

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/B2018/057298

International filing date (day/month/year)
21.09.2018

Priority date (day/month/year)
27.09.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/115

Applicant
ETHICON LLC

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

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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>5-16</u>
	No: Claims	<u>1-4, 17-20</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-20</u>
Industrial applicability (IA)	Yes: Claims	<u>1-20</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

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

1 **Re Item V**

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

1.1 Reference is made to the following documents:

- D1 EP 2 086 423 A2 (ETHICON ENDO SURGERY INC [US]) 12 August 2009 (2009-08-12)
- D2 EP 3 108 823 A2 (ETHICON ENDO-SURGERY LLC [PR]) 28 December 2016 (2016-12-28)
- D3 EP 2 517 650 A2 (TYCO HEALTHCARE [US]) 31 October 2012 (2012-10-31)
- D4 EP 2 128 021 A1 (EUROCOPTER FRANCE [FR]) 2 December 2009 (2009-12-02)
- D5 DE 10 2007 051263 A1 (HARTING ELECTRONICS GMBH & CO [DE]) 30 April 2009 (2009-04-30)
- D6 WO 2015/077139 A1 (ETHICON ENDO SURGERY INC [US]) 28 May 2015 (2015-05-28)

1.2 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

1.3 D1 discloses (figs. 77-94):

An apparatus, comprising:

- (a) a body (1600, fig. 77);
- (b) an anvil (1700) defining an annular array of staple forming pockets;
- (c) a firing assembly (1664 + 1634, § 114) comprising:
 - (i) a staple driver (1614),
 - (ii) a deck member, and
 - (iii) an annular array of staples (1618), wherein the staple driver is operable to actuate between an unfired position and a fired position to drive the annular array of staples through the deck member and against the annular array of staple forming pockets; and
- (d) a closure assembly comprising (§ 116):
 - (i) a trocar (1644) configured to selectively couple with the anvil and actuate

the anvil relative to the body to capture tissue between the anvil and the deck member,

(ii) a knob (1740, see figs. 79 and 81) rotatably coupled with the body, where the knob is configured to rotate relative to the body to actuate the trocar relative to the body, and

(iii) a limiting adjustment feature associated with the knob (clutch 1830, fig. 81), wherein the limiting adjustment feature is configured to selectively rotate the knob to actuate the trocar and the anvil proximally until tissue captured between the anvil and the deck member is compressed under a predetermined maximum clamping force, wherein the limiting adjustment feature is configured to slip relative to the knob when tissue captured between then anvil and the deck member is compressed over the predetermined maximum clamping force (§ 122).

1.4 D2 discloses (2, 32A, 32B):

An apparatus (10), comprising:

(a) a body (100);

(b) an anvil (400) defining an annular array of staple forming pockets;

(c) a firing assembly (§ 60) comprising:

(i) a staple driver (350),

(ii) a deck member, and

(iii) an annular array of staples (90), wherein the staple driver is operable to actuate between an unfired position and a fired position to drive the annular array of staples through the deck member and against the annular array of staple forming pockets; and

(d) a closure assembly (§ 24-28) comprising:

(i) a trocar (330) configured to selectively couple with the anvil and actuate the anvil relative to the body to capture tissue between the anvil and the deck member,

(ii) a knob (proximal portion of nut 160 having the same diameter as 5550 in fig. 32A) rotatably coupled with the body, where the knob is configured to rotate relative to the body to actuate the trocar relative to the body (§ 92-96), and

(iii) a limiting adjustment feature associated with the knob (clutch 5560; § 95), wherein the limiting adjustment feature is configured to selectively rotate the knob to actuate the trocar and the anvil proximally until tissue captured between the anvil and the deck member is compressed under a predetermined maximum clamping force, wherein the limiting adjustment

feature is configured to slip relative to the knob when tissue captured between then anvil and the deck member is compressed over the predetermined maximum clamping force (§ 96).

- 1.5 Dependent claims 2-20 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 novelty and/or inventive step.
- 1.6 D1 discloses furthermore:
 - 1.6.1 Claim 2: torque limiting adjustment knob (1800).
 - 1.6.2 Claim 3: see fig. 81.
 - 1.6.3 Claim 4: proximal knob portion (1810) and distal narrowed body (1824).
 - 1.6.4 Claim 5: as the proximal end of knob (1740) in D1 is designed with a threaded portion (1748) to drive adjustment shaft (1650), D1 **teaches away** from housing the distal portion of torque limiting adjustment knob in the proximal opening of knob.
 - 1.6.5 Claims 6-12 are dependent on claim 5 and are therewith novel and inventive over D1.
 - 1.6.6 Claims 13-16: considered to be not inventive in light of the combination of D1 and D6 (figs. 11A and 11B).
 - 1.6.7 Claims 17-20: see item 1.3 and § 117-122 of D1.
- 1.7 D2 discloses furthermore:
 - 1.7.1 Claim 2: torque limiting adjustment knob (5550).
 - 1.7.2 Claim 3: see figs. 32.
 - 1.7.3 Claim 4: proximal grasping body (outer surface of knob); distal narrowed body (gear 5562).
 - 1.7.4 Claims 5-12: considered to be not inventive in light of the torque limiting mechanism disclosed by D4-D6. The person skilled in the art of torque sensitive apparatuses is well aware of how to redesign the mechanical structure of the device of the invention in order to implement on of the alternative torque limiting mechanism disclosed by D4-D6.

- 1.7.5 Claims 13-16: considered to be not inventive in light of the combination of D2 and D6 (figs. 11A and 11B).
- 1.7.6 Claim 17-20: see item 1.4 and § 95.

2 Re Item VII

Certain defects in the international application

- 2.1 Any independent claim should be drafted 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 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).
- 2.2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 2.3 An incorporation of documents by reference (see § 3, 47, 56, 60, 64, 67, 74, 163 and 164) is not possible in some of the designated states (see also PCT Guidelines II-4.27).
- 2.4 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D-1-D6 is not mentioned in the description, nor are these documents identified therein.

3 Re Item VIII

Certain observations on the international application

- 3.1 The application does not meet the requirements of Article 6 PCT, because claims 1, 17 and 20 are not clear.
- 3.2 Although claims 1, 17 and 20 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to 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.