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**Datasheet for the decision
of 13 March 2020**

Case Number: T 0720/15 - 3.2.02

Application Number: 08250524.9

Publication Number: 2074953

IPC: A61B17/00, A61B17/12

Language of the proceedings: EN

Title of invention:

Percutaneous catheter directed intravascular occlusion devices

Patent Proprietor:

AGA Medical Corporation

Opponent:

Occlutech Holding AG

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 83, 84, 100(c), 123(2)

RPBA Art. 12(4)

RPBA 2020 Art. 13(1)

Keyword:

Amendments - added subject-matter - main request (yes),
auxiliary request 1 (no)

Claims - clarity - auxiliary request 1 (yes)

Sufficiency of disclosure - auxiliary request 1 (yes)

Novelty - auxiliary request 1 (yes)

Inventive step - auxiliary request 1 (yes)

Late-filed auxiliary request 1 - admitted (yes)

Late-filed documents - admitted (yes)

Late-filed argument - admitted (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0720/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 13 March 2020

Appellant: Occlutech Holding AG
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 5 February 2015
rejecting the opposition filed against European
patent No. 2074953 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Böttcher
Y. Podbielski

Summary of Facts and Submissions

I. The opponent filed an appeal against the decision of the opposition division to reject the opposition against European patent No. 2 074 953.

II. Oral proceedings before the Board took place on 13 March 2020.

The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked.

The appellant furthermore requested that the auxiliary requests not be admitted into the proceedings.

The respondent (patent proprietor) requested that the appeal be dismissed (and the patent be maintained as granted) or, on an auxiliary basis, that the patent be maintained on the basis of auxiliary request 1 or 2, both filed with letter dated 10 February 2020.

The respondent furthermore requested that neither documents E22 and E23 nor the objection under Article 100(b) EPC entitled "Further disks" on page 18 of the grounds of appeal be admitted into the proceedings.

III. Claim 1 of the main request reads as follows:

"A medical device (10) for occluding a left atrial appendage, the medical device comprising:

a first portion (14) having a first diameter and comprising at least one plane of occlusion configured to be positioned outside of the left atrial appendage;
and

a second portion (12) having a second diameter smaller than the first diameter and comprising at least one plane of occlusion configured to be positioned within a cavity defined by the left atrial appendage, the second portion comprising a cylindrical surface formed of a metal fabric comprising a plurality of wire strands configured to engage the cavity wall along the entire length of the second portion; and

a transition segment (19) having a transition diameter substantially smaller than the first and second diameters and coupling the first portion (14) and the second portion (12) and configured to provide flexibility therebetween, the second portion (12) having said cylindrical surface along the entire length of the second portion from a non-tapered end surface distal to the first portion (14) to an opposing end surface proximal to the transition segment (19) and the first portion (14)."

IV. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the term "planar" has been introduced in front of "non-tapered end surface".

V. The following documents are cited in this decision:

E2: EP 2 014 240 A1

E4: US 20070265656 A1

E5: Premarket notification under 510(k) related to Amplatzer Vascular Plug II, available under the freedom to information act from 18 June, 2007

E8: WO 02/071977 A2

E13: WO 2008/125689

E22: David S. Beutler et al., The Morphology of Left Atrial Appendage Lobes: A Novel Characteristic

Naming Scheme Derived through Three-
Dimensional Cardiac Computed Tomography; World
Journal of Cardiovascular Surgery, 2014, 4, 17-24
E23: Sahar S. Abdelmoneim, Sharon L. Mulvagh,
Techniques To Improve Left Atrial Appendage
Imaging, Journal of Atrial Fibrillation, June-
July, 2014, Vol. 7, Issue 1

VI. The arguments of the appellant, as far as relevant for
the decision, can be summarized as follows:

Admittance of documents E22 and E23

E22 and E23 were filed to demonstrate that left atrial
appendages (LAA) may have various different shapes, as
shown in Figures 2 and 3 of E22 and Figure 1 of E23.
The castings of LAA in E22 and E23 had to be regarded
as common general knowledge. The documents should
therefore be admitted into the proceedings.

Admittance of the objection entitled "Further disks"

This objection was filed as a reaction to the decision
by the Opposition Division finding with respect to
novelty that the devices of E2 and E4 were not suitable
for occluding a LAA. The discussion of novelty happened
only during the oral proceedings when the discussion
regarding sufficiency of disclosure had already been
closed. Hence, the objection was put forward at the
earliest point in time in the proceedings and should be
admitted.

Main request - added subject-matter

"Non-tapered end surface"

The feature "non-tapered end surface" could not be derived directly and unambiguously from the application as originally filed. The passage on page 12, lines 2 to 4, indicated as a basis by the proprietor, did not mention an end surface at all. Figure 1a referred to in this passage showed that the cylindrical surface of the second portion was tapered towards the end. The wording "not include a tapered surface as shown in FIGS. 4 - 6" therefore could only mean that the cylindrical surface was not tapered.

Furthermore, claim 1 defined an opposing end surface of the second portion located proximal to the first portion, hence on the side of the first portion where the proximal end clamp was located. Since Figure 6 did not show an opposing end surface at the location of the proximal end clamp, this figure could not be regarded as a basis for the feature "non-tapered end surface".

"Entire length of the second portion"

The feature "the second portion comprising a cylindrical surface formed of a metal fabric comprising a plurality of wire strands configured to engage the cavity wall along the entire length of the second portion" in claim 1 had to be interpreted such that the word "configured" was referring back to the wire strands from which the cylindrical surface was formed.

This feature was not directly and unambiguously derivable from the application as originally filed. In the application as originally filed it was disclosed

that the body portion was oversized and in its expanded state engaged only a part of the wall of the LAA (page 3, lines 17 to 20). Engagement along the entire length was not disclosed. Such an engagement would even not be possible in view of the various different shapes of the LAA as shown in E22 and E23.

Figures 3A-3C, 10 and 11 of the application, which illustrated the occlusion device positioned in a LAA, also did not show that the second portion was in engagement with the cavity wall over its entire length.

Thus, the requirements of Article 123(2) EPC were not met.

Auxiliary request 1 - admittance

Auxiliary request 1 should be considered late filed since it could have been filed during the opposition proceedings or in response to the appeal. Moreover, claim 1 of auxiliary request 1 was not prima facie allowable, since it still included added subject-matter, irrespective of the added word "planar", and since the amendment introduced a lack of clarity. Thus, auxiliary request 1 should not be admitted.

Auxiliary request 1 - added subject matter

By addition of the word "planar" the added subject-matter objection was not overcome. According to claim 1 of auxiliary request 1 the end surface could be convex and planar towards the end. However, such an embodiment could not be derived from the application as originally filed.

Moreover, the term "planar" was not mentioned in the

description of the application as originally filed. The description only disclosed a tapered surface with angle C, which was not present in the embodiment of Figures 4 to 6.

Hence, the amendment made to claim 1 of auxiliary request 1 infringed Article 123(2) EPC.

Auxiliary request 1 - clarity

It was not clear whether "planar" meant that the end surface had to be strictly planar, i.e. that it did not include a distal end clamp. Furthermore, it was not clear whether the embodiment of Figure 1a fell under the scope of claim 1 since in this embodiment the very end surface was planar and non-tapered.

Hence, claim 1 of auxiliary request 1 lacked clarity.

Auxiliary request 1 - sufficiency of disclosure

Claim 1 contained features which related to the anatomy of the patient, such as the features "one plane of occlusion configured to be positioned outside of the left atrial appendage", "one plane of occlusion configured to be positioned within a cavity defined by the left atrial appendage" and "configured to engage the cavity wall along the entire length of the second portion". Since the sizes and shapes of the LAA and the openings of the LAA differed from one patient to another, the skilled person would not know how to select the dimensions of the occlusion device. The description only suggested that the diameter of the cylindrical portion should be the same or larger than the inner diameter of the lumen in which it was to be deployed (page 18, lines 2 to 8 of the application).

However, it was not disclosed how to choose the dimensions of the cylindrical portion in order to achieve an engagement with the cavity wall over its entire length, in particular in view of the fact that the lumen of the LAA was not regularly shaped.

As mentioned in paragraph [0007] of the patent application, the occlusion device could include a third portion extending distally from the second portion. This third portion, or "further disc", could have a diameter of the same size or larger than the second diameter. The presence of such a third portion would prevent the device from engaging the cavity wall along the entire length of the second portion as required by claim 1. Thus, the skilled person was not given any guidance on how to design the third portion.

Claim 17 defined the device to be configured for delivery over a guidewire. However, the patent did not provide any guidance of how to achieve this.

According to claim 25 the first portion was configured to flex up to about 30 degrees with respect to the second portion. However, the patent did not provide any guidance of how to achieve this, in particular since the description contained some contradictions concerning the diameters of the first portion and the transition portion. Hence, the skilled person would not be able to carry out the invention.

For these reasons, the invention was not sufficiently disclosed to be carried out by the skilled person.

Auxiliary request 1 - novelty in view of E8

E8 disclosed in Figures 11a and 11b a device having all

the features of claim 1. It was mentioned on page 6, lines 22 to 23 that the elastic structure had a generally cylindrical shape. A cylindrical shape did not have to be a right circular cylinder. The band 820 shown in Figure 11a created a planar end surface. It was mentioned on page 20, lines 7 to 12 that also the distal end of the structure 800 shown in Figure 8a could be closed off by means of a band.

Furthermore, the diameter of the device structure 1200 shown in Figure 11a could be the same over the entire length of the structure as in the embodiment of Figure 8a. It was mentioned on page 19, lines 23 to 25 that the varied diameters were only optional.

Thus, the subject-matter of claim 1 lacked novelty over E8.

Auxiliary request 1 - novelty in view of E2 and E4

E2 disclosed devices for occlusion of body cavities to stop blood flow therethrough (page 2, paragraph [0007]). Since an LAA was a cavity, the devices of E2 were suitable to be used as LAA occlusion devices.

The embodiment of Figure 5A of E2 was novelty destroying for the subject-matter of claim 1 since it was mentioned in paragraph [0057] that the cylindrical portion G, to which the tapered surface belonged, could have other shapes, e.g. concave. In that case, the second portion could be regarded as being cylindrical along its entire length.

The device illustrated in Figure 3 of E2 also showed all the features of claim 1. It was mentioned in paragraph [0039] that the distal disc preferably had a

larger diameter than the shunt. Hence, the diameter of the distal disc could also be smaller such that the device could be positioned in the cavity of a LAA. This was in line with the teaching of a third portion in the present patent (paragraph [0009]).

Even if the diameter of the second disc was larger than the diameter of the cylindrical portion, this would not prevent engagement of the cylindrical portion with the wall of the cavity. A sufficiently soft and flexible second disc would flatten out such that full engagement would not be prevented under any circumstances.

The same argument applied to the devices illustrated in Figures 11a, 12a and 16b of E4.

Hence, the subject-matter of claim 1 lacked novelty over E2 and E4.

Auxiliary request 1 - novelty in view of E13

Figures 10 and 17 of E13 illustrated devices for occluding a LAA comprising all the features of claim 1, in particular a cylindrical portion 3 and a planar end surface 21. Thus, the subject-matter of claim 1 lacked novelty over E13.

Auxiliary request 1 - novelty in view of E5

The devices illustrated on pages 23 and 34 of E5 comprised all the features of claim 1, in particular a "second portion having said cylindrical surface along the entire length of the second portion from a planar, non-tapered end surface distal to the first portion to an opposing end surface proximal to the transition segment and the first portion". Hence, the subject-

matter of claim 1 lacked novelty over E5.

Auxiliary request 1 - inventive step starting from E8

The subject-matter of claim 1 might be considered to differ from the device of Figure 11a of E8 in that the cylindrical surface extended along the entire length of the second portion and that the distal end surface was planar and non-tapered. These features did not provide an advantage and did therefore not solve any problem.

Depending on the shape of the LAA the skilled person would select a device wherein the portions 1200p and 1200d of structure 1200 (Figure 11a) had the same diameter, as shown in the embodiment of Figure 8a.

To provide the second portion with a strictly cylindrical shape was merely an arbitrary choice for the skilled person. Therefore, the subject-matter of claim 1 did not involve an inventive step.

VII. The arguments of the respondent, as far as relevant for the decision, can be summarized as follows:

Admittance of documents E22 and E23

Documents E22 and E23 filed with the statement of grounds of appeal should not be admitted into the appeal proceedings since they were not more relevant than the documents relied on in the opposition proceedings.

Admittance of the objection entitled "Further disks"

This objection should be disregarded because it could and should have been raised in the first instance

proceedings.

Main request - added subject-matter

"Non-tapered end surface"

Basis for the feature "non-tapered end surface" could be found on page 12, lines 2 to 4. According to this passage, in the embodiment of Figures 4 to 6 the second portion did not have a taper at all, neither on the cylindrical surface nor on the end surface.

Although Figure 6 showed a distal end surface which appeared to be planar, the feature "non-tapered" did not constitute an unallowable intermediate generalisation. It was clear from the application as filed (e.g. page 6, lines 16 to 21, page 10, lines 8 to 20, and page 12, lines 4 to 7) that there was no intention that specific features appearing in the figures should be regarded as mandatory.

Claim 1 did not require that the opposing surface was positioned on the side of the proximal end clamp. The terms "proximal to" and "distal to" in the claim were positional statements which described the relative position of the elements.

Hence, the introduction of this feature did not add subject-matter.

"Entire length of the second portion"

The feature "the second portion comprising a cylindrical surface formed of a metal fabric comprising a plurality of wire strands configured to engage the cavity wall along the entire length of the second

portion" was disclosed on page 9, lines 1 to 5, 15 to 18 and 25 to 26.

For the second portion having a cylindrical surface over its entire length there was basis on page 2, lines 13 to 14, page 10, lines 21 to 23, page 10, lines 27 to 31, page 11, lines 24 to 25, page 12, lines 1 to 2, page 12, line 14 to page 13, table 1, and in Figures 4 to 6, 10 and 11.

Hence, the introduction of this feature did not add subject-matter.

Auxiliary request 1 - admittance

In auxiliary request 1 claim 1 was amended to include the term "planar" in response to the preliminary opinion of the Board. There had been no need to file an auxiliary request earlier in the proceedings since the decision of the Opposition Division was favorable with regard to this issue. The amendment did not add any complexity to the case. Hence, auxiliary request 1 should be admitted.

Auxiliary request 1 - added subject matter

The feature "planar, non-tapered end surface" could be directly and unambiguously derived from Figure 6. Thus, claim 1 of auxiliary request 1 did not include added subject-matter.

Auxiliary request 1 - clarity

Figure 1a did not show an embodiment of the invention, since in this embodiment the second portion was not cylindrical over its entire length. Hence, claim 1 of

auxiliary request 1 did not lack clarity.

Auxiliary request 1 - sufficiency of disclosure

The features of claim 1 allegedly offending Article 83 EPC were functional features. The patent taught clearly how the devices of the invention might be configured and how the dimensions should be selected (page 7, paragraph [0040], page 9, lines 2 to 9, and Table I).

As stated by the Opposition Division, the septal occluder devices of E2 and E4 were not suitable to be used as occlusion devices for a LAA because the second disc would prevent those devices from engaging the cavity of the wall. However, this did not have any bearing on the question of sufficiency of disclosure in relation to the devices claimed in the present patent, which did not have such a bigger disc.

A device configured for delivery over a guidewire as defined in dependent claim 17 was described on page 9, paragraph[0055].

How to implement the feature of dependent claim 25 concerning the flexing angle of up to about 30 degrees was explained on page 6, paragraph [0034].

The invention was therefore sufficiently disclosed to be carried out by the skilled person.

Auxiliary request 1 - novelty in view of E8

The device of E8 was not an occlusion device but a filter. Furthermore, the strawberry-shaped device of Figures 11a and 11b did not constitute a cylindrical body portion as claimed in claim 1. The device shown in

Figures 8a and 8b neither possessed a first portion nor a transition segment as claimed. There was no teaching that this embodiment could be combined with the embodiment of Figures 11a and 11b. Hence, the subject-matter of claim 1 was novel over E8.

Auxiliary request 1 - novelty in view of E2 and E4

There was no indication in E2 that any device described was intended for occluding a LAA. The devices were rather used as septal occluders (paragraphs [0039] and [0043]).

Furthermore, the device of E2 having a second disc was not shown to be suitable for occluding a LAA and did not include the feature that the surface of the second portion was configured to engage the cavity wall along its entire length.

As to the device of Figure 5, it had a taper between the end surface and the cylindrical surface. Also in E4 the arrangement of the second disc prevented engagement of the second portion with the LAA cavity wall along the entire length of the second portion. This rendered the device incapable of satisfying the requirements of claim 1.

Hence, the subject-matter of claim 1 was novel over E2 and E4.

Auxiliary request 1 - novelty in view of E13

The embodiment of Figure 10 did not include a "first portion comprising at least one plane of occlusion configured to be positioned outside of the LAA".

Furthermore, the devices of E13 did not comprise a planar, non-tapered end surface.

Hence, the subject-matter of claim 1 was novel over E13.

Auxiliary request 1 - novelty in view of E5

E5 disclosed a vascular plug device and not an occluder for a LAA. All three elements of the vascular plug device had the same diameter. Hence, E5 did not disclose a second portion having a second diameter smaller than the first diameter as required by claim 1.

Hence, the subject-matter of claim 1 was novel over E5.

Auxiliary request 1 - inventive step

The subject-matter of claim 1 differed from the device of Figure 11a of E8 in that the cylindrical surface extended along the entire length of the second portion and in that the distal end surface was planar and non-tapered.

This distinguishing feature solved the problem of providing an enhanced balance between retention and length of the device. Due to the cylindrical shape the device was configured to engage the cavity wall along its entire length and even a shorter device would be retained reliably in the LAA.

There was no motivation for the skilled person to modify the strawberry-shaped portion of the device of Figure 11b of E8 into a cylindrical shape. E8 did not disclose a cylindrical shape for the second portion in its final configuration. It rather suggested even more

complicated shapes.

Hence, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. Subject-matter of the invention

The invention relates to a device for occluding a left atrial appendage (LAA). The device comprises a first portion (14), a second portion (12) and a transition segment (19) coupling the first portion and the second portion. As can be seen in Figure 6, reproduced below, the second portion (12) has a smaller diameter than the first portion (14), and the transition segment (19) has a smaller diameter than the first and the second portion. The second portion comprises a cylindrical surface formed of a metal fabric configured to engage the wall of the cavity defined by the LAA. The cylindrical surface extends over the entire length of the second portion from a non-tapered end surface distal to the first portion to an opposing end surface proximal to the transition segment and the first portion and is configured to engage the cavity wall along its entire length.

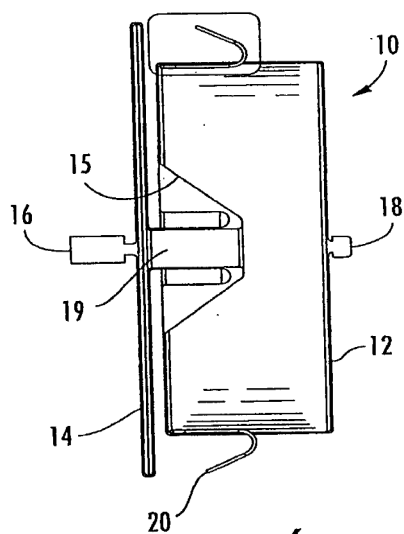


FIG. 6

2. Admittance of documents E22 and E23

The Figures in E22 and E23 referred to by the appellant illustrate the various shapes a LAA can have. The Board agrees with the appellant that this content of the documents is to be considered as common general knowledge. The documents were presented by the losing party with the statement setting out the grounds of appeal and thus at the earliest opportunity in the appeal proceedings. In the exercise of its discretion under Article 12(4) RPBA 2007 (applicable under the provision of Article 25(2) RPBA 2020), the Board therefore decided to admit these documents into the proceedings.

3. Admittance of the objection entitled "Further disks"

This objection was submitted by the appellant in the statement of grounds of appeal as a reaction to the decision of the Opposition Division stating that the

second discs in E2 and E4 would prevent the engagement of the cylindrical portion with the LAA.

Since the finding of the Opposition Division was based on the novelty discussion at the oral proceedings which followed the debate on sufficiency of disclosure, the objection could not have been submitted earlier in the proceedings. The Board therefore decided to admit this objection into the appeal proceedings.

4. Main request - added subject-matter

4.1 "Non-tapered end surface"

This feature is allegedly based on page 12, lines 2 to 4 and Figure 6 of the application as originally filed. However, the "tapered surface of angle C" mentioned in the above-mentioned passage, is part of the cylindrical surface since the body portion is said to have a total length G, and, according to Figure 1A, this includes the tapered surface. Hence, the passage on page 12, lines 2 to 4, does not refer to the end surface mentioned in the claim.

The Board does not concur with the respondent that the above-mentioned passage on page 12 teaches the absence of any tapered surface. The wording "or not include a tapered surface as shown in FIGS. 4 to 6 and define a body portion 12 having a total length G" clearly means that the body portion does not have a tapered surface along its length. This wording does not exclude that the end surface is tapered, as for instance the recessed proximal end surface as shown in Figures 4 to 6.

It follows that support for the feature concerning the

end surface can only be found in Figure 6. The Board does not agree with the appellant that claim 1 requires the opposing surface to be positioned on the side of the proximal end clamp. The terms "proximal to" and "distal to" in the claim are positional statements which describe the relative position of the elements. Hence, Figure 6 shows an embodiment of the invention.

However, in this figure, which is a cross-sectional view of the occlusion device, the distal end surface of the second portion is planar. The term "non-tapered" encompasses also other types of surfaces, such as recessed (as the opposing end surface 15), concave or convex surfaces. Since Figure 6 is the only basis in the application as originally filed for the characteristics of the end surface, it is not permissible to generalise the feature concerning the form of this end surface. Hence, the introduction of the term "non-tapered end surface" constitutes an unallowable intermediate generalisation.

Consequently, claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

4.2 "Entire length of the second portion"

Claim 1 requires that the second portion comprises a cylindrical surface configured to engage the cavity wall along the entire length of the second portion. This means, in the Board's view, that the surface of the second portion is cylindrical over its entire length such that it is possible to engage the cavity wall with any portion of the surface. This feature can be derived directly and unambiguously from page 12, lines 1 to 4 and Figures 4 to 6, 10 and 11. Hence, contrary to the appellant's view, the Board holds that

it is not required by claim 1 that the whole second portion engages the cavity wall.

It follows that the introduction of the statement "a cylindrical surface configured to engage the cavity wall along the entire length of the second portion" does not infringe Article 123(2) EPC.

5. Auxiliary request 1 - admittance

Auxiliary request 1 filed on 10 February 2020 is an amendment to the respondent's case, the admission of which is at the Board's discretion under Article 13(1) RPBA 2020 and Article 13 RPBA 2007 (applicable under the provision of Article 25(3) RPBA 2020). The discretion is to be exercised in view of, inter alia, the complexity of new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

Compared with the main request, the only amendment made to claim 1 of auxiliary request 1 was the introduction of the term "planar" before the feature "non-tapered end surface". By this amendment, the respondent addressed in a straightforward way the issue of non-compliance of claim 1 of the main request with Article 123(2) EPC, which was referred to in the preliminary opinion of the Board.

The Board therefore admitted this request into the appeal proceedings.

6. Auxiliary request 1 - basis in the application as originally filed

The introduction of the term "planar" meets the

objection above that the "non-tapered end surface" constitutes an unallowable intermediate generalisation.

Although the term "planar" is not mentioned in the description of the application as originally filed, it can be derived directly and unambiguously from Figure 6, showing that the distal end surface of the second portion is planar and non-tapered, thus excluding also the tapered surface with an angle C as mentioned in the application as an example of tapered surface.

Contrary to the appellant's view an embodiment having an end surface which was first convex and then planar towards the end would not fall under the scope of the claim, because the claim defines that the cylindrical surface extends from the planar surface.

Hence, the requirements of Article 123(2) EPC are met.

7. Auxiliary request 1 - clarity (Article 84 EPC)

According to claim 1, the cylindrical surface of the second portion extends from the planar, non-tapered end surface to the opposing end surface. Hence, the distal end clamp extending further from the distal end surface is not considered to be a part of the second portion. The distal end surface is therefore regarded as planar, contrary to the appellant's view.

The embodiment of Figure 1a does not fall under the scope of claim 1 since the second portion does not have a cylindrical surface along its entire length.

The introduction of the term "planar" does therefore not render claim 1 of auxiliary request 1 unclear.

8. Auxiliary request 1 - sufficiency of disclosure

8.1 In the appellant's view it is not possible for the skilled person to carry out the invention since the features "plane of occlusion configured to be positioned outside of the LAA", "plane of occlusion configured to be positioned within a cavity defined by the LAA" and "cylindrical surface configured to engage the cavity wall along the entire length" purely related to the anatomy of the LAA. The skilled person would have to rely on trial and error to obtain the correct properties of the device.

The Board does not share this position. The patent refers to differently sized vessels and cavities and teaches in paragraph [0040] how to correspondingly dimension the claimed device. From table I of the patent it can be derived how the dimensions of the device can be varied for the differently sized LAA cavities. Hence, the person skilled in the art has sufficient information to dimension the claimed device.

Nor does the fact that the provision of a third portion is mentioned in the patent (paragraph [0009]) render the invention insufficiently disclosed to be carried out by the person skilled in the art. It is clearly mentioned in the above-mentioned paragraph that the third portion is coupled to and extending distally from the second portion, and that the third portion has to have a third diameter smaller than the second portion. Hence, the person skilled in the art is given sufficient information to implement the third portion in the device without rendering it unsuitable for occluding a LAA.

Hence, the skilled person is able to put the invention

as defined in claim 1 into practice.

- 8.2 Furthermore, it is explained in paragraph [0055] how to deliver the occlusion device using an over-the-wire technique, as mentioned in dependent claim 17. In this case, the device has to have proximal and distal end clamps designed for passage of a guidewire therethrough.

In paragraph [0038] it is stated that the flexibility of the first portion depends on the disc diameter in relation to the diameter of the transition segment. Hence, the person skilled in the art is taught which parameters are to be considered in order to obtain the device of claim 25.

Hence, the skilled person is given sufficient information to implement the features of claim 17 and 25.

- 8.3 In conclusion, the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent on the basis of auxiliary request 1.

9. Auxiliary request 1 - novelty in view of E8

E8 relates to devices that may be implanted in an atrial appendage for filtering blood flowing from the atrial appendage to the associated atrium of the heart (page 1, lines 11 to 16). With reference to Figures 11a and 11b, E8 discloses such a device comprising a structure 1200 intended to be placed in an atrial appendage. Although the balloon-like shape of the device structure 1200 is called "cylindrical" in the description (page 19, lines 28 to 30), this structure cannot be regarded as having a "cylindrical surface

along the entire length from a planar, non tapered end surface to an opposing end surface".

It is mentioned on page 19, line 30 to page 20, line 1 that the diameters of the device structure 1200 may be varied along the structure length with consideration to the different shapes of atrial appendages in which the devices are deployed. However, the Board does not agree with the appellant that this statement teaches an embodiment having the same diameter along the entire length of the structure as required by claim 1.

Contrary to the appellant's view, the Board considers that the wording of claim 1 requires the cylindrical surface to be the surface of a right circular cylinder as shown in Figure 6 of the patent. Evidently, the bands 810 and 820 shown in Figure 11a do not create a defined end surface, and even less a planar, non-tapered end surface (also in the hypothetical case of their application to the open-ended structure shown in Figure 8a).

Hence, E8 does not anticipate the subject-matter of claim 1.

10. Auxiliary request 1 - novelty in view of E2 and E4

E2 and E4 relate to intravascular occlusion devices for selective occlusion of a vessel to stop the flow of blood there through. Although in E2 reference is made to a cavity (paragraph [0007]), it is not mentioned that the device can be used for occlusion of a LAA.

E2 illustrates in Figures 5 and 6 the same device as shown in Figures 1 and 2 of the present patent. In this embodiment, the cylindrical surface does not extend

along the entire length of the second portion from the planar, non-tapered end surface to an opposing end surface, contrary to the requirements of claim 1. Nor does paragraph [0057] cited by the appellant disclose that the device of Figures 5 and 6 can be modified to have such a shape.

There is no evidence on file that the devices shown in Figures 3, 8A to 8C of E2 with their second, large distal disc 304, 304' could be suitable for occluding a LAA. The device of Figures 3, 8A to 8C is rather used to occlude an atrial septal defect (paragraphs [0039] and [0043]). The Board agrees with the appellant that it depends on the specific configuration if a further distal disc prevents engagement of the cylindrical portion with the cavity wall. However, the size and the position of the second disc in the embodiment of these figures of E2 is such that, even when bending the disc to insert the device in a small cavity, full engagement along the entire length of the cylindrical surface would be impossible. Furthermore, the Board does not concur with the appellant that E2 discloses that the distal disc 304 could have a smaller diameter than the cylindrical middle portion. It can only be derived from E2 that the diameter of the discs 302 and 304 is preferably sufficiently larger than the diameter of the shunt 306 (paragraph [0039] and Figure 3).

For the same reasons, the devices of Figures 11a, 12a or 16b of E4 do not anticipate the subject-matter of claim 1. Since all these devices have a second disc having a considerably larger diameter than the cylindrical portion they do not directly and unambiguously disclose the subject-matter of claim 1 either.

The subject-matter of claim 1 is therefore novel over E2 and E4.

11. Auxiliary request 1 - novelty in view of E13

E13 discloses an occlusion device for occluding an atrial appendage having a proximal retention region (2), a distal retention region (3) and a cylindrical central region (5) having a reduced diameter (Figure 10).

However, the distal retention region (3) of the device shown in Figure 10 is cigar-shaped and cannot be regarded as cylindrical along the entire length from one planar, non-tapered end surface to an opposing end surface. Likewise, contrary to the appellant's view, the distal end (21) of the device shown in Figure 17 cannot be considered a planar, non-tapered end surface.

The subject-matter of claim 1 is therefore novel over E13.

12. Auxiliary request 1 - novelty in view of E5

E5 discloses a vascular plug device that is designed for treating arterial and venous embolisations in the peripheral vasculature. The device shown in the Figures on pages 23 and 34 has a central portion flanked by two lobes. All three elements have the same diameter.

Hence, in this device the second portion has the same diameter as the first portion. However, claim 1 requires that the second portion has a smaller diameter than the first portion.

It follows that the disclosure of E5 does not

anticipate the subject-matter of claim 1.

13. Auxiliary request 1 - inventive step

When starting from E8, the subject-matter of claim 1 differs from the device shown in Figure 11a in that the second portion has a cylindrical surface along the entire length from one planar, non-tapered end surface to an opposing end surface.

Due to this distinguishing feature any portion of the entire surface of the second portion can be used for anchoring the device in the LAA. Hence, even if the body portion is shorter, a reliable retention can be achieved.

This feature therefore solves the problem of improving the balance between retention and length of the device.

For solving the objective technical problem, there is no teaching in the prior art suggesting the provision of a cylindrical surface along its entire length. Hence, the person skilled in the art would not implement this distinguishing feature in the LAA occlusion device of Figures 11a and 11b of E8.

Figure 8 of E8 also does not show a device that has a "strictly cylindrical shape" as alleged by the appellant. The device of Figure 8 rather does not have a distal end surface at all. Therefore, the combination of the embodiments of Figures 11a and 8 of E8 would not lead to a device according to claim 1.

Furthermore, the Board does not concur with the appellant in that the strictly cylindrical shape is merely an arbitrary choice by the person skilled in the

art. As explained above, the cylindrical shape allows the device to be made shorter while achieving the same retention since the entire surface of the second portion is available to anchor the device in the LAA.

It follows that the subject-matter of claim 1 of auxiliary request 1 involves an inventive step when starting from E8.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

Claims 1-29 of auxiliary request 1 filed with letter dated 10 February 2020

Description: pages 2 to 10 of the patent specification

Figures 1A to 11 of the patent specification.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated