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/US2016/062003	15.11.2016	25.11.2015

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/32 A61B18/12 A61B90/00

Applicant
ETHICON ENDO-SURGERY, 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 P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	see form PCT/ISA/210	Ioanovici, T Telephone No. +31 70 340-0

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. 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. 14-20

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. 14-20

☐ 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 13*ter*.1(a) or (b).

☐ See Supplemental Box for further details

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. 1-13

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	5-13
	No:	Claims	1-4
Inventive step (IS)	Yes:	Claims	6-8, 10
	No:	Claims	1-5, 9, 11-13
Industrial applicability (IA)	Yes:	Claims	1-13
	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

1 **Re Item IV**

Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention and that there are 2 inventions covered by the claims indicated as follows:

Inventions or groups of inventions

The following separate inventions or groups of inventions are not so linked as to form a single general inventive concept.

Group I. claims: 1-13

Apparatus comprising a surgical generator capable of receiving usage data from an instrument memory and preventing operation based on the received data, and an adaptor with an override chip configured to modify the set of usage data before it is received by the generator.

Group II. claims: 14-18 and 19-20

Apparatus comprising a surgical generator with a display capable of receiving usage data from an instrument memory. The generator determines if the instrument will become inoperable after the present use and informs the user about the inoperability of the instrument once the instrument is no longer in use.

Independent claim 19 and its dependent claim 20 were grouped together with claims 14-18 because they also concern the determination of a future inoperability state and informing the user about this.

Single general inventive concept

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The single general inventive concept between independent claims 1 and 14 is a surgical generator capable of receiving usage data from an instrument memory. This subject matter is not new (D1=US2011/0087212A1, paragraph [0108]), and therefore cannot form a special technical feature.

The requisite of unity is not fulfilled as a technical relationship between the subject-matter of the upper claims does not exist.

Possible "Special technical features"

Group I. The possible "special technical features" are the features of claim 6, since the features of the previous claims are at least implicitly disclosed in D1, meaning the override chip that stores a set of override data which is modified in response to the set of data usage being modified.

Group II. The possible "special technical features" are the features of claim 14, meaning the surgical generator detecting if a device will become inoperable after the present use and notifying the user of the inoperability of the surgical instrument once the generator detected that the instrument is no longer in use.

Problems to be solved by the "Special technical features"

Considering that these features are different and that they solve different problems, there is a case of non-unity.

Group I. Problem: how to increase safety in the surgical procedure.

Group II. Problem: how to improve surgical instrument management.

The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

Re Item V

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

Reference is made to the following documents:

D1 US 2011/087212 A1 (ALDRIDGE JEFFREY L [US] ET AL) 14 April 2011 (2011-04-14)

D2 WO 2013/102058 A1 (ST JUDE MEDICAL ATRIAL FIBRILL [US]) 4 July 2013 (2013-07-04)

D3 US 6 338 657 B1 (HARPER RICHARD M [US] ET AL) 15 January 2002 (2002-01-15)

D4 EP 2 641 552 A2 (ETHICON ENDO SURGERY INC [US]) 25 September 2013 (2013-09-25)

D5 WO 98/06338 A2 (STRYKER CORP [US]; CULP JERRY A [US]; SCHEMANSKY KEVIN J [US]; MONK DA) 19 February 1998 (1998-02-19)

Novelty

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

D1 (abstract; paragraphs [0108], [0128], [0140], [0147] - [0151], [0176] - [0203], [0226] - [0228]; figures 1, 11-62) discloses:

An apparatus comprising:
(a) a surgical generator (abstract,102,1050) comprising an instrument receptacle (902,1058); and
(b) an adaptor (paragraphs [0147], [0226]-[0228]), the adaptor comprising a first end, a second end, and an override chip (the first data circuit 206 which can be in the adaptor may comprise an EEPROM memory device which is an erasable chip that can be re-written, paragraph [0147]), wherein the first end of the adaptor is shaped to fit the instrument receptacle, wherein the second end of the adapter is shaped to fit a surgical instrument connector (fig. 58-62); wherein the surgical generator (102,1050) is configured to, upon being connected to a surgical instrument via the adaptor (paragraphs [0147], [0226]-[0228]), receive a set of usage data from a memory of the surgical instrument (paragraphs [0108], [0149]-[0150]); wherein the surgical generator (102,1050) is further configured to prevent operation of the surgical instrument based upon the set of usage data (paragraphs [0140], [0148]); wherein the override chip (the first data circuit 206 which can be in the adaptor may comprise an EEPROM memory device which is an erasable chip that can be re-written, paragraph [0147]) is configured to modify the set of usage data before it is received by the surgical generator (paragraph [0150] - update number of operations).

Dependent claims 2 - 6, 9 and 11 - 13 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meet the requirements of the PCT in respect of novelty or inventive step. The technical features of these claims are either disclosed in D1 - D5 or are minor constructional detail changes. For example claim 5 in not inventive since the surgical instruments usage counters can either count up the performed uses or count down the remaining uses.

The combination of the features of dependent claim 6 is neither known from, nor rendered obvious by, the available prior art. None of the cited documents discloses an override chip storing a set of override data which is being modified in response to the set of usage data being modified.

Therefore dependent claim 6 seems to meet the requirements of the PCT with respect to novelty and inventive step.

Claims 7 - 8 are dependent on claim 6 whose subject-matter seems to be new and inventive, as discussed above, and as such said dependent claims also seems to meet the requirements of the PCT with respect to novelty and inventive step.

The combination of the features of dependent claim 10 is neither known from, nor rendered obvious by, the available prior art. None of the cited documents discloses an override chip configured to modify a set of usage data by adding a flag indicating that the memory has been previously modified, and the chip only modifying the memory when the override flag is not present.

Therefore also dependent claim 10 seems to meet the requirements of the PCT with respect to novelty and inventive step.

2 **Re Item VII**

Certain defects in the international application

The present application does not meet the requirements of Rule 6.3(b) PCT regarding the use of the two-part form in claims, of Rule 6.2(b) PCT regarding reference signs, nor those of Rule 5.1(a)(ii) PCT regarding mentioning relevant prior art in the description.