

**Internal distribution code:**

- (A) [ - ] Publication in OJ
- (B) [ - ] To Chairmen and Members
- (C) [ - ] To Chairmen
- (D) [ X ] No distribution

**Datasheet for the decision  
of 23 May 2024**

**Case Number:** T 0436/22 - 3.2.02

**Application Number:** 15875271.7

**Publication Number:** 3241498

**IPC:** A61B17/00, A61B17/12

**Language of the proceedings:** EN

**Title of invention:**  
LEFT ATRIAL APPENDAGE OCCLUDER

**Patent Proprietor:**  
Lifetech Scientific (Shenzhen) Co., Ltd.

**Opponents:**  
karo IP Patentanwälte Kahlhöfer Rößler  
Kreuels PartG mbB  
AGA Medical Corporation

**Headword:**

**Relevant legal provisions:**  
EPC Art. 56

**Keyword:**

Inventive step - main request (no) - auxiliary request (no)  
Prohibition of reformatio in peius

**Decisions cited:**

G 0001/99

**Catchword:**



**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 0436/22 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 23 May 2024**

**Appellant:** AGA Medical Corporation  
(Opponent 2) 5050 Nathan Lane North  
Plymouth, MN 55442 (US)

**Representative:** Potter Clarkson  
Chapel Quarter  
Mount Street  
Nottingham NG1 6HQ (GB)

**Respondent:** Lifetech Scientific (Shenzhen) Co., Ltd.  
(Patent Proprietor) Floor 1-5, Cybio Electronic Building  
Langshan 2nd Street  
North Area of High-tech Park  
Nanshan District  
Shenzhen, Guangdong 518057 (CN)

**Representative:** Prinz & Partner mbB  
Patent- und Rechtsanwälte  
Rundfunkplatz 2  
80335 München (DE)

**Party as of right:** karo IP Patentanwälte Kahlhöfer Rößler  
(Opponent 1) Kreuels PartG mbB  
Platz der Ideen 2  
40476 Düsseldorf (DE)

**Representative:** karo IP  
karo IP Patentanwälte  
Kahlhöfer Rößler Kreuels PartG mbB  
Platz der Ideen 2  
40476 Düsseldorf (DE)

**Decision under appeal:** **Interlocutory decision of the Opposition**  
**Division of the European Patent Office posted on**

**9 December 2021 concerning the maintenance of  
European Patent No. 3241498 in amended form**

**Composition of the Board:**

<b>Chairman</b>	M. Alvazzi Delfrate
<b>Members:</b>	D. Ceccarelli
	C. Schmidt

## **Summary of Facts and Submissions**

I. Opponent 2 appealed against the Opposition Division's decision that, account having been taken of the amendments according to auxiliary request 8, the patent and the invention to which it relates met the requirements of the EPC.

II. Oral proceedings took place on 23 May 2024.

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

The respondent requested that the appeal be dismissed (main request) or that the patent be maintained on the basis of one of auxiliary requests 1a to 7a and 1b to 7b, all filed by letter dated 4 May 2023.

The party as of right (opponent 1) made neither requests nor other submissions.

III. The following document is mentioned in this decision:

D5: EP 2 716 237 A1

IV. **Claim 1 of the main request** reads as follows:

"A left atrial appendage occluder (100, 200, 300, 400, 500, 600, 700), comprising a sealing part (110, 220, 320, 420, 520, 620, 720) being disc-shaped, a fixing part (120, 210, 310, 410, 510, 610, 710) disposed at one side of the sealing part (110, 220, 320, 420, 520, 620, 720), and a connection part (130, 230, 330, 430, 530, 630, 730) connecting the sealing part (110, 220, 320, 420, 520, 620, 720) and the fixing part (120, 210,

310, 410, 510, 610, 710), characterised in that the axial deformation capacity of the sealing part (110, 220, 320, 420, 520, 620, 720) is greater than that of the fixing part (120, 210, 310, 410, 510, 610, 710)."

**Claim 1 of auxiliary requests 1a and 1b** correspond to claim 1 of the main request except that the expression "being disc-shaped" has been deleted.

**Claim 1 of auxiliary request 2a** corresponds to claim 1 of the main request except that the following wording has been added after the term "disc-shaped,":

"wherein the sealing part (110, 220, 320, 420, 520, 620, 720) is a single-layer disc or a dual-layer disc or wherein the sealing part (110, 220, 320, 420, 520, 620, 720) is of a disc surface structure or wherein the sealing part (110, 220, 320, 420, 520, 620, 720) comprises a disc-shaped portion adjoined to a fixed connecting part,".

**Claim 1 of auxiliary request 3a** corresponds to claim 1 of the main request except that the following wording has been added after the term "disc-shaped,":

"wherein the sealing part (110, 220, 320, 420, 520, 620, 720) is a single-layer disc being a braided single-layer disc or a cut single-layer disc or wherein the sealing part (110, 220, 320, 420, 520, 620, 720) is a dual-layer disc being a braided dual-layer disc or a cut dual-layer disc or wherein the sealing part (110, 220, 320, 420, 520, 620, 720) is of a disc surface structure and is connected to a connection part on the disc surface or wherein the sealing part (110, 220, 320, 420, 520, 620, 720) comprises a disc-shaped portion adjoined to a fixed connecting part and a

transition portion extending between the disc-shaped portion and a proximal end of the fixed connection component, the disc-shaped portion and the transition portion being different regions of a same braided body, wherein the left atrial appendage occluder (100, 200, 300, 400, 500, 600, 700) also comprises".

**Claim 1 of auxiliary requests 4a and 4b** correspond to claim 1 of the main request except that the following wording has been added at the end of the claim:

", wherein with the application of the same axial force, a displacement of the sealing part (110, 220, 320, 420, 520, 620, 720) along a direction of the axial force is greater than a displacement of the fixing part (120, 210, 310, 410, 510, 610, 710) along the direction of the axial force".

**Claim 1 of auxiliary requests 5a and 5b** correspond to claim 1 of auxiliary requests 1a and 1b except that the following wording has been added at the end of the claim:

", wherein with the application of the same axial force, a displacement of the sealing part (110, 220, 320, 420, 520, 620, 720) along a direction of the axial force is greater than a displacement of the fixing part (120, 210, 310, 410, 510, 610, 710) along the direction of the axial force".

**Claim 1 of auxiliary request 6a** corresponds to claim 1 of auxiliary request 2a except that the following wording has been added at the end of the claim:

", wherein with the application of the same axial force, a displacement of the sealing part (110, 220,

320, 420, 520, 620, 720) along a direction of the axial force is greater than a displacement of the fixing part (120, 210, 310, 410, 510, 610, 710) along the direction of the axial force".

**Claim 1 of auxiliary request 7a** corresponds to claim 1 of auxiliary request 3a except that the following wording has been added at the end of the claim:

", wherein with the application of the same axial force, a displacement of the sealing part (110, 220, 320, 420, 520, 620, 720) along a direction of the axial force is greater than a displacement of the fixing part (120, 210, 310, 410, 510, 610, 710) along the direction of the axial force".

**Claim 1 of auxiliary request 2b** corresponds to claim 1 of auxiliary request 2a except that the following wording has been added after the fifth occurrence of term "sealing part (110, 220, 320, 420, 520, 620, 720)":

", the sealing part (110, 220, 320, 420, 520, 620, 720) and the fixing part (120, 210, 310, 410, 510, 610, 710) being braided or cut structures".

**Claim 1 of auxiliary request 3b** corresponds to claim 1 of auxiliary request 3a except that the following wording has been added after the sixth occurrence of term "sealing part (110, 220, 320, 420, 520, 620, 720)":

", the sealing part (110, 220, 320, 420, 520, 620, 720) and the fixing part (120, 210, 310, 410, 510, 610, 710) being braided or cut structures".



**Claim 1 of auxiliary request 6b** corresponds to claim 1 of auxiliary request 2b except that the following wording has been added at the end of the claim:

", wherein with the application of the same axial force, a displacement of the sealing part (110, 220, 320, 420, 520, 620, 720) along a direction of the axial force is greater than a displacement of the fixing part (120, 210, 310, 410, 510, 610, 710) along the direction of the axial force".

**Claim 1 of auxiliary request 7b** corresponds to claim 1 of auxiliary request 3b except that the following wording has been added at the end of the claim:

", wherein with the application of the same axial force, a displacement of the sealing part (110, 220, 320, 420, 520, 620, 720) along a direction of the axial force is greater than a displacement of the fixing part (120, 210, 310, 410, 510, 610, 710) along the direction of the axial force".

V. The appellant's arguments relevant to this decision can be summarised as follows.

*Main request*

The subject-matter of claim 1 of the main request lacked inventive step in view of D5.

D5 disclosed a left atrial appendage occluder (100), described with respect to Figures 6 to 8, comprising a sealing part (11) being disc-shaped, a fixing part (111) disposed at one side of the sealing part and a connection part connecting the sealing part and the fixing part.

D5 also disclosed, in column 9, lines 9 to 13, that the sealing part had greater deformability than the fixing part, for adjusting the relative positions and relative distances between the sealing part and the fixing part. Column 13, line 53 to column 14, line 2 explicitly disclosed an embodiment of the left atrial appendage occluder formed by direct connection of an elastic closure disc and a fixing frame and an embodiment having a flexible connection structure between the closure disc and the fixing frame.

Even accepting that D5 did not disclose that the axial deformation capacity of the sealing part was greater than that of the fixing part, there was no specific advantage associated with this distinguishing feature. The patent (in particular paragraphs [0062], [0063] and [0096]) taught that it was the deformation capacity in general of the sealing part being greater than that of the fixing part which was beneficial for the sealing effect of the occluder.

Since there was no particular advantage associated with the distinguishing feature, there was no demonstrated technical effect which this feature could provide. It followed that the selection of this claim feature could be considered merely to be an obvious design option that the skilled person might choose to take.

Hence, claim 1 of the main request was not inventive in view of D5 in combination with the common general knowledge.

Auxiliary requests

Auxiliary requests 1a, 1b, 5a and 5b were not allowable because deletion of the feature of the sealing part being disc-shaped extended the scope of these requests compared to the request found allowable by the Opposition Division in the impugned decision. This was against the principle of prohibition of *reformatio in peius*.

Auxiliary requests 2a to 4b and 6a to 7b were not allowable due to lack of inventive step, because the additional features of their claim 1 over claim 1 of the main request were all disclosed in D5 (paragraphs [0021] and [0027]).

VI. The respondent's arguments relevant to this decision can be summarised as follows.

*Main request*

D5 did not disclose a left atrial appendage occluder as defined in claim 1, with the axial deformation capacity of the sealing part being greater than that of the fixing part.

D5 taught neither to specifically consider axial deformation capacity nor how to design the axial deformation capacities of the sealing part and the fixing part.

Moreover, D5 did not disclose that the sealing part had a greater deformation capacity than the fixing part. The sentence in column 9, lines 9 to 13 of D5 was ambiguous in this respect. It appeared from this sentence that the struts of the fixing part made it possible to adjust the relative positions of the sealing part and the fixing part. In addition,

paragraph [0028] of D5 taught an embodiment in which a flexible connector between the sealing part and the fixing part provided better deformability of the left atrial appendage occluder.

The person skilled in the art would have recognised that it was the radial, and not the axial, deformation capacity of the sealing part which was of major significance. The patent distinguished between radial deformation capacity and axial deformation capacity and taught that the axial placement of the left atrial appendage occluder had to be finely adjusted to prevent mutual pulling actions between the fixing part and the sealing part after implantation leading to separation of the fixing part from the left atrial appendage and, in turn, implantation failure. This adjustment could be obtained by specifically designing the sealing part and the fixing part such that the axial deformation capacity of the sealing part is greater than that of the fixing part.

Hence, the technical effect of the distinguishing feature solved the problem of providing better sealing.

There was no teaching in the prior art to adjust the axial deformation capacities as claimed to solve this problem. It followed that the subject-matter of claim 1 of the main request was inventive when starting from D5.

#### *Auxiliary requests*

Auxiliary requests 1a, 1b, 5a, and 5b had been filed as a precautionary measure in case the Board concluded that claim 1 of the main request included added subject-matter. They were allowable because an

exception to the principle of the prohibition of *reformatio in peius* could be made where the Opposition Division had allowed an inadmissible amendment.

Auxiliary requests 2a to 3b had also been filed to avoid objections of added subject-matter.

Auxiliary requests 4a to 7a included a limitation specifying the axial behaviour of the sealing part and the fixing part in the presence of the same axial force, which was not disclosed in the prior art. This limitation contributed to inventive step.

## **Reasons for the Decision**

### 1. Subject-matter of the patent

The patent relates to a left atrial appendage occluder. The left atrial appendage is a muscular ear-shaped, pouch-like structure located in the upper part of the left atrium, which is one of the two upper chambers in the heart. The left atrium receives oxygen-enriched blood from the pulmonary circulation. From the left atrium the blood is pumped into the left ventricle of the heart. The left ventricle contracts (ventricular systole) and pumps the blood into the systemic circulation throughout the body.

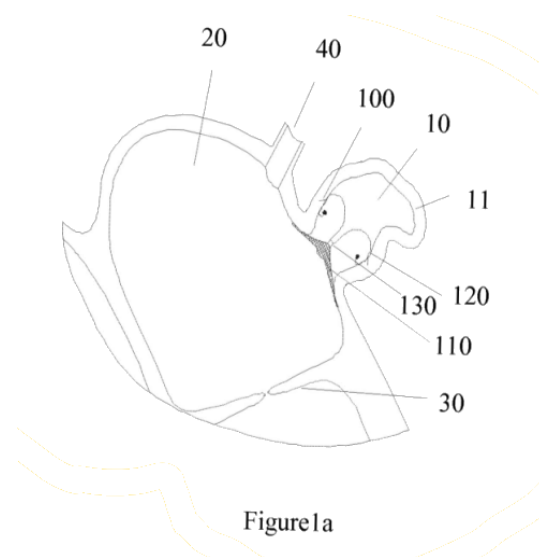
The left atrial appendage appears to function as a decompression chamber when left atrial pressure is high (for example during ventricular systole). It also modulates intravascular volume by secreting several peptides which enter into the blood circulation. With certain conditions such as atrial fibrillation, blood clots may form in the left atrial appendage,

enter the bloodstream and cause a stroke. Left atrial appendage occlusion is a procedure used to reduce the risk of stroke in those with atrial fibrillation.

The left atrial appendage may be occluded by ligation. Ligation eliminates perfusion of the left atrial appendage but also negates its endocrine contribution (its secretions cannot enter into the blood circulation).

Another method for performing left atrial appendage occlusion is the implantation of an occluder, which functions as a one-way valve, permitting the secretions of the left atrial appendage to enter into the blood circulation, but preventing blood in the atrium from entering the left atrial appendage and forming clots.

The claimed invention relates to such an occluder. Figure 1a of the patent, reproduced below, shows the implanted position of the occluder (100) in the left atrial appendage (10) in the left atrium (20), between the mitral valve (30) and the left superior pulmonary vein (40) of the heart.



The left atrial appendage occluder as defined in claim 1 of the main request comprises a disc-shaped

sealing part (110) for sealing against the contour of the atrial appendage, a fixing part (120) disposed at one side of the sealing part for placing within the atrial appendage and fixing the occluder in place, and a connection part (130) connecting the sealing part and the fixing part.

The axial deformation capacity of the sealing part is greater than that of the fixing part. This contributes to improving the sealing properties of the left atrial occluder and preventing tissue damage at the opening of the left atrial appendage (paragraph [0024] of the patent).

2. Main request - inventive step

2.1 The appellant argued that the subject-matter of claim 1 of the main request lacked an inventive step when starting from D5.

D5 discloses a left atrial appendage occluder 100 (Figures 5 and 6 reproduced below).

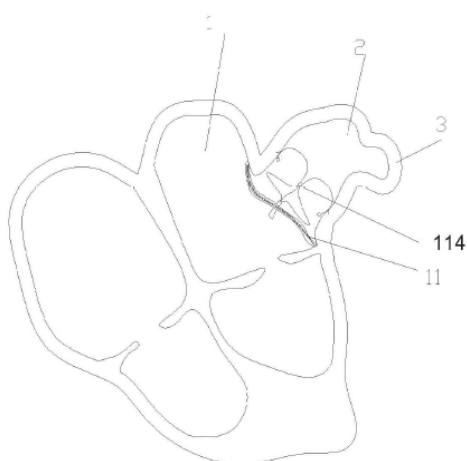


Figure 5

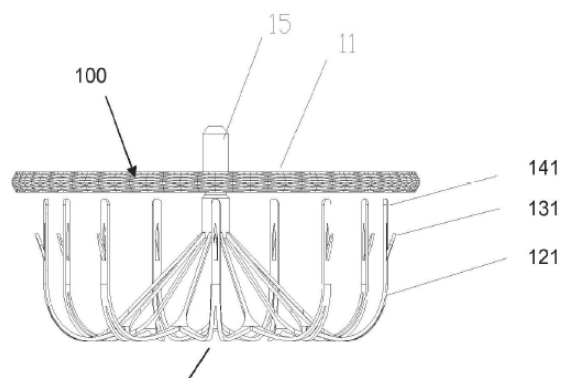


Figure 6

The left atrial appendage occluder comprises a sealing part being disc-shaped (closure disc 11), a fixing part

(fixing frame 111 comprising struts 121) disposed at one side of the sealing part, and a connection part (15) connecting the sealing part and the fixing part.

- 2.2 D5 does not disclose that the axial deformation capacity of the sealing part is greater than that of the fixing part.

This distinguishing feature contributes to improving the sealing and fixing properties of the occluder when subject to pulling forces which may develop in the left atrial appendage. Hence, it contributes to solving the problem of providing a more effective left atrial appendage occluder.

- 2.3 However, as the appellant pointed out, according to the patent it is not the specific relative axial deformation alone which provides this, but the combination of radial and axial deformation of the sealing part and the fixing part. For example, paragraphs [0062] and [0063] of the patent discuss the advantages of the sealing part having a higher radial deformation capacity than the fixing part so as to seat the occluder more firmly in the left atrial appendage and improve its sealing action. Paragraph [0024] recites: *"the radial or axial deformation capacity of the sealing part is set to be greater than the corresponding radial or axial deformation capacity of the fixing part, so that the situation that the sealing part cannot be optimally fitted with the opening of the left atrial appendage after the fixing part is placed in the left atrial appendage can be avoided, thereby enhancing the occlusion effect; and meanwhile, owing to the great deformation capacity of the sealing part, risks of abrasion or break of the opening of the left atrial appendage caused by the sealing part may be*



*reduced*".

- 2.4 D5 discloses the importance of the sealing part having good flexibility and the fixing part displaying a certain degree of deformability: "*The closure disc 11 has good flexibility, while the struts 121 have certain deformability, so that they may play a role in adjusting relative positions and relative distances between the closure disc 11 and the fixing frame 111 to a certain extent*" (column 9, lines 9 to 13).

Contrary to the respondent's arguments in this respect, this sentence of D5, together with the disclosure that the left atrial appendage occluder may be "*formed by direct connection of an elastic closure disc with a membrane mounted inside it and a fixing frame comprising a plurality of struts*" (column 13, line 53 to column 14, line 2) amounts to teaching that the (*elastic*) sealing part should have a higher deformation capacity (*good flexibility*) than that (*certain deformability*) of the fixing part. This makes it possible to adjust "*relative positions and relative distance between the closure disc 11 and the fixing frame 111 to a certain extent*".

- 2.5 In view of this teaching, the fact that no special effect is associated with the particular axial direction of the deformation capacities and common general knowledge, the provision of the sealing part with a deformation capacity greater than that of the fixing part in all directions, and therefore also in the axial direction, would have become obvious to the person skilled in the art in the course of optimising the occluder by testing, for use in a real situation. It follows that the main request cannot be allowed due to lack of inventive step (Article 56 EPC) of the

subject-matter of claim 1.

3. Auxiliary requests

- 3.1 In claim 1 of auxiliary requests 1a, 1b, 5a and 5b, the feature of the sealing part being disc-shaped has been deleted compared to claim 1 of the main request. It is common ground that this deletion extends the scope of the claims of the auxiliary requests. Since the proprietor did not appeal, the amendment of claim 1 of auxiliary requests 1a, 1b, 5a and 5b goes against the principle of the prohibition of *reformatio in peius*, as explained in decision G 1/99.

The respondent stated that the auxiliary requests were filed to avoid an objection of added subject-matter against claim 1 of the main request and therefore an exception to this principle could be made. However, claim 1 of the main request is not allowable due to lack of inventive step. Hence, the reason for making an exception to the principle of the prohibition of *reformatio in peius* put forward by the respondent does not arise. It follows that auxiliary requests 1a, 1b, 5a and 5b are not allowable.

- 3.2 In claim 1 of auxiliary requests 2a, 2b, 3a and 3b, the disc-shaped sealing part and the fixing part are further defined according to various alternatives.

The subject-matter of claim 1 of these requests is not inventive (Article 56 EPC) when starting from D5 for the same reasons as those given for the main request, because D5 discloses one of the alternatives claimed for each of the sealing part and the fixing part, i.e. a sealing part in the form of a braided single-layer disc and a fixing part as a cut structure (paragraph

[0021] and column 8, lines 23 to 28).

- 3.3 In claim 1 of auxiliary requests 4a, 6a, 7a, 4b, 6b and 7b, wording has been introduced which provides an inherent definition of what is understood by "axial deformation capacity". This wording provides no additional technical limitation compared to the feature in claim 1 of the main request according to which the axial deformation capacity of the sealing part is greater than that of the fixing part.

Hence, the subject-matter of claim 1 of these requests does not involve an inventive step (Article 56 EPC) when starting from D5 for the reasons given for the main request.

4. In conclusion, there is no request which could provide a basis for maintaining the patent.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated