

**Internal distribution code:**

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

**Datasheet for the decision  
of 7 June 2023**

**Case Number:** T 0477/20 - 3.2.02

**Application Number:** 04752603.3

**Publication Number:** 1624810

**IPC:** A61B17/04

**Language of the proceedings:** EN

**Title of invention:**

FIXATION DEVICES AND SYSTEMS FOR ENGAGING TISSUE

**Patent Proprietor:**

Evaluate, Inc.

**Opponents:**

Oppositions withdrawn

**Headword:**

**Relevant legal provisions:**

EPC Art. 111(1), 123(3)

RPBA 2020 Art. 11, 12(2)

**Keyword:**

Amendments - extension of the scope of protection of the  
patent as granted (no)  
Remittal - special reasons for remittal (yes) -  
primary object of appeal proceedings to review decision

**Decisions cited:**

**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 0477/20 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 7 June 2023**

**Appellant:** Evalve, Inc.  
(Patent Proprietor) 4045 Campbell Avenue  
Menlo Park, CA 94025 (US)

**Representative:** Boulton Wade Tennant LLP  
Salisbury Square House  
8 Salisbury Square  
London EC4Y 8AP (GB)

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
3 January 2020 concerning the maintenance of  
European Patent No. 1624810 in amended form

**Composition of the Board:**

**Chairman**            M. Alvazzi Delfrate  
**Members:**            D. Ceccarelli  
                              C. Schmidt

## **Summary of Facts and Submissions**

- I. The proprietor appealed against the Opposition Division's decision that, account being taken of the amendments made by the patent proprietor during the opposition proceedings according to auxiliary request 11, the patent and the invention to which it relates met the requirements of the EPC.

The main request was not allowed because it was considered to extend the scope of protection of the patent as granted, contrary to the requirements of Article 123(3) EPC.

- II. The opponents withdrew their oppositions.
- III. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main request and the first to the thirty-second auxiliary requests, all filed with the statement of grounds of appeal on 13 May 2020.

The appellant also requested oral proceedings as an auxiliary measure but then withdrew this request on the condition that the Board decided that the subject-matter of claim 1 of the main request did not extend the scope of protection of the patent as granted, that the impugned decision should be set aside and that the case should be remitted to the Opposition Division for further prosecution.

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

"A fixation device for engaging tissue comprising:

a pair of fixation elements (18) each having a first end, a free end opposite the first end, and an engagement surface (50) therebetween for engaging the tissue, the first ends being movably coupled together such that the fixation elements (18) are moveable between 1) a closed position wherein the engagement surfaces (50) face each other, and 2) an inverted position wherein the engagement surfaces (50) face away from each other; and

an actuation mechanism (58) coupled to the fixation elements adapted to move the fixation elements (18) between the closed position and the inverted position, further comprising a pair of gripping elements (16), each gripping element (16) moveable with respect to one of the fixation elements (18) and being disposed in opposition to one of the engagement surfaces (50) so as to capture tissue therebetween, wherein the gripping elements (16) are movable from an undeployed configuration in which each gripping element (16) is separated from an opposing engagement surface (50), to a deployed configuration in which the gripping element (16) is adjacent to the opposing engagement surface (50) and wherein each fixation element (18) is at least partially concave and each gripping element (16) is at least partially recessed within the fixation element (18) in the deployed configuration or wherein the gripping elements (16) are approximately parallel to each other in the undeployed configuration."

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

The Opposition Division had incorrectly decided that the feature of "an actuation mechanism (58) adapted for coupling to the fixation elements" as present in claim 1 of the patent as granted restricted the claim

to the actuation mechanism and fixation elements being separate entities that could be coupled together and that amending that feature to "an actuation mechanism (58) adapted for coupling coupled to the fixation elements" removed this restriction and extended the scope of protection.

There was nothing within the wording of claim 1 of the patent as granted which required such a restrictive interpretation.

An actuation mechanism being adapted for coupling to fixation elements did not stop being so adapted once it had been coupled to the fixation elements.

Rather, components coupled together, including those which had been coupled together, had been and still were adapted for the coupling. Hence, the scope of the meaning of components being "adapted for coupling" was not narrower than the scope of the meaning of components being "coupled".

## **Reasons for the Decision**

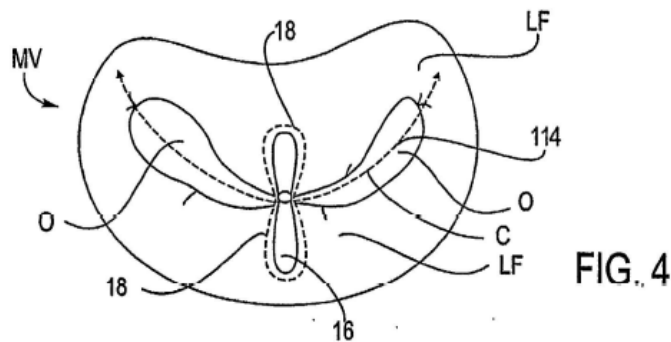
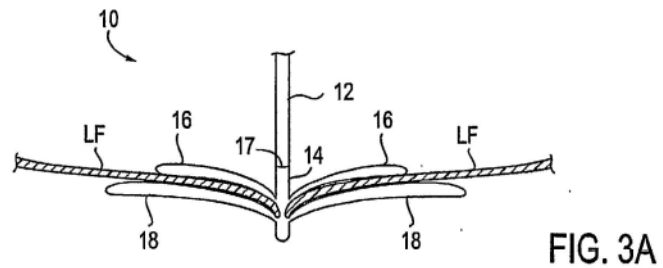
### 1. The patent

The patent relates to a fixation device for engaging tissue.

The typical application disclosed in the patent is the treatment of the heart, more particularly, the repair of a mitral valve for treating mitral valve regurgitation (paragraphs [0003] and [0004]). Paragraphs [0045] and [0046], together with Figures 1 to 2B, illustrate the anatomy of the heart and the

mitral valve, including the pathological conditions which can be treated with the device being claimed.

The fixation device comprises a pair of fixation elements each having a first end, a free end opposite the first end and an engagement surface between the two ends for engaging the tissue which typically belongs to a valve leaflet. Figures 3A and 4 of the patent, reproduced below, show the fixation elements (18) in engagement with two leaflets of the mitral valve.



The first ends of the fixation elements are movably coupled together such that the fixation elements are movable between a closed position in which the engagement surfaces face each other and an inverted position in which the engagement surfaces face away from each other. Figures 7A and 7D of the patent, reproduced below, respectively show fixation elements (18) in a closed position and an inverted position.

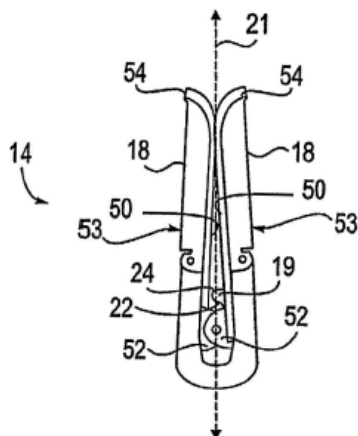


FIG. 7A

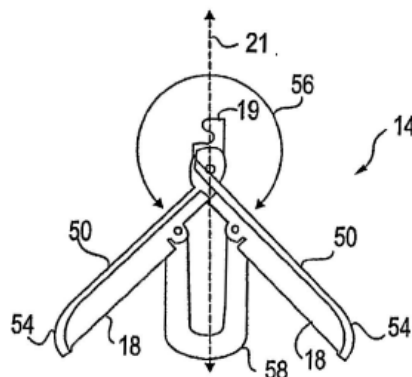


FIG. 7D

The fixation device also comprises an actuation mechanism (58) coupled to the fixation elements adapted to move the fixation elements between the closed position and the inverted position.

A pair of gripping elements (16) is also provided, each of which is movable with respect to one of the fixation elements and disposed in opposition to one of the engagement surfaces to capture tissue between the engagement surface and the gripping element.

The gripping elements are movable from an undeployed configuration in which each gripping element is separated from an opposing engagement surface to a deployed configuration in which the gripping element is adjacent to the opposing engagement surface.

Each fixation element is at least partially concave, and each gripping element is at least partially recessed within the fixation element in the deployed configuration. Alternatively, the gripping elements are approximately parallel to each other in the undeployed configuration.

The fixation device as claimed should allow repair of mitral and other cardiac valves without the need for open chest access (paragraph [0006]).

2. Extension of the scope of protection

Compared with claim 1 of the patent as granted, claim 1 of the main request has only been amended to recite that the actuation mechanism is "coupled", instead of being "adapted for coupling", to the fixation elements.

The Opposition Division concluded that claim 1 of the patent as granted required the actuation mechanism and the fixation elements to be separate entities that could be coupled together, whereas claim 1 of the main request was not limited in that way.

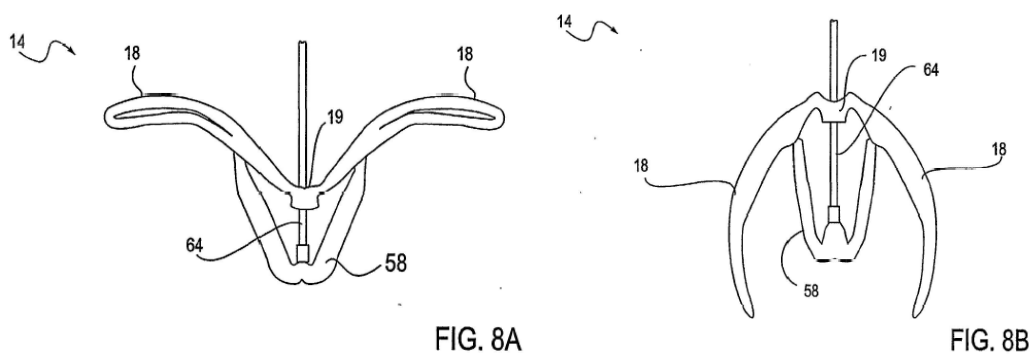
The Board does not share this view.

The wording "adapted for coupling" does not limit the claim to a fixation device in which the actuation mechanism and the fixation elements must be or must have been separate entities that could be coupled together. The wording does not place a temporal limitation on when the coupling has to take place. In other words, "adapted for coupling" does not imply that the actuation mechanism and the fixation elements should be able to be brought into a coupled state but can also mean that the configuration of the actuation mechanism and the fixation elements allows them to be in a coupled state.

Considering the patent as a whole, it is even clearer that the wording "adapted for coupling" could not be meant to limit the claim as the Opposition Division considered. A hypothetical fixation device with the

actuation mechanism and the fixation elements which had still to be coupled together would not be a finished fixation element and could not function as claimed and disclosed in the patent. Moreover, the patent does not show such a fixation device at all. In all of the embodiments, the fixation device is shown in a finished manufactured state, with the actuation mechanism and the fixation elements coupled to each other in an unreleasable way.

Contrary to the Opposition Division's conclusions, according to a technically sensible interpretation, the wording "adapted for coupling" did not exclude the embodiment of Figures 8A and 8B, reproduced below, from falling within the scope of claim 1 of the patent as granted either.



Although the actuation mechanism and the fixation elements of this embodiment are disclosed to be moulded as one part (paragraph [0065]), since they can be distinguished functionally and can exist in a coupled state, they are "adapted for coupling" in accordance with the wording of claim 1 of the patent as granted.

In conclusion, compared with the scope of the wording "adapted for coupling", the scope of the wording "coupled to" in claim 1 of the main request is not

broader but narrower since it excludes a situation in which the actuation mechanism and the fixation elements are not (yet) coupled to each other.

Hence, the subject-matter of claim 1 of the main request does not extend the scope of protection of the patent as granted, and Article 123(3) EPC is complied with.

### 3. Remittal

Since the objection under Article 123(3) EPC, based on which the Opposition Division did not allow the main request, does not prejudice the maintenance of the patent as granted, the impugned decision is to be set aside.

In the opposition proceedings, the former opponents raised objections of lack of novelty over a number of documents. The Opposition Division considered novelty and inventive step of the eleventh auxiliary request. However, claim 1 of that request comprised the feature that the fixation device was suitable for engaging heart valve leaflet tissue for the repair of a valve of the heart, and this feature was decisive in the assessment of novelty and inventive step.

Since this feature is not present in claim 1 of the main request, the examination of patentability in view of the former opponents' objections is to be performed anew.

In view of the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (Article 12(2) RPBA 2020), there are special reasons within the meaning of Article 11 RPBA 2020

which justify remittal of the case to the Opposition Division for further prosecution under Article 111(1) EPC.

## 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 for further prosecution.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated