

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/US2018/012478

International filing date (day/month/year)
05.01.2018

Priority date (day/month/year)
09.01.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/84

Applicant
ZIMMER, 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. 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. 1-12

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. 1-12

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>13-20</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>17, 18</u>
	No: Claims	<u>13-16, 19, 20</u>
Industrial applicability (IA)	Yes: Claims	<u>13-20</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

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 1 **Claims 1-12** define **methods** for treatment of the human or animal body by **surgery** (Rule 39.1(iv) PCT).

Re Item V

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

- 2 Reference is made to the following documents:
- D1 US 2015/0150687 A1 (HOPKINS ANDREW [CH]) 4 June 2015
 cited in the application
 - D2 US 2014/0277183 A1 (STALCUP GREGORY C [US] ET AL)
 18 Sept 2014
 - D3 US 2014/0030675 A1 (SANCHEZ RAMIRO [US] ET AL) 30 Jan 2014
 - D4 US 2007/0233071 A1 (DEWEY JONATHAN [US] ET AL) 4 Oct 2007
- 3 The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of **claims 13-16, 19, and 20** does **not** involve an **inventive step**.
- 3.1 The applicant's own patent application publication **D1** may be regarded as being the prior art closest to the subject-matter of these claims. It discloses
 a fixation post (bone screw 120) for attaching an orthopedic device to a bone comprising:
 a quasi-spherical head (screw head 123) with a textured outer surface; and

a shaft (shaft 128) including a proximal end attached to the quasi-spherical head, a distal end opposite the proximal end, and a bearing surface (proximal section 133 and/or distal section 134) between the proximal and distal ends.

3.2 The subject-matter of **claim 13** therefore differs from this known fixation post by

a porous metal sleeve including a central bore with a bore surface, the porous metal sleeve surrounding at least a portion of the shaft, wherein the bore surface substantially conforms with the bearing surface; and

a cap attached to the distal end of the shaft to retain the porous metal sleeve on the shaft.

3.3 The problem to be solved by the present invention may therefore be regarded as enhancing ingrowth of the surrounding bone into the fixation post.

3.4 The solution proposed in claim 13 of the present application **cannot** be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

Documents **D2** (see Figs. 4, 5, and 18), **D3** (see Fig. 2), and **D4** (see Fig. 10) each disclose similar fixation posts having the differentiating features for solving the above problem, specifically:

porous metal sleeve: fixation material 34, 148 in D2; first porous section 120, second porous section 122 in D3; bone interface portion 218 in D4

cap: distal part of shaft 42, distal end 146 in D2; threaded sections 110, 112 in D3; distal region 212a in D4

enhancing bone ingrowth: see paragraph [0041], line 6 in D2; see paragraphs [0037] and [0038] in D3; see paragraph [0033], lines 9-14 in D4

3.5 Dependent **claims 14-16, 19, 20**:

Claim 14: see each of D1-D4

Claim 15: see D4, Fig. 10

Claim 16: see D4, bone interface portion 218 must be rotationally fixed to bone engaging portion 212 (= shaft)

Claim 19: see D3, Fig. 2

Claim 20: see D1, Figs. 10-12 or D2, Fig. 18

4 The combination of the features of dependent **claims 17 and 18** is neither known from, nor rendered obvious by, the available prior art because the differentiating features are not known from the available prior art.

Re Item VII

Certain defects in the international application

- 5 The independent claim is 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 closest prior art document **D1** being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

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