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Datasheet for the decision of 18 May 2022

Case Number: T 2571/16 - 3.2.02

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IPC: A61B17/00, A61B17/12, A61F2/01

Language of the proceedings: EN

Title of invention:
OCCLUDER FOR OCCLUDING AN ATRIAL APPENDAGE

Patent Proprietor:
Occlutech Holding AG

Opponent:
AGA Medical Corporation

Relevant legal provisions:
EPC Art. 54, 56, 108
EPC R. 99(2)
RPBA Art. 12(2), 12(4)
RPBA 2020 Art. 13(2)

Keyword:

Admissibility of appeal - appeal sufficiently substantiated (yes)
Novelty - (yes)
Inventive step - (yes)
Late-filed objection - admitted (no)

Decisions cited:

T 2096/15

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Beschwerdekammern

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Case Number: T 2571/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 18 May 2022

Appellant: (Opponent)	AGA Medical Corporation 5050 Nathan Lane North Plymouth, MN 55442 (US)
Representative:	Potter Clarkson The Belgrave Centre Talbot Street Nottingham NG1 5GG (GB)
Respondent: (Patent Proprietor)	Occlutech Holding AG Feldstrasse 22 8200 Schaffhausen (CH)
Representative:	KIPA AB P O Box 1065 251 10 Helsingborg (SE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 6 October 2016 rejecting the opposition filed against European patent No. 2134263 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt

Summary of Facts and Submissions

I. The appeal was filed by the opponent against the Opposition Division's decision to reject the opposition against the contested patent.

In its decision, the Opposition Division held that the subject-matter of claim 1 as granted was novel and involved an inventive step, especially over the following documents:

D1 WO 2005/099365 A2
D3 US 2007/0043391 A1
D18 US 2007/0225760 A1
D19 WO 02/071977 A2

II. Oral proceedings before the Board took place on 18 May 2022.

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

IV. The respondent (patent proprietor) requested that the appeal be rejected as inadmissible or dismissed, i.e., as its main request, that the patent be maintained as granted. As an auxiliary measure, the respondent requested that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 9 filed with the reply to the statement of grounds of appeal.

V. The present decision also refers to the following documents:

D5 Meier et al., *Catheterization and Cardiovascular Interventions* 60, 2003, 417-22

D6 US 5,725,552

D7 Fischer et al., *Heart* 89, 2003, 199-204

D8 Cruz-Gonzalez et al., *International Journal of Cardiology* 134, 2009, e1-e3

D9 Park et al., *Catheterization and Cardiovascular Interventions* 77, 2011, 700-6

D10 Chiam and Ruiz, *Journal of Invasive Cardiology* 20 2008, E109-E113

D11 Cruz-Gonzalez et al., *Catheterization and Cardiovascular Interventions* 75, 2010, 806-13

D12 Luis et al., *Cardiology Research and Practice* Article ID 304626, 2012, 1-9

D13 Khattab and Meier, *Cardiovascular Medicine* 13(4), 2010, 130-4

D15 CN 2613248Y

D15a English translation of D15

D16 CN 1736346A

D16b English translation of D16

D20 Heist et al., *Heart Rhythm* 3(11), 2006, 1313-8

D21 Motiei et al., *Journal of the American College of Cardiology, Abstracts - Noninvasive Imaging* 45(3 Suppl):301A, 2005, 1165-90

D22 Bayard et al., Abstract O-25, *Catheterization and Cardiovascular Interventions*, *PICS/ENTICHS 2006* 68(3), 2006, 466

D23 Bayard et al., Abstract O-20, *Catheterization and Cardiovascular Interventions*, *PICS/ENTICHS 2005* 66(1), 2005, 68

VI. Claim 1 of the **main request** ("claim 1"), i.e. claim 1 as granted, reads as follows:

"*An atrial appendage occlusion device (80) comprising a mesh or braiding (7) of at least one wire or thread (7a), wherein the occlusion device (1) has been given a shape using a reshaping and/or heat treatment process, and is self-expandable, as well as configured for safe anchoring in an atrial appendage (10) of the left or right atrium of a heart, comprising*
a proximal retention region (2) at a proximal end (20) of the occlusion device (1); a distal retention region (3); and a central region (5) between said proximal retention region (2) and said distal retention region (3);
wherein the occlusion device (1) has a closed distal end (21) without a hub for said wire or thread, and wherein said proximal retention region (2) of said occlusion device (1) is of elongate spherical shape and at least partly hollow, and wherein said distal retention region comprises a distal anchoring element integrally made of the same mesh or braiding (7) as the hollow elongate spherical proximal retention region (2), and
wherein said distal retention region comprises at least one further distal anchoring element integrally made of the same mesh or braiding (7) as the hollow elongate spherical retention region."

VII. The **appellant's arguments** relevant for the present decision can be summarised as follows.

Admissibility of the appeal

The appellant has not commented on this issue.

Admittance of the documents D8 to D13, D15 and D16

D8 to D13 supplemented the teaching of D5 to D7 to support the argument that "Amplatzer" devices for treating atrial septal defects - to which the devices disclosed in D3 and D18 were similar - were also suitable for occluding an atrial appendage. D8 to D13 were discussed in detail in the notice of opposition. D15 was also presented in the notice of opposition as providing an equivalent disclosure to D14. Therefore, the documents D8 to D13, D15 and D16 should be admitted into the proceedings.

Main request - novelty over D1

The subject-matter of claim 1 was not novel over D1.

In particular, the first end 122 of the occluding device disclosed in Figure 3 of D1 formed a proximal retention region having an "elongate spherical shape" as stipulated in claim 1.

Indeed, the expression "elongate spherical shape" was unclear and undefined in the contested patent. Claim 3 as granted specified that the proximal retention region had a "substantially circular cross section that gradually taper[ed] towards an end region of said anchoring region". Moreover, "elongate spherical" could be considered to refer to an elongated sphere, for example an ellipse or rugby-ball shape, which had a substantially spherical cross-section but with the radius stretched in certain planes. Thus, any spherical shape or a shape that had a substantially circular cross-section but that was elongated in at least one plane was an elongate sphere in accordance with the contested patent. This was the case for the first end 122 as shown in Figure 3 of D1.

Main request - inventive step starting from D1

Even if the Board were to find that D1 did not disclose a proximal retention region having an "elongate spherical shape", this shape of the proximal retention region would not lend inventive step to the subject-matter of claim 1.

Indeed, the contested patent disclosed no special advantage associated with this shape. Hence, this shape merely contributed to solving the technical problem of providing an alternative design to the atrial appendage occlusion device shown in Figure 3 of D1.

D1 taught that, irrespective of the rest of the device, the proximal end 122 of the occluding device could take a variety of alternative shapes. In particular, it could also be bulbous (page 8, lines 3-6). In this case, the resulting occlusion device would have a proximal retention region with an "elongate spherical shape" as required by claim 1. Therefore, the person skilled in the art proceeding from D1 alone and seeking to find an alternative design to the occlusion device of Figure 3 would have arrived at an occlusion device with a proximal retention region having an "elongate spherical shape" without exercising any inventive skill.

D19 disclosed atrial appendage occlusion devices having various "balloon-like" cylindrical shapes which could also be regarded as "elongate spherical" (page 19, lines 28-33; see e.g. Figures 10a-10b). The combination of D1 with D19 would thus equally have led the person skilled in the art to an occlusion device with a proximal retention region having an "elongate spherical shape" in an obvious manner.

Main request - inventive step starting from D19

D19 disclosed in Figures 10a-10b and 11a-11b various atrial appendage occlusion devices, all made from a mesh or braiding and including a body 1200 having a "balloon-like cylindrical" shape (page 19, lines 28-29), hence forming a proximal retention region having an "elongate spherical shape". Their distal end might also be "close[d]-off" by tying or crimping, hence lacking a hub for the wire of the braiding (page 20, lines 11-12).

Therefore, the subject-matter of claim 1 differed from these known occlusion devices only by the distal retention region comprising a distal anchoring element and at least one further distal anchoring element, both integrally made of the same mesh or braiding as the proximal elongate spherical retention region.

Whereas, according to the contested patent, the elongate spherical shape of the proximal retention region enabled the occlusion device to engage with the interior tissue of the appendage over a large surface, thus resulting in an interference fit, the distal anchoring elements engaged with and deformed the interior appendage tissue at further locations deeper within the appendage. The distal anchoring elements thus enabled the occlusion device to be inserted deeper within the appendage and to better conform to its morphology. This resulted in improved anchoring.

The additional distal anchoring elements could therefore be regarded as solving the technical problem of improving the anchoring of the occlusion device

within atrial appendages having different depths and morphologies.

The person skilled in the art was aware, for example from D20 to D23, that occlusion devices had to be adapted to the morphology of atrial appendages, which could have various depths and morphologies. D1 also disclosed that occlusion devices could be undesirably expelled from the appendage due to forces generated by atrial fibrillation (page 1, lines 28-31). Therefore, the person skilled in the art would have been motivated to improve the anchoring of the occlusion devices disclosed in D19, especially in view of their implantation in appendages of different depths or morphologies.

The atrial appendage occlusion device known from D1 also comprised a body made from a tubular mesh. One or more flanges provided on the body assisted in anchoring the device within the appendage. D1 further taught that the body could narrow in a stepwise manner to better conform to the narrowing of the appendage interior (page 10, lines 23-31). In light of this teaching, it would have been obvious to the person skilled in the art to add one or more tubular body segments distally to the elongate spherical body 1200 of the device of D19, each segment having a flange at its distal end.

Contrary to the reasoning in point 4.4.2 of the decision under appeal, the person skilled in the art would not have provided the flanges directly on the body 1200 because this would have destroyed the interference fit with the interior of the appendage. Rather, the person skilled in the art would have sought to advantageously combine both the interference fit achieved by the elongate spherical proximal retention

region and the additional anchoring achieved by the flanges at the distal end.

Therefore, the combination of D19 with D1 would have led the person skilled in the art to the subject-matter of claim 1 in an obvious manner.

Main request - inventive step starting from D3 or D18

Claim 1 was not validly entitled to priority. Thus, like D3, D18 was also prior art under Article 54(2) EPC and thus relevant for inventive step.

Both D3 and D18 disclosed occlusion devices for occluding an atrial septal defect. It was established, for example from D5 to D7, that atrial septal occlusion devices commonly known as "Amplatzer" devices were also suitable for occluding an atrial appendage, namely by implanting them partly or entirely within the appendage (D5, page 421, top of the right-hand column). The occlusion devices disclosed in D3 and D18 had a design similar to that of the "Amplatzer" devices and were therefore also suitable for occluding an atrial appendage. This conclusion was also reached in T 2096/15 (point 2.5 of the Reasons).

In a first line of argument, the occlusion devices of D3 and D18 could be regarded as comprising a proximal retention region having an "elongate spherical shape" (retention area 8), a distal retention region comprising a distal anchoring element (retention area 6) and a central region in between (see Figure 1(a) of D3 and Figure 3 of D18). The three regions were all integrally made of the same mesh or braiding. Moreover, the occlusion devices had a closed distal end without a hub (D3, paragraph [0021]; D18, paragraph [0026]).

The subject-matter of claim 1 thus differed from these known devices only by the further distal anchoring element.

The problem to be solved could be formulated as to improve the anchoring of the occlusion device within the atrial appendage.

Prompted by D1 as explained above for the inventive-step objection starting from D19, the person skilled in the art would have found it obvious to form in the braiding an additional anchoring retention flange or disc at the distal end of the occlusion device to enable the device to be inserted deeper in the appendage and thus to solve the technical problem.

In a second line of argument, the retention areas 6 and 8 could be regarded as two anchoring elements, so the subject-matter of claim 1 differed from these devices only by the proximal retention region having an "elongate spherical shape".

As explained above, this shape provided an interference fit within the atrial appendage. This solved the same technical problem of improving the anchoring of the occlusion device within the atrial appendage.

Faced with this problem, the person skilled in the art would have been motivated to adapt the device of D3 or D18 so that it extended further into the atrial appendage and became more firmly lodged in it. D19 (page 19, line 28 to page 20, line 1) would have prompted the person skilled in the art to form proximally in the braiding of the occlusion device of

D3 or D18 a proximal retention region having an elongate spherical shape.

According to both lines of argument, the person skilled in the art proceeding from D3 or D18 would have arrived at the subject-matter of claim 1 without exercising inventive activity.

Main request - inventive step starting from D5

During the oral proceedings before the Board, the appellant further submitted that the subject-matter of claim 1 lacked an inventive step considering D5 as the starting point. The appellant did not provide any explanation why this objection had not been raised before.

Lack of inventive step due to failure to solve the technical problem over the whole scope of claim 1

In the decision under appeal, the Opposition Division considered that one of the features that made the subject-matter of claim 1 inventive was the feature that the occlusion device had a "closed distal end without a hub" for the wire or thread of the braiding or mesh of the device.

However, paragraphs [0062] and [0063] of the contested patent made it clear that implementing this "closed distal end without a hub" was only possible if the device was produced from "only one wire". Since this latter feature was not defined in claim 1, claim 1 encompassed embodiments that were not produced from only one wire, meaning that the alleged technical problem was not solved. This was in breach of

Article 56 EPC, which required that the technical problem be solved over the whole scope of the claim.

VIII. The **respondent's arguments** relevant for the present decision can be summarised as follows.

Admissibility of the appeal

The inventive-step objection against claim 1 as granted based on the combination of D19 with D1 were not sufficiently substantiated in the statement of grounds of appeal. In particular, the arguments provided in support of this objection under point 5.2 referred to features not defined in claim 1, such as a "flexible cylindrically elongate distal middle portion (155)". Thus, these arguments did not relate to claim 1 as granted but to a different claim. The appeal was therefore inadmissible.

Admittance of the documents D8 to D13, D15 and D16

These documents were cited in the statement of grounds of appeal merely generally, without any reference to relevant passages or figures. This did not allow the respondent and the Board to understand the appellant's case in respect of these documents without first having to make investigations of their own. The documents D8 to D13, D15 and D16 should therefore not be admitted into the proceedings.

Main request - novelty over D1

D1 failed to disclose an occluding device comprising a proximal retention region having an elongate spherical shape, i.e. a spheroid which was longer than it was

wide. The subject-matter of claim 1 was thus novel over D1 at least for this reason.

Main request - inventive step starting from D1

Without hindsight, the person skilled in the art would not have formed the proximal retention region of the occlusion device of D1 with an "elongate spherical shape" in an obvious manner. Neither the teaching in D1 that the proximal end 122 could also be formed with a bulbous shape or "any other configuration" nor the disclosure in D19 of an occlusion device shaped to be "balloon-like" as a whole would have led the person skilled in the art to this design. Hence, at least for this reason, the subject-matter of claim 1 was inventive over D1.

Main request - inventive step starting from D19

The combination of D19 with D1 did not lead to the subject-matter of claim 1.

First, D19 did not disclose an occlusion device having an "elongate spherical shape" as claimed. The figures of D19 were merely schematic, and the "balloon-like cylindrical" shape mentioned in the description (page 19, lines 28-30) was different from an "elongate spherical shape".

Moreover, even under the assumptions that the occlusion devices of Figures 10a-10b and 11a-11b had an "elongate spherical shape" and that the person skilled in the art would have been motivated to provide them with additional flanges to assist anchoring, the resulting devices would still lack a proximal retention region having itself an "elongate spherical shape".

At least for this reason, the subject-matter of claim 1 was inventive over D19 as well.

Main request - inventive step starting from D3 or D18

The occluding device disclosed in D3 was not for occluding an atrial appendage like the device of claim 1 but for occluding a septal defect. Hence, it had a different purpose. Consequently, D3 was not a suitable starting point to assess whether the subject-matter of claim 1 involves an inventive step.

The person skilled in the art would not have read D3 in conjunction with D5, D6 or D7 without hindsight. In fact, the person skilled in the art would not have considered the device of D3 suitable for occluding an atrial appendage due to its shape being significantly different from the shape of the "Amplatzer" devices described in D5 to D7.

Thus, the subject-matter of claim 1 involved an inventive step over D3.

The same reasoning applied to D18. Moreover, claim 1 was entitled to priority, which was validly claimed by the contested patent. Thus, D18 was not prior art under Article 54(2) EPC and was therefore irrelevant to inventive step.

Main request - inventive step starting from D5

The appellant's inventive-step objection starting from D5 was raised for the first time during the oral proceedings before the Board. There were no exceptional circumstances that could justify the admission of such

a late submission. Hence, this objection should not be admitted in the proceedings.

Lack of inventive step due to failure to solve the technical problem over the whole scope of claim 1

The appellant's interpretation of paragraphs [0062] and [0063] was incorrect. These paragraphs merely related to an embodiment of an occlusion device according to claim 1 in which not only the distal end of the device but also the proximal end was closed and lacked a hub. The appellant's objection was therefore unfounded.

Reasons for the Decision

1. The invention of the contested patent

1.1 Atrial appendages are small, dead-end pouches formed in the muscle wall of the atria of the heart. In patients suffering from atrial fibrillation, the left atrial appendage is a frequent site of formation of blood clots, which can induce stroke when they are carried along with the blood flow (paragraph [0005] of the patent). To reduce this risk, the appendages may be occluded surgically. The contested patent relates to an occlusion device for this purpose.

1.2 An example of an occlusion device (80) according to claim 1 as granted is illustrated in Figures 8 and 9, reproduced below:

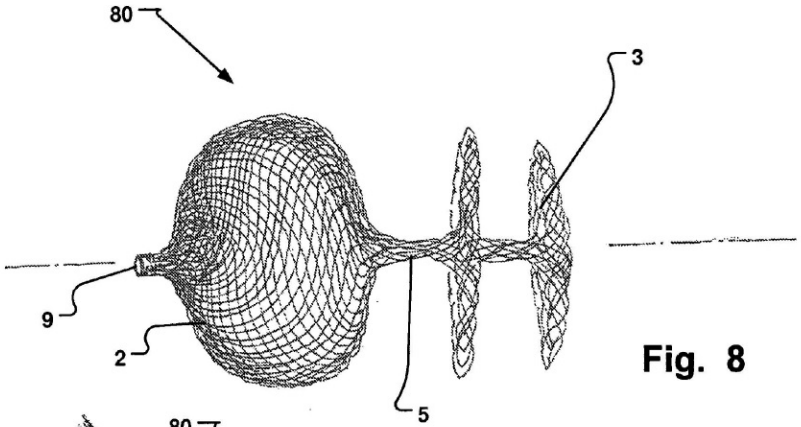


Fig. 8

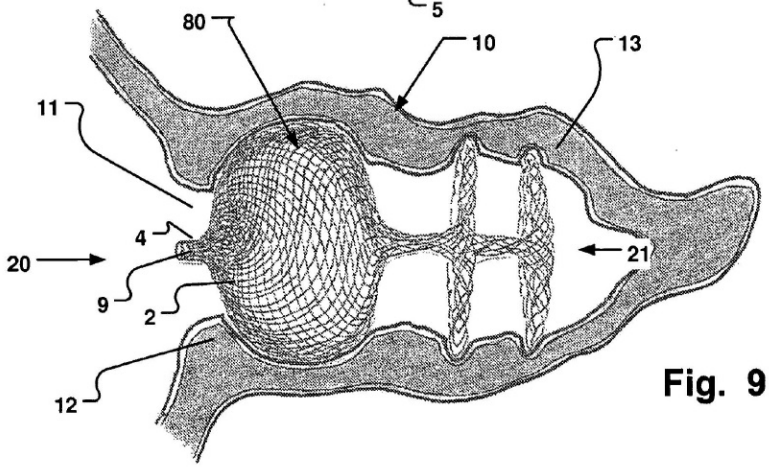


Fig. 9

The occluding device comprises a self-expandable mesh or braiding of at least one wire or thread given a shape so as to include a proximal retention region (2), a distal retention region (3) and a central region (5) in between, for safe and robust anchoring of the device in an atrial appendage (10).

The proximal retention region (2) is at least partly hollow and has an elongate spherical shape. This shape enables the occlusion device to engage to a large extent with the interior tissue of the appendage (10) and to seat tightly in it without requiring fixing hooks or other anchoring means, which could be problematic given the thin-walled nature of the surrounding tissue (paragraphs [0033], [0059], [0087]).

The distal retention region (3) comprises two distal anchoring elements, both integrally made of the same mesh or braiding as the proximal retention region. The absence of connective element between the different portions enables the occluding device to be collapsed into a state of reduced dimensions. This facilitates its delivery via a catheter in a minimally invasive intervention (paragraphs [0082], [0091]).

Moreover, the occluding device has a closed distal end (21) without a hub for the wire or thread of the mesh or braiding. This minimises the risk of defence reactions of the body or other complications (paragraph [0061]).

2. Admissibility of the appeal

Irrespective of whether the inventive-step objection based on the combination of D19 with D1 was sufficiently substantiated in the statement of grounds of appeal as contended by the respondent, other sections of the statement of grounds of appeal contain detailed reasons why, in the appellant's view, the decision under appeal is incorrect and must be set aside. In particular, the appellant explained in points 3.1 to 3.3 that the decision was based on a wrong interpretation of the expressions "without a hub" and "elongate spherical shape" used in claim 1. According to the appellant, if these expressions had been interpreted correctly, the Opposition Division would have come to the conclusion that the subject-matter of claim 1 lacked novelty over D1. Hence, the outcome of the first-instance proceedings would have been different, namely the opposition would not have been rejected.

In the Board's view, this is sufficient to meet the requirements of Article 108 EPC in combination with Rule 99(2) EPC, and thus for the appeal to be admissible.

3. Admittance of the documents D8 to D13, D15 and D16

3.1 The respondent requested that the documents D8 to D13, D15 and D16 should not be admitted into the appeal proceedings.

3.2 Under Article 12(4) RPBA 2007 (which applies in the case at hand by virtue of the transitional provisions of Article 25(2) RPBA 2020), a fact, a request or evidence presented by a party in the appeal proceedings may be taken into account by the Board only if and to the extent it meets the requirements of Article 12(2) RPBA 2007.

3.3 As put forward by the respondent, the appellant cited the documents D8 to D13, D15 and D16 in the statement of grounds of appeal merely generally, without mentioning any specific passages or figures (as to D8 to D13, see page 11, line 40) or even without relying on them in its argument (D15 and D16 are only cited in the prior-art list of section 2 on pages 1-2).

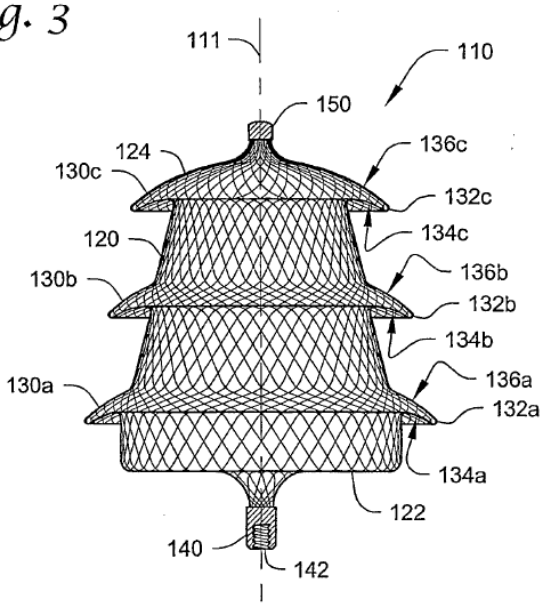
Referring generally to documents does not meet the requirement of Article 12(2) RPBA 2007 that the statement of grounds of appeal must "set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended" and should "specify expressly all the facts, arguments and evidence relied on". It is immaterial that D8 to D13, D15 and D16 may have been cited and/or discussed in the notice of opposition as argued by the appellant.

The Board therefore decided not to take into account the documents D8 to D13, D15 and D16 in accordance with Article 12(4) RPBA 2007.

4. Main request - novelty over D1

4.1 It is common ground that D1 discloses in Figure 3, reproduced below, an atrial appendage occlusion device 110 (page 4, lines 28-30) comprising a mesh or braiding of at least one wire or thread ("braided tubular structure"; page 3, line 11).

Fig. 3



4.2 A point of dispute between the parties is whether this occlusion device has a proximal retention region with an "elongate spherical shape" as stipulated in claim 1.

4.3 The appellant identified the first end 122 as forming a proximal retention region. Arguing that the contested patent gave no clear meaning to the expression "elongate spherical", the appellant inferred from the definition of dependent claim 3 of the patent that any spherical shape or shape that had a substantially

circular cross section but that was elongated in at least one plane was an elongate sphere according to the opposed patent. This was the case for the proximal end 122.

4.4 This reasoning does not convince the Board.

As put forward by the respondent and held by the Opposition Division (point 3.2 of the decision under appeal), a person skilled in the art would construe the expression "elongate spherical" as substantially referring to the shape of a deformed spheroid longer than it is wide. The appellant itself identified an "elongate spherical shape" as having the shape of a "rugby ball". This interpretation is further confirmed by the figures of the contested patent, which all consistently illustrate regions having an "elongate spherical shape" as deformed spheroids (see Figures 1, 2, 5 and 6; paragraph [0036]). This is also in line with claim 3, which merely provides an additional limitation of the "elongate spherical shape" defined in claim 1.

By contrast, the first end 122 of the embodiment shown in Figure 3, which is the proximal face of tube 120, has a concave shape (page 10, lines 17-18 in combination with page 8, lines 3-4). Therefore, it does not have an "elongate spherical shape". Neither does the alternative embodiment described in D1, in which the first end 122, instead of being concave, has a "bulbous" configuration (page 8, lines 4-6). This applies even if, *arguendo*, a proximal end of the tube 120 were assumed to be part of the proximal retention region in combination with the first end 122.

The Board therefore concludes that, contrary to the appellant's view, D1 fails to disclose an occlusion device with a proximal retention region having an "elongate spherical shape".

4.5 It follows, at least for this reason, that the subject-matter of claim 1 is novel over D1, as held by the Opposition Division (point 3.3 of the decision under appeal).

5. Main request - inventive step starting from D1

5.1 The appellant based its inventive-step objections starting from D1 on the argument that the "elongate spherical shape" of the proximal retention region had no technical effect. Hence, this shape constituted a mere alternative design option lacking inventive step.

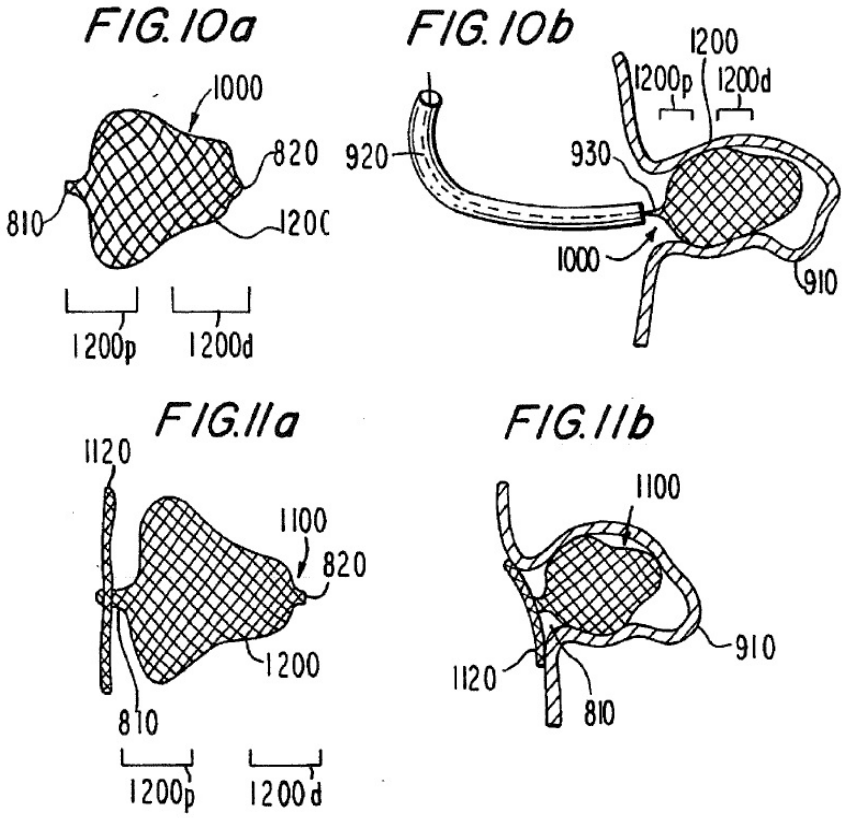
5.2 The Board disagrees. Contrary to the appellant's argument, the contested patent explains that the "elongate spherical shape" of the proximal retention region leads to an interference fit between the occlusion device and the interior tissue of the atrial appendage (called "force-fit" in paragraph [0059]; see also paragraphs [0033] and [0087]). This feature therefore solves the technical problem of improving the anchoring of the device within the atrial appendage. This is mentioned in point 4.1 of the decision under appeal and was acknowledged by the appellant in its other inventive-step attacks, for example in that starting from D19.

5.3 It is true, as put forward by the appellant, that D1 suggests that the shape of the first end 122 may be modified - although without suggesting an elongated spherical shape.

Nevertheless, as shown in Figure 4 of D1, the first end - concave in the embodiment of Figure 3 - is not intended to come into contact with the atrial appendage internal walls. Thus, the person skilled in the art proceeding from D1 would not have been motivated to modify the shape of the first end 122 to improve the anchoring. Faced with this problem, the person skilled in the art would have instead left the end 122 unchanged and contemplated modifying other features of the occlusion device, such as the tube's width or cross-sectional shape as taught in D1 (page 7, lines 12-18), or the flange design, also discussed throughout D1 (see e.g. the last two paragraphs of page 8). Therefore, the person skilled in the art would not have arrived at a proximal retention region having an elongate spherical portion without exercising an inventive step.

5.4 Nor would the combination of D1 with D19 lead to the subject-matter of claim 1 in an obvious manner.

D19 indeed discloses several atrial appendage occlusion devices formed from a self-expandable mesh or braiding, like the device of D1, having various "balloon-like cylindrical" shapes (page 19, lines 28-29). The Board concurs with the appellant's view that the hollow structures 1200 shown in Figures 10a-10b and 11a-11b reproduced below have, as a whole, an "elongate spherical shape" as interpreted in point 4.4 above.



However, as argued by the respondent, the person skilled in the art combining D19 with D1 would at most make the body 120 of the occlusion device of D1 *as a whole* "balloon-like cylindrical" - hence "elongate spherical" - instead of merely tubular or cone-like as shown in Figure 3 (page 10, line 28). Implementing this modification would indeed be in line with the suggestion made in D1 (page 7, lines 15-18) that the body 120 may have various tubular shapes. But, contrary to the appellant's assertion, the resulting device would not include a proximal retention region having *itself* an elongate spherical shape.

5.5 It follows that the subject-matter of claim 1 involves an inventive step over D1, as considered by the Opposition Division (point 4.1 of the decision under appeal).

6. Main request - inventive step starting from D19

6.1 The appellant argued that conversely the person skilled in the art proceeding from D19 would have been prompted by D1 to add distally to the structures 1200 of Figures 10a-10b or 11a-11b - while preserving their shape - one or more tubular body segments, each carrying a flange at its distal end. This would have solved the technical problem of improving the anchoring of the occlusion device within atrial appendages having different depths and morphologies. Thus, the person skilled in the art would have arrived at the subject-matter of claim 1 without exercising an inventive step.

6.2 This objection does not convince the Board either.

6.2.1 Even if D1 discloses that the tubular body 120 may narrow in a stepwise manner (page 10, line 31), the person skilled in the art would not, without hindsight, have regarded the device of Figure 3 as being constructed of several juxtaposed, distinct tubular segments each holding a flange and, from this reading of D1, have been motivated to include one or more such isolated tubular segments at the distal end of the devices of D19.

Rather, the person skilled in the art would have regarded the structures 1200 of D19 as equivalent to the body 120 of D1, all being hollow structures made of a braiding or mesh. Accordingly, if the skilled person were to include any flanges in the occlusion devices of D19, they would at most form them along the *whole* structures 1200. The resulting devices would not have, however, a proximal retention region having *itself* an elongate spherical shape as required by claim 1.

6.2.2 In fact, the Board notes that D19 already teaches a solution to the technical problem formulated by the appellant. D19 discloses indeed that the "[d]evice structure 1200 diameters may be varied along the structure length *keeping in consideration the shapes of atrial appendages in which the devices are deployed*, in order to obtain interference fits in the atrial appendages" (page 19, line 30 to page 20, line 1; emphasis added by the Board).

Faced with this technical problem, the person skilled in the art would have therefore simply increased the diameter of the structures 1200, and if needed their length as well, to improve their interference fit with the interior tissue of the atrial appendage. Without the benefit of hindsight, the person skilled in the art would not have been motivated to add any additional flanges as disclosed in D1.

6.3 It follows that the subject-matter of claim 1 also involves an inventive step in view of D19, as held by the Opposition Division (point 4.4.2 of the decision under appeal).

7. Main request - inventive step starting from D3 or D18

7.1 It is common ground that D3 and D18 disclose occlusion devices for occluding an opening in a septum, such as an atrial septal defect. As illustrated in Figure 1(a) of D3 and Figure 3 of D18, both reproduced below, each of these occlusion devices comprises two retention areas 6 and 8 connected by a cylindrical crosspiece 10. The retention areas 6 and 8 are intended to be positioned against the two sides of the opening to be occluded while the crosspiece 10 traverses the opening (D3, paragraph [0035]; D18, paragraph [0074]). The

appellant argued that the retention area 8 had an "elongate spherical shape".

