

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/US2018/043444

International filing date (day/month/year)
24.07.2018

Priority date (day/month/year)
02.08.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61M1/00

Applicant
KCI LICENSING, 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 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

Authorized Officer

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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. 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. 30-32

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. 30-32

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 13ter.1(a) or (b).

See Supplemental Box for further details

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>4-7, 10-13</u>
	No: Claims	<u>1-3, 8, 9, 14-29</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-29</u>
Industrial applicability (IA)	Yes: Claims	<u>1-29</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

Reference is made to the following documents:

- D1 US 2011/224630 A1 (SIMMONS TYLER [US] ET AL) 15 September 2011 (2011-09-15)
- D2 WO 2016/015001 A2 (KCI LICENSING INC [US]) 28 January 2016 (2016-01-28)
- D3 US 2014/316353 A1 (RIESINGER BIRGIT [DE]) 23 October 2014 (2014-10-23)

Re Item III.

- 1 Claims 30, 31 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT. The method disclosed therein has the explicit purpose of treating a wound site; hence it is considered a method for treatment of the human or animal body by therapy/surgery.
- 2 Claim 32 contains references to the description. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

Re Item V.

- 3 INDEPENDENT CLAIM 1
- 3.1 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.
- 3.2 Document D1 discloses (see paragraphs 0021, 0027, 0033, 0037, 0038, 0045; figures 1, 2) a dressing for treating a tissue site, the dressing comprising:
 - a first layer being made from a liquid-impermeable material (first liquid-impermeable layer 118) and being at least partially fenestrated (layer 118 is formed with fenestrations 122);
 - a second layer being made from a liquid-impermeable material (second liquid-impermeable layer 120) and being at least partially fenestrated (layer 120 is formed with fenestrations 124), the second layer coupled to the first layer to define a chamber between the first layer and the second layer (layers 118,

120 are coupled by bonds 162 which surround ends 164 of foam spacer 125, thereby forming a chamber where foam spacer 125 is comprised); and a third layer disposed within the chamber (foam spacer 125), the third layer comprising a manifold having a central region and a perimeter region (see paragraphs 0027, 0038: foam spacer 125 is made from the same material as manifold 126 and has a manifold function of communicating reduced pressure; see figure 2: foam spacer 125 comprises a center portion 166 and a perimeter region), the perimeter region containing perforations arranged in a pattern that defines a plurality of sub-regions of the perimeter region (see figure 2: several perforations are defined in foam spacer 125, defined between members 170 and 172 of foam spacer 125); wherein the first layer and the second layer are coupled together by a plurality of welds or bonds through the perimeter region of the third layer comprising the manifold (see figure 2: bonds 162 are located in the perforations defined between members 170 and 172 of foam spacer 125, and therefore they extend through the perimeter region of foam spacer 125 where the perforations are comprised).

3.3 The subject-matter of claim 1 is therefore not new.

4 DEPENDENT CLAIMS 2-29

4.1 Note: Although claim 16 has been drafted as a separate independent claim, it comprises all the features of claim 1 and is therefore *de facto* dependent thereupon.

4.2 Dependent claims 2-29 do not appear to contain any additional 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, for at least the following reasons:

Claim 2: see D1, paragraph 0038.

Claim 3: see D1, figure 2: bonds 162 are located in the perforations defined between members 170 and 172 of foam spacer 125, and therefore they extend through the perforations of the perimeter region of foam spacer 125.

Claim 4 relates to a feature well known in the art. See for example D2, paragraphs 0025, 0067; figures 1, 3; disclosing a dressing for use in an abdominal cavity (see paragraph 0025; figure 1), which comprises as well a manifold enclosed between fenestrated layers (see paragraphs 0061, 0063;

figures 4A-B), and which comprises visual indicia (276) in the form of cut lines to provide convenience in cutting, tearing, or otherwise sizing the dressing (see paragraph 0067; figure 3)

Claims 5-7 relate to constructional details which come within the scope of the skilled in the art.

Claim 8: see D1, figure 2, peripheral edge 167.

Claim 9: see D1, paragraphs 0027.

Claims 10, 11 relate to a feature which is well known in the art in order to avoid painful removal caused by growth of granulation tissue into a manifold. See for example D3, paragraphs 0046, 0164, 0174.

Claim 12, 13 relate to straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem of selecting the appropriate material and thickness of the layers.

Claims 14, 15: see D1, figure 1, manifold 126.

Claim 16: see D1, figure 2, peripheral edge 167.

Claim 17: see D1, figure 1, reduced pressure source 138.

Claim 18: see D1, figure 1, reduced-pressure connector subsystem 132.

Claim 19: see D1, paragraph 0032, reservoir 146.

Claims 20-27: see D1, paragraph 0027.

Claims 28, 29: see D1, paragraph 0030.

Re Item VII.

- 5 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1 is not mentioned in the description, nor is this document identified therein.
- 6 The features of claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).