

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.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/US2007/023997

International filing date (day/month/year)  
15.11.2007

Priority date (day/month/year)  
17.11.2006

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

Applicant  
ST. JUDE MEDICAL, 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 43bis.1(a)(i) with regard to novelty, inventive step or 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 66.1bis(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.

**3. For further details, see notes to Form PCT/ISA/220.**

<p>Name and mailing address of the ISA:</p>  <p>European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840</p>	<p>Date of completion of this opinion</p> <p>see form PCT/ISA/210</p>	<p>Authorized Officer</p> <p>Amaro, Henrique</p> <p>Telephone No. +49 30 25901-562</p> 
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
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**Box No. I Basis of the opinion**

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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 and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - a sequence listing
    - table(s) related to the sequence listing
  - b. format of material:
    - on paper
    - in electronic form
  - c. time of filing/furnishing:
    - contained in the international application as filed.
    - filed together with the international application in electronic form.
    - furnished subsequently to this Authority for the purposes of search.
4.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in 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. 16-21

because:

- the said international application, or the said claims Nos. 16-21 relate to the following subject matter which does not require an international search (*specify*):

see separate sheet

- 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. 16-21
- a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
  - furnish a sequence listing on paper 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 a form and manner acceptable to it.
  - furnish a sequence listing in electronic form 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 a form and manner acceptable to it.
  - pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).
- a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- See Supplemental Box for further details

**WRITTEN OPINION OF THE  
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**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**

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1. Statement

Novelty (N)	Yes: Claims	<u>2-7</u>
	No: Claims	<u>1,8-15</u>
Inventive step (IS)	Yes: Claims	<u>6,7</u>
	No: Claims	<u>1-5,8-15</u>
Industrial applicability (IA)	Yes: Claims	<u>1-15</u>
	No: Claims	

2. Citations and explanations

see separate sheet

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**Box No. VII Certain defects in the international application**

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

see separate sheet

**Re Item III.**

Claims 16-21 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability (Article 34(4)(a)(I) PCT).

**Re Item V.**

Reference is made to the following documents:

- D1: WO 02/49540 A (CLEVELAND CLINIC FOUNDATION [US]) 27 June 2002 (2002-06-27)  
D2: US 2005/228496 A1 (MENSAH EUGENE A [US] ET AL) 13 October 2005 (2005-10-13)

1. Independent claims 1,8 refer to the same subject matter (prosthetic heart valve comprising a valve core and a mounting retainer structure extending radially out from the valve core). The subject matter from both claims differ in that:

In claim 1, the outer perimeter portion has a different shape than the perimeter of the valve core when both perimeters are viewed along an axis that will be the axis of the blood flow through the core valve when the core valve is in use in a patient; the perimeter portion of the mounting retaining structure can be made in any plane view shape enabling the heart valve to match its shape to the valve annulus to where is to be attached.

In claim 8, the outer perimeter is substantially rigid; the defined feature is an optional configuration of mounting retainer structure and therefore the not an essential feature for the definition of the invention. It is also not defined how the perimeter portion is adapted for attaching the heart valve to another structure (as it is in claim 1).

Due to the above mentioned multiplicity of independent claims seeking to define more or less the same invention in different ways, it is not feasible to perform a search

opinion on all the claims. As independent claim 1 seems best to define the idea underlying to the present application (see reasoning above), the search opinion examination is therefore being based on claim 1 and subsequent dependent claims.

2. The application does not meet the requirements of Article 6 PCT, because claim 1 is not clear. The reasons are the following:

It is clear from the description on page 6, lines 19-29; page 10, line 26 - page 12, line 18 that the mounting retainer structure including material spanning and at least substantially filling the space or radial distance between the core perimeter 26 and ultimate outer perimeter 40 of the mounting retainer structure is essential to the definition of the invention as it enables the chordae of the substituted natural valve to be attached closer to its original location helping to maintain the native shape of, for example, the left ventricle if the valve to be replaced is the mitral valve.

Since independent claim 1 does not contain this feature, it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

3. It seems that the subject-matter defined as claimed in independent claim 1 with the material spanning and at least substantially filling the space or radial distance between core perimeter 26 and ultimate outer perimeter 40 enabling the attachment of the chordae of the substituted valve to the mounting retainer structure meets the criteria mentioned in Article 33(1) PCT, i.e. it appears to be novel, involve an inventive step and to be industrially applicable for the following reasons: Not only none of the prosthetic heart valves disclosed in prior art documents D1, D2 seem to propose any solution to maintain the native shape of the left ventricle, it seems that the problem is even not addressed.

**Re Item VII.**

4. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.
5. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
6. The requirements of Rule 6.3(b) PCT are not met. The independent claims are not properly cast in the two-part form, with those features which in combination are part of the prior art acknowledged by the applicant 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).