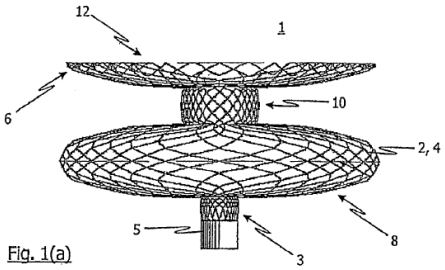


Fig. 1(a)

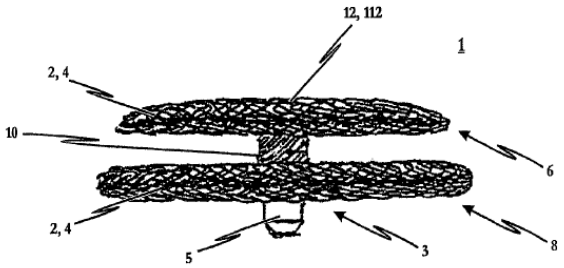


Fig. 3

7.2 It is also undisputed that the use of these devices to occlude an atrial appendage is not disclosed in D3 and D18. Referring to D5 to D7 (see especially D5, page 421, top of the right-hand column) and T 2096/15, the appellant submitted that, like the known "Amplatzer" occlusion devices, the occlusion devices of D3 and D18 were nevertheless suitable for occluding an atrial appendage. Consequently, they represented an appropriate starting point to assess whether the subject-matter of claim 1 involves an inventive step.

7.3 Even under this assumption, the Board disagrees with the appellant that the person skilled in the art would, as alleged, have modified the devices of D3 and D18 to arrive at an atrial appendage occlusion device according to claim 1 without exercising an inventive step.

Faced with the technical problem formulated by the appellant in respect of both D3 and D18, to improve the anchoring of the occlusion device within the atrial appendage, the person skilled in the art would not, without the benefit of hindsight, have merely kept the structure of D3 or D18 unchanged and added distally a further distal anchoring element (as disclosed in D1) or proximally a proximal retention region having an

elongate spherical shape (as disclosed in D19) as argued by the appellant.

Rather, it would have been obvious for the person skilled in the art to adopt one of the occlusion devices disclosed in D1 or D19 as a whole, not least because, in contrast to the devices of D3 and D18, these devices are explicitly designed - and disclosed as such - as atrial appendage occlusion devices and described throughout D1 and D19 as particularly well suited to remain safely anchored in an atrial appendage.

Moreover, no requirement for the shape of the retention area 8 is described in D3 or D18 apart from its suitability to be positioned flush against a side of the septal defect to be occluded (D3, paragraph [0035]; D18, paragraph [0074]). Therefore, without hindsight, the person skilled in the art would not have been motivated to preserve the shape of the retention area 8 - irrespective of whether this shape is an "elongate spherical shape" as asserted by the appellant - when seeking to adapt the septal occlusion devices of D3 or D18 to the occlusion of an atrial appendage.

7.4 It follows that, irrespective of whether D18 is prior art under Article 54(2) EPC, the subject-matter of claim 1 involves an inventive step in view of each of D3 and D18.

8. Main request - inventive step starting from D5

8.1 During the oral proceedings before the Board, the appellant raised for the first time in the appeal proceedings an inventive-step objection against claim 1

using D5 as the starting point. The respondent contested the admittance of this objection.

8.2 It is undisputed that this objection constitutes an amendment to the appellant's appeal case. Its admittance is thus subject to Article 13(2) RPBA 2020 in accordance with which any amendment to a party's appeal case made after notification of a summons to oral proceedings must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

In the present case, the appellant did not put forward any exceptional circumstances that could justify admitting this objection raised only at such a late stage of the appeal proceedings. Consequently, the Board decided not to take this objection into account.

9. Lack of inventive step due to failure to solve the technical problem over the whole scope of claim 1

This objection does not convince the Board.

First, as set forth above, the Board has come to the conclusion that the subject-matter of claim 1 involves an inventive step over the prior art relied on by the parties irrespective of whether the feature that "the occlusion device has a closed distal end without a hub for [the] wire or thread" of the mesh or braiding is inventive. At least for this reason, the appellant's objection, which refers to this feature, is without merit.

Moreover, as argued by the respondent, the appellant's contention that this feature can only be achieved if

the device is produced from "only one wire" relies on an incorrect interpretation of paragraphs [0062] and [0063] of the patent. These paragraphs merely relate to an embodiment of an occlusion device according to claim 1 in which, in addition to the distal end of the device, the proximal end is also closed and lacking a hub. The appellant's objection is therefore unfounded.

10. It follows that none of the objections raised by the appellant prejudices the maintenance of the contested patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated