

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/US2018/013940

International filing date (day/month/year)
17.01.2018

Priority date (day/month/year)
26.01.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/88 B23D29/02

Applicant
DEPUY SYNTHES PRODUCTS, 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. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- paid additional fees
 - paid additional fees under protest and, where applicable, the protest fee
 - paid additional fees under protest but the applicable protest fee was not paid
 - not paid additional fees
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- complied with
 - not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- all parts.
 - the parts relating to claims Nos.

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>9-11, 14-17, 20-22, 25-27, 30-32</u>
	No: Claims	<u>1-8, 12, 13, 18, 19, 23, 24, 28, 29, 33</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-33</u>
Industrial applicability (IA)	Yes: Claims	<u>1-33</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 IV

Lack of unity of invention

Reference is made to the following documents:

- D1 US 2011/062204 A1 (AEBI THIS [CH] ET AL) 17 March 2011
(2011-03-17)
- D2 US 2005/149086 A1 (HUXEL SHAWN T [US] ET AL) 7 July 2005
(2005-07-07)
- D3 US 5 980 547 A (RINNER JAMES A [US]) 9 November 1999
(1999-11-09)
- D4 WO 2008/073949 A1 (SYNTHESES USA [US]; SYNTHESES GMBH [CH];
DELL OCA ALBERTO A FERNANDEZ [UY]) 19 June 2008 (2008-06-19)
- D5 WO 97/04929 A1 (LENOX LINDA KATHLEEN [US]) 13 February 1997
(1997-02-13)

The application lacks unity (Rules 13.1 and 13.2 PCT), as 3 groups of invention are claimed:

- I) Claims 1-12, which essentially define a device for cutting a surgical cable, in which the first and second coaxial member each comprise at least two openings acting as shearing structures.
- II) Claims 13-23, which essentially define a cutting surgical device having a gear mechanism actuated by the handle unit.
- III) Claims 24-33, which essentially define a device for cutting a surgical cable, the device having a gear mechanism actuated by a handle unit for rotating two tubular members with respect to each other.

The common subject-matter between any two groups of inventions is at most:

A device for cutting a surgical cable, comprising:

an intervention unit comprising first and second members each comprising at least one opening in a distal end; and

a handle unit comprising an actuatable handle adapted to rotate the second coaxial member relative to the first;

wherein the two openings in the distal ends of the coaxial members function as coordinating shearing structures when the actuatable handle is actuated.

Said subject-matter is clearly not novel over the general common knowledge. There are also several documents disclosing said subject-matter, see for example document D2 (paragraphs [0031] - [0036]; figures 1-4B).

The features of each group which are not common with the other group also address different objective technical problems.

Said problems may be regarded as being:

- I) Provide at least two opening positions for cutting the cable
- II) Provide means for actuating the pinion against the coupling
- III) Provide a mechanism for rotating the first tubular member with respect to the second tubular member and thereby exert a shearing force on the cable.

Therefore, according to Rules 13.1 and 13.2 PCT the requirement of unity is not fulfilled, because there are no common or corresponding special technical features.

Re Item V

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

1. Novelty (Article 33(2) PCT):

1.1 First group of invention:

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-8 and 12 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (see paragraphs [0027] - [0033], [0035], [0037], [0040] - [0042], [0045], [0046]; figures 1-6):

A device for cutting a surgical cable, comprising:

an intervention unit comprising first (3, 13) and second (4, 14) coaxial members each comprising at least two openings (51, 52, 53) in a distal end; and

a handle unit comprising an actuatable handle (7) adapted to retain and engage the first and second coaxial members at a proximal end and to rotate the second coaxial member relative to the first;

wherein the at least two openings in the distal ends of the coaxial members function as coordinating shearing structures when the actuatable handle is actuated.

Claim 1 is therefore not new.

Document D1 also anticipates the subject-matter of claims 2-8 and 12 (see paragraphs [0027] - [0033], [0035], [0037], [0040] - [0042], [0045], [0046]; figures 1-6).

1.2 Second group of invention:

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 13, 18, 19 and 23 is not new in the sense of Article 33(2) PCT.

Document D3 discloses:

A surgical device for translating grip force to cutting force comprising:
an intervention unit comprising

an inner tubular member (10) disposed coaxially within an outer tubular member (11); and

a handle unit comprising

a housing (24);

a coupling disposed at the distal end of the housing;

a movable pinion (31) coupled to the coupling; and

a squeezable grip (43) coupled to the movable pinion and adapted to actuate axial rotation of the movable pinion against the coupling;

wherein the squeezable grip comprises a first set of teathed portions (42) configured to engage a second set of teathed portions attached to the movable pinion.

Claim 13 is therefore not new.

Document D3 also anticipates the subject-matter of claims 18, 19 and 23.

1.3 Third group of invention:

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 24, 28, 29 and 33 is not new in the sense of Article 33(2) PCT.

Document D3 discloses:

A device for cutting a surgical cable comprising:

first (27) and second (43) gripping members pivotally attached to one another;

first (28) and second (46) handle grips attached at proximal ends of the first and second gripping members, respectively;

an outer tubular member (11) attached on a proximal end of the outer tubular member to a distal end of the first gripping member;

an inner tubular member (10) located within the outer tubular member and having at least one coupling member attached on a circumference of a proximal end; and

a movable pinion (31) attached on a circumference of the proximal end of the coupling member;

wherein a distal end (42) of the second gripping member is engaged with a proximal end of the movable pinion;

wherein the distal end (21) of the inner tubular member abuts an internal surface (19) of the outer tubular member proximal the distal end thereof, the outer tubular member and inner tubular member comprising two openings (14, 16) at the distal ends thereof that are configured to be aligned to form a passage allowing a surgical cable to pass through and to exert a shearing force on the cable when the inner tubular member rotates with respect to the outer tubular member in response to compressing the first and second handle grips.

Claim 24 is therefore not new.

Document D3 also anticipates the subject-matter of claims 28, 29 and 33.

2. Inventive step (Article 33(3) PCT):

In claims 9-11, 14-17, 20-22, 25-27 and 30-32, slight constructional changes in the devices of claim 1, 13 and 24 are defined which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of claims 9-11, 14-17, 20-22, 25-27 and 30-32 lacks an inventive step in the sense of Article 33(3) PCT.

Re Item VII

Certain defects in the international application

1. The 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 (documents D1, D3) 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).
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in documents D1, D3 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

1. The application does not meet the requirements of Article 6 PCT, because claims 10, 11, 21, 22, 31 and 32 are not clear:
 - Claims 10, 21 and 31 recite that the handle unit or device "*allows for coincident radial alignment of the first coaxial member relative to the second coaxial member in multiple positions all leading to alignment of the at least two openings in the distal ends of the coaxial members*". This wording is unclear and is not supported by the description since it means that there is no position allowed by the handle unit or device in which the at least two openings are not aligned: At least during the cutting operation, the at least two openings of the devices shown in the description are not aligned.
 - Claims 11, 22 and 32 recite that "*the at least two openings are arranged in such a way that a change of alignment occurs coincidentally during each re-attachment of the intervention unit to the handle unit*". Said wording implies that the alignment of the at least two openings can not be the same as before after re-attachment of the intervention unit to the handle unit: there is no mention of any feature in the description or in the claims which can prevent re-attachment of the intervention unit to the handle unit with the same opening alignment as before.

2. The vague and imprecise statement "*As is readily apparent to those skilled in the art, variations and modifications can be effected while remaining within the spirit and scope of the invention. Further, various elements from the various embodiments may be combined to form other embodiments that are within the spirit and scope of the invention.*" in the description paragraph [0061] implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.