PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

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.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB2018/054258	12.06.2018	28.06.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/072

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 notifed 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:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Kamp, Martin Telephone No. +49 89 2399-0

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB2018/054258

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 43*bis*.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 13*ter*.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 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.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 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4, 7, 11, 14, 18
	No:	Claims	1-3, 5, 6, 8-10, 12, 13, 15-17, 19, 20
Inventive step (IS)	Yes:	Claims	4, 11, 18
	No:	Claims	1-3, 5-10, 12-17, 19, 20
Industrial applicability (IA)	Yes:	Claims	1-20
	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 1 479 348 A1 (ETHICON ENDO SURGERY [US]) 24 November 2004 (2004-11-24)
D2	US 2015/374373 A1 (RECTOR JASON M [US] ET AL) 31 December 2015 (2015-12-31)
D3	EP 1 479 345 A1 (ETHICON ENDO SURGERY [US]) 24 November 2004 (2004-11-24)
D4	WO 2016/144602 A2 (ETHICON ENDO-SURGERY LLC [US]) 15 September 2016 (2016-09-15)
D5	EP 2 366 341 A2 (ETHICON ENDO SURGERY INC [US]) 21 September 2011 (2011-09-21)
D6	WO 2016/144689 A1 (ETHICON ENDO-SURGERY LLC [US]) 15 September 2016 (2016-09-15)

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. 24-29):

A surgical cartridge assembly, comprising:
a proximal end;
a distal end;
an elongate channel (16), comprising:
a base; and
at least one opening (274; § 90) within the base;
a slot (45, § 75) configured to receive a cutting member (fig. 10);
a cartridge body (224 + 37) configured to be removably received within the elongate channel (fig .11); and
at least one lockout tab (272) extending from the proximal end of the cartridge body, wherein the at least one lockout tab is configured to cover the at least one opening when the cartridge body is received within the elongate channel,

and wherein the at least one lockout tab disables a lockout mechanism to allow the cutting member to advance distally through the slot (see figs. 25-29; § 84-91).

1.4 D2 discloses (figs. 5, 53-56):

A surgical cartridge assembly, comprising:
a proximal end;
a distal end;
an elongate channel (52), comprising:
a base (50); and
at least one opening within the base (235 in fig. 56);
a slot (see fig. 6) configured to receive a cutting member (84/284);
a cartridge body (410, fig. 53) configured to be removably received within the elongate channel; and
at least one lockout tab (412, § 262) extending from the proximal end of the cartridge body, wherein the at least one lockout tab is configured to cover the at least one opening when the cartridge body is received within the elongate channel, and wherein the at least one lockout tab disables a lockout mechanism to allow the cutting member to advance distally through the slot.

1.5 Dependent claims 2, 3, 5-10, 12-17, 19 and 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 Claims 2, 9 and 16: ledge: distal portion of lockout trough 274 in fig. 29.

1.6.2 Claims 3, 10 and 17: tab 272 covers the ledge 274.

1.6.3 Claims 5 and 12: portion of the cutting member 276 is received within the ledge 274.

1.6.4 Claims 6, 7, 13, 14, 19 and 20: staple cartridge 37; RF staple cartridge is considered to be not inventive in light of the combination of D1 with D5 or D6.

1.7 D2 discloses furthermore:

1.7.1 Claim 2: distal edge of opening 235 in fig. 56.

1.7.2 Claim 3: tab 412 is covering the opening 235; § 262.

1.7.3 Claim 5: tab 289 is received within opening 235; see fig. 56 and § 262.

1.7.4 Claim 6: cartridge 410.

1.7.5 For claims 7-20 it is here referred to items 3.2, 1.4 and 1.7.1-1.7.4 of this written opinion. A symmetric design (two tabs, two openings etc.) is considered to be not inventive for the person skilled in the art.

1.8 **Positive suggestions**

1.9 The cited prior art is silent about the content of claim 4 (11 and 18) being a lockout pad on the lockout tab that is configured to be received within the at least one opening of the cartridge body. If the applicant decides to amend the claim set accordingly he is invited to provide a convincing problem solution approach.

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 § 26-37, 43, 44, 47, 50, 51, 53, 55, 58, 59, 60, 67 and 92) is not possible in some of the designated states (see also PCT Guidelines II-4.27).

2.4 The unit "inch" employed in § 69 is not recognised in international practice / generally used, contrary to the requirements of Rule 10.1(d) PCT.

2.5 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1-D4 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, 8 and 15 are not clear.

3.2 Although claims 1, 8 and 15 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.