

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/US2016/039808

International filing date (day/month/year)
28.06.2016

Priority date (day/month/year)
02.07.2015

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

Applicant
BOSTON SCIENTIFIC SCIMED, 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 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 66.1bis(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.

Name and mailing address of the ISA:



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Date of completion of this opinion

see form
PCT/ISA/210

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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. 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>1-35</u> |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | <u>1-35</u> |
| Industrial applicability (IA) | Yes: Claims | <u>1-35</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

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 US 2003/078652 A1 (SUTHERLAND FRASER W H [US]) 24 April 2003 (2003-04-24)

D2 US 2005/228486 A1 (CASE BRIAN C [US] ET AL) 13 October 2005 (2005-10-13)

D3 WO 2009/038761 A1 (ST JUDE MEDICAL [US]; LI XUEMEI [US]; WOO YI-REN [US]) 26 March 2009 (2009-03-26)

2 INDEPENDENT CLAIMS 1, 16, 33

2.1 The present application does not meet the criteria of PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

Document D1 is regarded as being the prior art closest to the subject-matter of claim 1. This said document shows the following features thereof (the references in parentheses apply to this document):

A prosthetic heart valve leaflet (paragraphs [0005] - [0015], [0070] - [0073]; figures 12, 13) comprising a fiber-reinforced structure (figure 13) including a plurality of fibers (figure 13), each fiber comprising a core fiber (124/138), the core fiber (124/138) having a curvilinear shape (figure 13).

2.1.1 The subject-matter of claim 1 therefore differs from this known document D1 in that:

- (i) The fibers are composite fibers having a sheathing fiber disposed about the core fiber.

The current application (see description at paragraph 4) and document D1 (paragraphs [0005] - [0015]) solve the same problem: How to provide a prosthetic valve that has a longer life duration. Therefore, the skilled person would consider both solutions as technically equivalent in order to solve the problem posed. This is why the objective technical problem that follows will only take into account the contribution of feature (i) over the prior art.

The problem to be solved by the present invention may therefore be regarded as: How to provide a reinforced fiber for a prosthetic heart valve leaflet that gives to said leaflet mechanical properties closer to a native leaflet.

2.1.2 The contribution of feature (i) over the prior art falls within the scope of customary practices for the one skilled in the art, see for example:

- either document D2 (paragraphs [0096] - [0104]; figures 3A,3B,4A-4D, 5E,5D).
- or document D3 (paragraphs [0019] - [0030]; figures 1-5).

The subject-matter of claim 1 is considered as obvious in view of document D1 alone. The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

The same reasoning applies mutatis mutandis to claims 16 and 33. Method claim 33 is only a straightforward way to manufacture the products of claims 1 and 16.

3 DEPENDENT CLAIMS 2-15, 17-32, 34, 35

Dependent claims 2-15, 17-32, 34, 35 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step.

3.1 The subject-matter of claims 2-15, 17-32, 34, 35 falls within the scope of customary practices for the one skilled in the art, see for example:

- either document D2 (paragraphs [0096] - [0104]; figures 3A,3B,4A-4D, 5E,5D).
- or document D3 (paragraphs [0019] - [0030]; figures 1-5).

The subject-matter of said claims is considered as obvious and does not involve an inventive-step in view of document D1 alone.

Re Item VII

Certain defects in the international application

4 Independent claim 1 is not in the **two-part form** in accordance with Rule 6.3(b) PCT.

5 The features of the preamble of claim 1 are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

- 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.

Re Item VIII

Certain observations on the international application

- 7 Although claims 1 and 16 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter.

The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.