

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/B2018/054402

International filing date (day/month/year)
14.06.2018

Priority date (day/month/year)
27.06.2017

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 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 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. II Priority

1. The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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>1-20</u> |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | <u>1-20</u> |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | <u>1-20</u> |
| | No: Claims | |
2. Citations and explanations
- see separate sheet**

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)
and / or
2. Non-written disclosures (Rules 43*bis*.1 and 70.9)
see form 210

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 (Rule 13 PCT)

1 Reference is made to the following **documents**; the numbering will be adhered to in the rest of the procedure.

- D1 EP 3 342 356 A1 (ETHICON LLC [PR]) **(2018-07-04)**
- D2 EP 2 090 235 A2 (2009-08-19)
- D3 EP 3 064 144 A2 (2016-09-07)
- D4 EP 1 908 414 A2 (2008-04-09)
- D5 SANDVIK: "WELDING HANDBOOK",
, 10 August 2018 (2018-08-10), pages 1-8, XP002783762,
Retrieved from the Internet:
URL:<https://www.materials.sandvik/en/products/welding-products/welding-handbook/welding-handbook-pdf/><https://www.materials.sandvik/en/products/welding-products/welding-handbook/welding-handbook-pdf/>
[retrieved on 2018-08-10]
- D6 EP 3 235 444 A2 (2017-10-25)

1.1 The following separate groups of inventions have been identified:

1. Claims 1,2,7-10: a surgical stapling anvil with non-welded portion width less than or equal to about 105% of the width of the slot receiving the **anvil camming portion**
2. Claims 3-10: a surgical stapling anvil with a distance to slot axis of non-welded portion less than distance of outer boundary of **inner-most row of staple-forming pockets**
3. Claims 11-16: anvil for use with a surgical instrument with a welded third plane **angled** relative to a datum plane.

- 1.2 The common general concept between claims 1, 3 and 11, which links these groups, is not novel over D1 and D2 (see items 2 and 4 below).
- 1.3 The aforementioned groups of invention are furthermore directed to solving different technical problems, namely:
1. group 1: to provide a more rigid anvil so that deflection of the anvil is minimized (see §253,§254) by setting the relative position of the weld with respect to the width of the slot receiving the anvil camming portion
 2. group 2: to provide an alternative solution to the problem of making a more rigid anvil by setting the relative position of the weld with respect to the innermost row of staple-forming pockets (§253,§254)
 3. group 3: to provide an alternative solution to the problem of making a more rigid anvil (see §245,§247) by having a weld on an angled surface.
- 1.4 Hence, these groups are not so linked as to form a single general concept according to R. 13 PCT.
- 1.5 Nevertheless, all groups have been searched since it did not require a substantive additional effort. In case of further prosecution of the application, the applicant is asked to state upon which group of inventions it should be based.

Re Item V

Novelty, inventive step or industrial applicability

2 Disclosure of D1 and D2 with respect to claims 1, 7 and 15

- 2.1 With respect to claim 1, document D1 discloses in Fig. 32 and 33 a surgical stapling anvil (anvil arrangement 1130"), comprising:
- * an anvil body (anvil body 1132"), comprising:
 - a tissue-facing surface (see the undersurface of the elongate anvil body 1132", see also §88);
 - a plurality of staple forming pockets (visible on Fig. 14: staple forming pockets 1143, 1144 and 1145) defined in said tissue-facing surface; and
 - a longitudinal slot (visible in cross section in Fig. 32 and 33; see also anvil

slot 1138 in Fig. 14, §67), comprising:

+ a first portion (thinnest part of the slot) comprising a first width, wherein said first portion is configured to receive a cutting edge of a firing member therethrough (§67); and

+ a second portion (widest part of the slot) comprising a second width greater than said first width, wherein said second portion is configured to receive an anvil-camming portion of the firing member therethrough (§67); and

* an anvil cap (anvil cap 1170") welded to said anvil body (§84-§86), wherein said anvil cap comprises:

- a welded portion; and
- a non-welded portion. ~~wherein said non-welded portion comprises a non-welded width, and wherein said non-welded width is less than or equal to about 105% of said second width~~

The subject-matter of claim 1 is thus novel over D1.

2.2 With respect to claim 1, document D2 discloses in Fig. 93 a surgical stapling anvil (anvil arrangement 1130"), comprising:

* an anvil body (208 or 204+208), comprising:

- a tissue-facing surface (see the undersurface comprising cavities 206);
- a plurality of staple forming pockets (cavities 206) defined in said tissue-facing surface; and

- a longitudinal slot (slot 214), comprising:

+ a first portion (thinnest part of the slot, within 204, see reference sign 214) comprising a first width, wherein said first portion is configured to receive a cutting edge of a firing member therethrough; and

+ a second portion (widest part of the slot, within 208) comprising a second width greater than said first width, wherein said second portion is configured to receive an anvil-camming portion of the firing member therethrough; and

* an anvil cap (second cover plate 7081) welded to said anvil body (§81), wherein said anvil cap comprises:

- a welded portion (at the contact surfaces between 208 and 7081); and
- a non-welded portion. ~~wherein said non-welded portion comprises a non-welded width, and wherein said non-welded width is less than or equal to about 105% of said second width.~~

Hence, the subject-matter of claim 1 is novel over D2.

- 2.3 With respect to claim 7, document D2 discloses in Fig. 93 a surgical stapling anvil, comprising:
- * an anvil body (208 or 204+208), comprising:
 - a longitudinal slot (slot 214) defining a slot axis, wherein said longitudinal slot comprises slot surfaces facing each other; and
 - a tissue-facing surface (see the undersurface comprising cavities 206), comprising:
 - + a first side and a second side defined by said longitudinal slot;
 - + a plurality of staple-forming pockets (cavities 206) arranged in a plurality of longitudinal rows of staple-forming pockets (see also Fig. 22), wherein said plurality of longitudinal rows of staple-forming pockets comprises an inner-most row of staple-forming pockets closest to said longitudinal slot, wherein said inner-most row of staple-forming pockets defines a row axis a first distance from said slot axis and a first outer boundary axis a second distance from said slot axis which is greater than said first distance (see Fig. 14); and
 - * an anvil cap (anvil cap 1170") welded to said anvil body (§84-§86), wherein said anvil cap comprises:
 - a welded portion; and
 - a non-welded portion comprising an outer-most non-welded region defining a second outer boundary axis positioned a third distance from said slot axis, ~~wherein said third distance is less than said second distance.~~

Hence, the subject-matter of claim 7 is novel over D2.

- 2.4 D2 does not disclose any weld at an angled surface.
Hence, the subject-matter of claim 15 is novel over D2.

Re Item VI

Certain documents cited

- 3 Document D1 has been published after the priority date of the present application. However, it claims a priority which is anterior to the priority date of the present application.
Therefore these documents may become relevant in some national proceedings.

4 **Novelty of independent claims 7 and 15 over D1**

4.1 **Claim 7:** Document D1 discloses in Fig. 32 and 33 (the references under parentheses referring to this document) a surgical stapling anvil (anvil arrangement 1130"), comprising:

* an anvil body (anvil body 1132"), comprising:

- a longitudinal slot (visible in cross section in Fig. 32 and 33; see also anvil slot 1138 in Fig. 14, §67) defining a slot axis, wherein said longitudinal slot comprises slot surfaces facing each other; and

- a tissue-facing surface (see the undersurface of the elongate anvil body 1132", see also §88), comprising:

+ a first side and a second side defined by said longitudinal slot;

+ a plurality of staple-forming pockets (visible on Fig. 14: staple forming pockets 1143, 1144 and 1145) arranged in a plurality of longitudinal rows of staple-forming pockets,

wherein said plurality of longitudinal rows of staple-forming pockets comprises an inner-most row of staple-forming pockets closest to said longitudinal slot, wherein said inner-most row of staple-forming pockets defines a row axis a first distance from said slot axis and a first outer boundary axis a second distance from said slot axis which is greater than said first distance (see Fig. 14); and

* an anvil cap (anvil cap 1170") welded to said anvil body (§84-§86), wherein said anvil cap comprises:

- a welded portion; and

- a non-welded portion comprising an outer-most non-welded region defining a second outer boundary axis positioned a third distance from said slot axis, wherein said third distance is less than said second distance (since claim 3 does not define the outer-most non-welded region any further, one can select the third distance as in the following drawing - in view of Fig. 14, the third

distance is thus less than the second distance; see also the objection for lack of clarity in item 5 below).

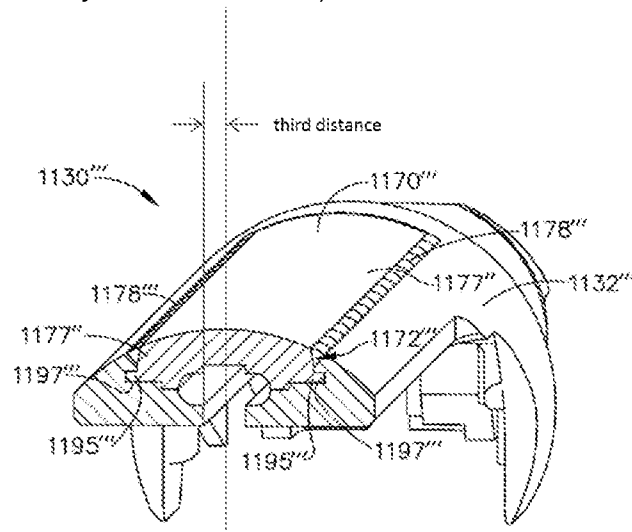


FIG. 33

- 4.2 **Claim 15:** D1, which discloses in Fig. 27 and 33 an anvil for use with a surgical instrument, wherein said anvil comprises:
- * a first anvil member (anvil body 1132''), comprising:
 - a tissue-facing surface defining a datum plane; and
 - a plurality of staple forming pockets defined in said tissue-facing surface; and
 - * a second anvil member (anvil cap 1170'') welded to said first anvil member by at least one weld (1178'', §84-§86),
- wherein said first anvil member and said second anvil member comprise:
- + a first mating region (see underside of tab 1195'') defining a first plane which is at least substantially parallel to said datum plane;
 - + a second mating region (outer-most surface of 1195'' which is perpendicular to the undersurface) defining a second plane which is at least substantially perpendicular to said datum plane; and
 - + a third mating region (perimeter 1172'' comprising the weld 1178'') defining a third plane which is angled relative to said datum plane (see Fig. 27 and 33), wherein said first anvil member and said second anvil member are welded by said at least one weld at said third mating region.

5 **Dependent claims 8-14, 18 and 19**

- 5.1 The features of these claims are disclosed in document D1, in particular the corresponding passages cited in the search report.
- 5.2 Regarding claims 6 and 14, the expression "Y-shaped cross section" has been interpreted in the light of the present application (see e.g. Fig. 79 of the application).

Re Item VII

Certain formal defects in the international application

- 6 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 6.1 To comply with the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 should be mentioned in the description.

Re Item VIII

Clarity of claim 1, 2, 5, 7 and 13 (Art. 6 PCT)

- 7 Claims 1 and 7: The "non-welded portion" should be more precisely defined. It is indeed not clear where this portion begins and stops. To this end, a reference to the weld itself should be added.
The same applies to the expression "outer-most non-welded region" in claim 7.
- 7.1 Claim 2: The wording "configured to" should be deleted since the claim relates to the anvil in an assembled state.
- 7.2 Claim 7: It is not defined of which element the first outer boundary axis.
- 7.3 Claims 5 and 13 are unclear since it cannot be derived where the third plane is. The wording of claim 15 appears to be more appropriate.