

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**
(PCT Rule 43*bis*.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2017/060834

International filing date (day/month/year)
09.11.2017

Priority date (day/month/year)
11.11.2016

International Patent Classification (IPC) or both national classification and IPC
INV. A61F2/24 A61B17/122

Applicant
EVALVE, INC

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of this opinion

see form
PCT/ISA/210

Authorized Officer

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - the international application in the language in which it was filed.
 - a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. forming part of the international application as filed:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

the entire international application

claims Nos. 1-11

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

no international search report has been established for the whole application or for said claims Nos. 1-11

a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>12-20</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>12-20</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>12-20</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Item III.

- 1 Rules 39.1 (iv) and 67.IV PCT - Method for treatment of the human or animal body by surgery. The feature ""positioning a repair device at a targeted cardiac valve" in claim 1 implies surgery.

Item V.

- 2 Reference is made to the following documents:

- D1 US 2015/257879 A1 (BÖRTLEIN GEORG [FR] ET AL) 17 September 2015 (2015-09-17)
- D2 WO 2012/103173 A2 (UNIV EMORY [US]; PADALA SAIMURALIDHAR [US]; THOURANI VINOD H [US]) 2 August 2012 (2012-08-02)

- 3 Independent claim 11

Claim 1 differs from the known subject matter of claim 1 in that the grasping elements are a distal **disk** and a proximal **disk**.

The fact that the elements are disks provides the technical effect of allowing "sandwiching" the tips of the leaflets when they are in an open position. This has the technical advantage of closing the space between the leaflets, solving the problem of valvular regurgitation.

The skilled person, when considering D1 would not arrive to the present solution. D1 relies in an artificial heart valve to solve the problem of valvular regurgitation (See paragraphs 2, 48,49). There is no hint or indication that the natural leaflets should still perform their function. On the contrary, they are rendered redundant by the grasping of the scaffold members.

Document D2 relates to a device for closing the gap in an aortic valve for avoiding regurgitation (see paragraph 53 and figure 11). This document nevertheless does not disclose disks that are suitable for grasping the leaflets.

4 Independent claim 18

The same reasoning as in point 3 applies, *mutatis mutandis*, to the subject-matter of the corresponding independent claim 18, which therefore is also considered to be novel and to involve an inventive step. claim 18 further includes a delivery device for the device of claim 11.

5 Dependent claims 12-17,1,20 meet the requirements of the PCT in respect of novelty (Article 33(2)) and inventive step.

Item VII.

6 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in document D1 is not mentioned in the description, nor is this document identified therein.

7 Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

8 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).