtronic Vascular Inc.

Opponents:

LANG & TOMERIUS
BIOTRONIK AG

Relevant legal provisions:

EPC Art. 54(2), 56, 123(2)
EPC R. 80

Keyword:

Amendments - main request - allowable (no) - auxiliary requests 4, 5, 6 - allowable (no) - auxiliary request 7 - allowable (yes)
Novelty - auxiliary requests 1, 2, 3, 3A (no)
Inventive step - auxiliary request 7 (yes)



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2091/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 25 March 2022

Appellant: Medtronic Vascular Inc.
(Patent Proprietor) 3576 Unocal Place
Santa Rosa, CA 95403 (US)

Representative: Zimmermann & Partner
Patentanwälte mbB
Postfach 330 920
80069 München (DE)

Appellant: LANG & TOMERIUS
(Opponent 1) Patentanwaltspartnerschaft mbB
Rosa-Bavarese-Str. 5
D-80639 München (DE)

Representative: Peterreins Schley
Patent- und Rechtsanwälte PartG mbB
Hermann-Sack-Strasse 3
80331 München (DE)

Appellant: BIOTRONIK AG
(Opponent 2) Ackerstrasse 6
8180 Bülach (CH)

Representative: Biotronik Corporate Services SE
Corporate Intellectual Property
Sieversufer 7-9
12359 Berlin (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
3 July 2017 concerning maintenance of the
European Patent No. 2651335 in amended form.**

Composition of the Board:

Chairwoman Y. Podbielski
Members: G. Buchmann
 C. Vetter

Summary of Facts and Submissions

- I. With the decision posted on 3 July 2017 the opposition division decided that European patent No. 2 651 335 in amended form fulfilled the requirements of the EPC.
- II. The proprietor and both opponents filed an appeal against that decision.
- III. Oral proceedings took place in the form of a videoconference before the Board on 25 March 2022.
- IV. Appellant 1 (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request), or that the patent be maintained on the basis of one of auxiliary requests 1-8 filed with the statement setting out the grounds of appeal on 7 November 2017, or on the basis of auxiliary request 3A filed on 25 February 2022.
- V. Appellant 2 (opponent 1) requested that the decision under appeal be set aside and that the patent be revoked.
- VI. Appellant 3 (opponent 2) had requested in writing that the decision under appeal be set aside and that the patent be revoked.
- VII. In the present decision, reference is made to the following documents:

D1 WO 2010/031060 A1

D9 US 2010/0274276 A1

D12 WO 02/067782 A2

VIII. **Main Request**

Claim 1 of the **main request** reads as follows (numbering added):

1

"An assembly for delivering an implantable prosthesis (10) to a target site in a body, the assembly comprising:

1.1

an elongate delivery member (306); and

1.2

a valve retainer (308) connected to the elongate delivery member (306), wherein

1.2.1

the valve retainer (308) has an outer surface, wherein

1.2.2

the valve retainer (308) is configured to releasably secure a prosthesis (10) to the elongate delivery member (306) during delivery to a target site in a body, and

characterized in that

1.2.3

the valve retainer (308) includes a rotational identifier (422) that identifies the rotational orientation of the valve retainer (308) when the valve retainer is positioned proximate to the target site in the body."

Claim 11 of the **main request** reads as follows:

"An apparatus comprising the assembly according to claim 1, 4, or 10 further comprising:
a valve prosthesis (10) comprising:

a prosthetic heart valve,
a support structure (12, 14), wherein the support
structure includes a first material having a first
radiopacity, and
one or more radiographic identifiers, wherein the
radiographic identifiers include a second material
having a second radiopacity different from the first
radiopacity;
wherein the prosthesis is the valve prosthesis."

IX. **Auxiliary requests**

(a) Auxiliary request 1

The dependency of claim 11 has been amended so that
claim 11 depends on claim 1 only.

(b) Auxiliary request 2

In the claims, the "prosthesis" has been specified
to a "heart valve prosthesis" and the "valve" has
been specified to a "heart valve".

(c) Auxiliary requests 3 and 3A

Dependent claims 2 and 4 have been introduced into
claim 1 as alternatives according to which
"the rotational identifier (422) includes a notch
formed from the outer surface of the heart valve
retainer (308) or a radiopaque material".

Claim 1 of auxiliary request 3A is identical to
claim 1 of auxiliary request 3.

(d) Auxiliary request 4

Former claim 11 (the valve) has been included into claim 1 (the delivery system).

(e) Auxiliary request 5

The subject-matter of claims 6, 7 and 8 has been included into claim 1, according to which
"the valve retainer (308) includes a top surface and a bottom surface, and [wherein] the top surface contains a prosthesis retaining slot,"

and

"the assembly further comprises a heart valve prosthesis (10) configured to be releasably secured by the valve retainer (308), wherein the heart valve prosthesis (10) includes a support member and a valve member, wherein the support member includes a commissural post (11)"

and

"the heart valve prosthesis (10) includes a connection member, and wherein the prosthesis retaining slot of the valve retainer (308) is configured to receive and secure the connection member of the heart valve prosthesis".

(f) Auxiliary request 6

In addition to claim 1 of auxiliary request 5, claim 9 has been added.

(g) Auxiliary request 7

Dependent claims 2-5 have been introduced into claim 1 as alternatives according to which
"the rotational identifier (422) includes a notch

formed from the outer surface of the heart valve retainer (308) or a radiopaque material, wherein the notch or radiopaque material extends approximately 180 degrees around the outer surface of the valve retainer (308)".

X. **The arguments of appellant 1, as far as relevant for the present decision, can be summarised as follows:**

Main Request - added subject-matter

It was clear to the reader that the two valve prostheses formally present in claim 11, when dependent on claim 10, were one and the same. Only a single valve was present in the set of claims. This valve had to be re-cited in claim 11 where it was further specified. The raised objections were based on a lack of clarity instead of added subject-matter.

Auxiliary request 1 - novelty

D12 referred to a stent delivery device only. The retainer in Figures 6-10 was shown together with a stent (12), not with a prosthetic valve. The passage on page 17, lines 1-7, which mentioned percutaneous valves, referred to the scope of the invention of D12 but did not represent a disclosure of subject-matter. Furthermore, the delivery system of D12 was specific for an asymmetric stent. The reader of D12 would not have taken this specific system for a heart valve which was symmetric. Additionally, the function of the "indicator" according to claim 1 was essentially different from the "indicia" of D12.

Auxiliary request 2 - novelty

D12 did not refer to heart valve prostheses but only to percutaneous valves. A heart valve prosthesis was more specific and therefore novel.

Auxiliary request 3 and 3A - novelty

The indicia (15') of D12, formed from a single projection, was not described to be made from radiopaque material.

Auxiliary request 4 - added subject-matter

The arguments submitted in view of the main request apply.

Auxiliary requests 5 and 6 - added subject-matter

The arguments submitted in view of the main request apply.

Auxiliary request 7

Amendments - Article 123(2) EPC

The combination of a prosthesis retaining slot and the specific identifiers according to the amended claim 2 was disclosed in Figure 11 and the description as originally filed. The assembly of claim 6 did not comprise two valve prostheses and therefore did not contravene Article 123(2) EPC.

Amendments - Rule 80 EPC

Claim 7 only represents a different presentation of

subject-matter which was already present in the granted set of claims. The separate claim was made necessary by the amendments made to overcome an objection under Article 123(2) EPC.

Inventive step - Article 56 EPC

The subject-matter of claim 1 of auxiliary request 7 differed from the prior art in that "the notch or radiopaque material extends approximately 180 degrees around the outer surface of the valve retainer (308)".

The objective problem was to provide a highly visible marker for allowing identification of the rotational orientation of a valve retainer during an implantation procedure.

Indicators extending 180 degrees around the outer surface of a valve retainer were neither disclosed nor suggested by the cited documents.

XI. **The arguments of appellants 2 and 3, as far as relevant for the present decision, can be summarised as follows:**

Main Request - added subject-matter

Claim 11 of the main request, when taken as dependent on claim 10, comprised a heart valve prosthesis and a valve prosthesis. However, such an assembly comprising two valve prostheses was not disclosed in the application as filed.

Auxiliary request 1 - novelty

D12 disclosed an assembly according to claim 1. Page

17, lines 1-7 of D12 described that the delivery system of D12 was suitable for prosthetic valves. Claim 1 did not require more than this suitability. The system of D12 provided the same function in view of rotational orientation as needed for a prosthetic valve. The indicia (15'), when used as single indicia (page 14, lines 11-15), delivered the same information as the single notch of the valve retainer of the patent.

Auxiliary request 2 - novelty

An assembly for delivering a percutaneous valve was also suitable for delivering a heart valve prosthesis.

Auxiliary request 3 and 3A - novelty

The complete collar (27) of D12, including the indicia (15') in the form of a single projection, was made from radiopaque material, corresponding to the feature added into claim 1.

Auxiliary request 4 - added subject-matter

In the same way as in the main request, claim 7 comprised two valve prostheses. This was not originally disclosed.

Auxiliary requests 5 and 6 - added subject-matter

In the same way as in the main request, claims 8 and 7, respectively, comprised two valve prostheses. This was not originally disclosed.

Auxiliary request 7

Amendments - Article 123(2) EPC

The combination of a prosthesis retaining slot and the specific identifiers according to the amended claim 2 was not present in the original set of claims. This contravened Article 123(2) EPC.

Similar to claim 11 of the main request, the assembly of claim 6 comprised two valve prostheses. However, such an assembly comprising two valve prostheses was not disclosed in the application as filed.

Amendments - Rule 80 EPC

The addition of dependent claim 7 was not based on a ground of opposition, contrary to the requirements of Rule 80 EPC.

Inventive step - Article 56 EPC

The subject-matter of claim 1 lacked an inventive step in view of D12 in combination with D1 or D9. D1 explained the advantage of providing markers such that left-handed and right-handed 2-dimensional images could be obtained. D9, Figures 21B and 21D and paragraphs [0086]-[0096] taught indicators extending 180 degrees around the outer surface of a valve retainer.

Reasons for the Decision

1. Main request - added subject-matter

1.1 Claim 11 of the main request, when taken as dependent on claim 10, indirectly also depends on claim 7.

Claim 7 first introduces "a heart valve prosthesis" into the assembly of claim 1. Claim 11 then specifies an apparatus "further comprising: a valve prosthesis".

Summing up the respective features of claim 11 in combination with claim 7, it specifies an assembly comprising

- a heart valve prosthesis including
 - a support member and
 - a valve member

and further comprising

- a valve prosthesis including
 - a support structure,
 - a prosthetic heart valve.

1.2 This means that the assembly of claim 11 comprises a heart valve prosthesis and a valve prosthesis. However, such an assembly comprising two valve prostheses is not disclosed in the application as filed.

1.3 Appellant 1 argued that it was clear to the reader that the two valve prostheses were one and the same.

They are, however, described using a different terminology (support structure vs. support member, valve member vs. prosthetic heart valve). Therefore, it is not evident that the two valve prostheses are

intended to be the same entity.

- 1.4 Appellant 1 further argued that claim 11, when dependent on claim 4, comprised only a single valve prosthesis. This made clear that only a single valve prosthesis was present in all of the claims.

However, the presence of a single valve prosthesis in one claim combination does not exclude the presence of two valve prostheses in another claim combination.

Also appellant 1's argument that claim 11 added features of the valve, and therefore the valve must be re-cited in the claim, is not convincing. Such an addition of features to the valve can be formulated without introducing a further valve.

- 1.5 Appellant 1 also argued that the claims were open to an ambiguous interpretation. Hence, the disputed issue was a mere matter of clarity.

The wording of the claims is, however, clear with respect to the fact that according to claim 7, the assembly comprises a heart valve prosthesis, and according to claim 11 it further comprises a valve prosthesis.

- 1.6 Therefore, claim 11 when dependent on claim 10 contravenes Article 123(2) EPC.

2. **Auxiliary request 1 - novelty**

- 2.1 Claim 1 of auxiliary request 1 is identical to claim 1 of the main request.

2.2 Document D12 discloses

1

"An assembly (10) for delivering an implant (12) to a target site in a body the assembly comprising (Figures 1-2 and 6-10):

1.1

an elongate delivery member (inner tubular member 14);
and

1.2

a retainer (collar or marker 27) connected to the elongate delivery member, wherein

1.2.1

the retainer (27) has an outer surface, wherein

1.2.2

the retainer (27) is configured to releasably secure the implant (12) to the elongate delivery member during delivery to a target site in a body (page 9, lines 13-29).

This disclosure of D12 is not disputed among the parties.

2.3 Appellant 1 correctly stated that the detailed description of D12 refers to a stent delivery device (10). The retainer in Figures 2 and 6-10 is shown together with a stent (12). However, on page 17, lines 1-7, D12 describes that "the various aspects of the present invention are also applicable to systems for delivering other types of self-expandable implants". One of the examples given are "percutaneous valves" which include heart valve prostheses. From that, it can be concluded that the delivery device (10), and in particular the retainer (27) are suitable for retaining and delivering a heart valve prosthesis.

Appellant 1 argued that said passage on page 17 only

referred to the scope of the invention of D12 but did not represent a disclosure of subject-matter. However, said passage indicates a suitability of the described delivery devices. Since claim 1 does not require more than a suitability (a valve retainer is a retainer for holding a valve), this is a sufficient disclosure to fall under the definition of the claim.

Therefore, D12 discloses an assembly for delivering an implantable prosthesis (Feature 1), the assembly comprising a valve retainer (Feature 1.2).

- 2.4 Appellant 1 further argued that the embodiment of Figure 9 which was cited by appellant 2, comprised a delivery device specifically for an asymmetric stent which was used close to a bifurcation of a blood vessel (see page 13, line 26 - page 14, line 15). That stent had to be implanted in one certain orientation. In contrast, a heart valve was symmetric and could be implanted in several orientations. Therefore, the skilled reader would not have taken the specific retainer of Figure 9 for implantation of a heart valve.

The situation underlying the claimed invention is, however, that the heart valve must be oriented correctly (in one of three possible orientations). The retainer (27) of D12 allows the correct insertion in one possible orientation since the stent is rotationally fixed to the retainer. Therefore, the skilled reader will understand that the retainer (27) is also suitable for insertion of a heart valve which has three possible correct orientations, and that the retainer of Figure 9 may be regarded as a valve retainer, as indicated on page 17 of D12.

2.5 D12 further discloses that the valve retainer (27) includes indicia (15') in the form of projections (Figures 7 and 9). The Figures show pairs of indicia. However, page 14, lines 11-15, explains that in all embodiments a single indicia can be provided on the retainer (27). Such a single indicia in the form of a projection identifies the rotational orientation of the valve retainer in the same way as e.g. the single notch or the radiopaque marker according to the patent. The single indicia (15') therefore corresponds to the rotational identifier of **Feature 1.2.3**.

Appellant 1 explained that according to the patent, the notch (as an example of the rotational identifier) appears either on the right side of a 2-dimensional fluoroscopic picture, or on the left side. In combination with the picture of the heart valve, including the commissure posts, the user could derive the absolute orientation of the heart valve. This was different to the prior art. However, the same is the case for the single indicia of D12: It appears either on the right side or on the left side of the 2-dimensional picture thereof.

Appellant 1's argument that an "identifier" according to the claim had a different function than an indicator or indicia as described in D12, is not convincing. The identifier according to the patent does by itself not provide an absolute orientation value to the user, as alleged by appellant 1. In contrast, it provides the same qualitative information (left/right) which must be combined with the picture of the heart valve prosthesis in order to arrive at the absolute orientation of the valve prosthesis at the implantation site. The Board agrees with appellant 2 that the alleged difference between the "indicia" of D12 and the "identifier" of

the claim is purely linguistic because there are no differences in the real function of these two elements.

2.6 Appellant 1 also argued that the indicia 15' indicated only an axial "position of the collar". However, D12 describes that "a non-symmetrical stent feature... can be aligned with the indicia" (page 14, lines 12-13) and "therefore, a physician can easily visualise the position of any non-symmetrical stent feature" (lines 14-15). This passage makes clear that the indicia are used for visualisation of the rotational orientation of the stent.

2.7 For the above reasons, the subject-matter of claim 1 of auxiliary request 1 lacks novelty with respect to document D12.

3. **Auxiliary request 2 - novelty**

In auxiliary request 2, the assembly has been restricted to be suitable for delivering a heart valve prosthesis and the valve retainer to be a heart valve retainer.

Appellant 1 invoked that document D12 referred to "percutaneous valves". The term "heart valve prosthesis" was more specific and therefore provided novelty with respect to D12.

It must, however, be noted that claim 1 does not comprise a heart valve prosthesis but it merely defines the assembly to be suitable for delivering a heart valve prosthesis. A device which is suitable for delivering a percutaneous valve (including e.g. venous valves or heart valves) is also suitable for delivering a heart valve.

Therefore, the subject-matter of claim 1 of auxiliary request 2 lacks novelty with respect to document D12.

4. **Auxiliary request 3 and 3A - novelty**

In auxiliary requests 3 and 3A the features have been added to claim 1 according to which "the rotational identifier (422) includes a notch formed from the outer surface of the heart valve retainer (308) or a radiopaque material".

In document D12, the collar (27) which forms the stent retainer has also the function of a "marker (27)". In particular on page 6, lines 3-9, it is described that the radiopaque markers (27, 28) form the collar which interlocks with the stent. Hence, the valve retainer of D12 is formed from radiopaque material and the (single) indicia in the form of a projection (15') extending from the valve retainer is also formed from radiopaque material.

Therefore, the rotational identifier of document D12 includes a radiopaque material, and the subject-matter of claim 1 of each of auxiliary requests 3 and 3A lacks novelty with respect to document D12.

5. **Auxiliary request 4 - added subject-matter**

Similar to claim 11 of the main request, claim 7 of auxiliary request 4 specifies an assembly comprising

- a valve prosthesis including
 - a support structure,
 - a prosthetic heart valve (claim 1)

and further comprising

- a heart valve prosthesis including

- a support member and
- a valve member (claim 7).

Therefore, auxiliary request 4 contravenes Article 123(2) EPC for the same reasons as given above with respect to the main request.

6. Auxiliary requests 5 and 6 - added subject-matter

Similar to claim 11 of the main request, claim 8 of auxiliary request 5 and claim 7 of auxiliary request 6 specify an assembly comprising

- a heart valve prosthesis including
 - a support member and
 - a valve member (claim 1)
- and further comprising
- a valve prosthesis including
 - a support structure,
 - a prosthetic heart valve (claim 8/7).

Therefore, auxiliary requests 5 and 6 contravene Article 123(2) EPC for the same reasons as given above with respect to the main request.

7. Auxiliary request 7

7.1 Amendments - Article 123(2) EPC

Claim 1 of auxiliary request 7 combines the features of claims 1-5 as originally filed. Furthermore, claim 6 (former claim 11) has been made dependent on claim 1 only.

The objection raised by appellant 2 in the letter of 27 March 2018 refers to a second prosthetic heart valve being present in claim 6. However, claim 6 which

depends on claim 1 only, does not comprise more than one valve prosthesis. Therefore, this objection does not apply.

Appellant 3 argued that the subject-matter of claim 2 of auxiliary request 7 which referred to a prosthesis retaining slot, had newly been combined with the subject-matter of former claims 2+3 or 4+5 which refer to a notch or radiopaque marker extending 180° around the outer surface of the valve retainer. This combination of features had not been originally disclosed in the application.

However, Figure 11 of the application which is described in paragraph [0048], shows the valve retainer (408) having both the retaining slots (426) and the notch (422). The radiopaque material is described as an alternative for the notch on the same valve retainer (see e.g. paragraph [0059] of the application as filed). Therefore, the combination of both, the notch (422) and the radiopaque material with the retaining slots of present claim 2 are originally disclosed in the application.

Hence, auxiliary request 7 fulfils the requirements of Article 123(2) EPC.

7.2 **Amendments - Rule 80 EPC**

Appellant 2 raised an objection under Rule 80 EPC because dependent claim 7 was added in auxiliary request 7.

This claim comprises the subject-matter of former claims 10 and 11. This replaces the dependence of claim 11 on claim 10 which has been deleted in order to

comply with Article 123(2) EPC.

Therefore, the addition of claim 7 is caused by the amendments which were necessary to overcome the objection under Article 123(2) EPC. Consequently, the introduction of claim 7 does not contravene Rule 80 EPC.

7.3 **Inventive Step - Article 56 EPC**

The subject-matter of claim 1 of auxiliary request 7 differs from the prior art at least in that "the notch or radiopaque material extends approximately 180 degrees around the outer surface of the valve retainer (308)".

This feature solves the objective problem of providing a highly visible marker for allowing identification of the rotational orientation of a valve retainer during an implantation procedure.

Appellant 2 argued that a motivation for implementing the notch or radiopaque material in such a way was already provided in document D1 which explained the advantage of providing markers such that left-handed and right-handed 2-dimensional images could be obtained.

However, the passage cited as evidence by appellant 2 (page 6, last paragraph - page 7, first paragraph), only describes the problems caused by the (only) 2-dimensional images when trying to identify the rotational orientation of the prosthetic heart valve. It neither refers to right- or left-handed images nor does it suggest any circumferential extension of any markers. Other parts of D1 describe markers located at

the commissural posts of the prosthetic heart valve. These markers do not extend about 180° of the prosthetic heart valve.

Appellant 2 further cited document D9, allegedly teaching indicators extending 180 degrees around the outer surface of a valve retainer. They referred to Figures 21B and 21D and to paragraphs [0086]-[0096].

D9 describes a delivery device for insertion of a selective occlusion device (SOD, 10) which treats an aneurysm. The SOD comprises a stent which is held on a delivery wire (50). The delivery wire (50) is provided with indicators (52) which are used for rotational and axial adjustment of the SOD (paragraph [0092]). The indicators (52) are represented in Figures 21B and 21D by black wire portions which extend parallel to the axis of the delivery wire. No extension of 180 degrees around the outer surface of the delivery wire is shown. Also the description, paragraph [0096], neither describes nor suggests such a configuration.

Therefore, neither D1 nor D9 render the subject-matter of claim 1 of auxiliary request 7 obvious, as alleged by appellant 2.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent on the basis of auxiliary request 7 filed with the statement setting out the grounds of appeal on 7 November 2017 and a description to be adapted thereto.

The Registrar:

The Chairwoman:



C. Moser

Y. Podbielski

Decision electronically authenticated