

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: SPRUSON & FERGUSON  GPO BOX 3898 Sydney New South Wales 2001 Australia		Date of mailing (day/month/year) <b>13 October 2015 (13.10.2015)</b>
Applicant's or agent's file reference P142828C2		<b>FOR FURTHER ACTION</b> See paragraph 2 below
International application No. <b>PCT/AU2015/000425</b>	International filing date (day/month/year) <b>22 July 2015 (22.07.2015)</b>	Priority date(day/month/year) 22 July 2014 (22.07.2014)
International Patent Classification (IPC) or both national classification and IPC <b>A61B 19/04(2006.01)i</b>		
Applicant <b>ANSELL LIMITED</b>		

1. This opinion contains indications relating to the following items:

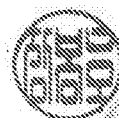
- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step 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 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/KR International Application Division Korean Intellectual Property Office 189 Cheongsu-ro, Seo-gu, Daejeon Metropolitan City, 35208, Republic of Korea Facsimile No. +82-42-472-7140	Date of completion of this opinion  13 October 2015 (13.10.2015)	Authorized officer  CHANG, Bong Ho  Telephone No. +82-42-481-3353
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
**PCT/AU2015/000425**

**Box No. 1 Basis of this 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*. I(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*. I(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*. I(a)).
    - on paper or in the form of an image file (Rule 13*ter*. I(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:

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International application No.  
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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. 5-15

because:

the said international application, or the said claims Nos. 15

relate to the following subject matter which does not require an international search (*specify*):

The subject-matter of claim 15 does not require an opinion, as it is directed to a method for treatment of the human body by surgery (PCT Rules 43 bis.1(b) and 67.1(iv)).

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 12, 14

are so unclear that no meaningful opinion could be formed (*specify*):

Claims 12 and 14 are unclear, because they refer to multiple dependent claims 11 and 13, respectively, which do not comply with PCT Rule 6.4(a).

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 said claims Nos. 5-15

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.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

**PCT/AU2015/000425**

**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)	Claims	<u>1-4</u>	YES
	Claims	<u>NONE</u>	NO
Inventive step (IS)	Claims	<u>1-4</u>	YES
	Claims	<u>NONE</u>	NO
Industrial applicability (IA)	Claims	<u>1-4</u>	YES
	Claims	<u>NONE</u>	NO

2. Citations and explanations :

Reference is made to the following documents:

- D1: US 5224221 A (RICHARDSON et al.) 6 July 1993
- D2: US 2011-0287553 A1 (HASSAN et al.) 24 November 2011
- D3: US 2012-0090074 A1 (VENABLES et al.) 19 April 2012
- D4: US 6175962 B1 (MICHELSON, GARY KARLIN) 23 January 2001
- D5: US 5527618 A (GRAIVER et al.) 18 June 1996
- D6: US 2014-0165263 A1 (ANSELL LIMITED) 19 June 2014

1. Novelty and Inventive Step

1.1 Claims 1-4

D1, which is considered to be the closest prior art to the subject matter of claim 1, discloses a tamper or damage indicating glove, comprising: an outer glove(3) which is transparent or translucent; an inner glove(1) which may be highly colored, wherein the outer glove(3) and the inner glove(1) are made of a thin flexible, elastic material such as rubber; and a space between the gloves(1, 3) which is substantially evacuated of air, so that adjacent surfaces of the gloves(1, 3) are pressed firmly together and the inner and outer gloves(1, 3) act as a single glove, wherein if a small puncture or leak is made in either of the gloves(1, 3) in the presence of aqueous liquids, such as blood or body fluids, a color change in the vicinity of the puncture becomes apparent, indicating the existence of the puncture or leak, and at the same time, the outer glove(3) becomes relatively more mobile over the inner glove(1) in the vicinity of the puncture, causing a detectable change of feel of the glove, and wherein visual indication of the leak may be further enhanced by inclusion, within the space between the inner and outer gloves(1, 3), of a chemical which changes color in the presence of oxygen, or an acceptable dye which is wet by any aqueous liquid which reaches the dye through the puncture or leak (see column 3, line 43-column 4, line 3; claims 1-10; figure 1).

Continued on Supplemental Box

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International application No.

**PCT/AU2015/000425**

**Box No. VII Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

Claims 5-11, 13 and 15 do not comply with PCT Rule 6.4(a) because multiple dependent claims should not serve as a basis for any other multiple dependent claim.

**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:

The following phrases are technically or grammatically unclear contrary to PCT Article 6, and the better replacements are suggested for clarity:

- 1) "an top elastomer layer" and "an bottom elastomer layer" in lines 3 and 5 of claim 1 should be respectively replaced with "a top elastomer layer" and "a bottom elastomer layer",
- 2) "(ii) an alkyl-aryl compound or a siloxane compound ~, (iii) a quaternary amine~" in lines 10-12 of claim 1 should be replaced with "(ii) an alkyl-aryl compound or a siloxane compound ~, or (iii) a quaternary amine~",
- 3) "the top elastomer or bottom layer" in lines 16-17 in claim 1 should be replaced with "the top elastomer or bottom elastomer layer",
- 4) "a pendent" in lines 2 and 3 of claim 3 should be replaced with "the pendent", and
- 5) "the top glove" of claim 4 has not been previously defined. And referring to the description, "the top glove" in claim 4 seems to be "the top elastomer layer" as defined in claim 1. Accordingly, the phrases "the top glove" in line 1 of claim 4 and "the top glove outer surface" in lines 3-4 of claim 4 should be respectively replaced with "the top elastomer layer" and "the outer surface of the top elastomer layer" which can also be named as "the outer-top surface".

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of : Box No. V

The subject matter of claim 1 differs from that of D1 in that to either an inner-top or outer-bottom surface has been applied a hydrophilicity promoting composition of (i) a polyvinyl alcohol or (ii) an alkyl-aryl compound or a siloxane compound having a pendent one to two oxy-polymers, or (iii) a quaternary amine including an alkyl of C8 to C24, or (iv) a mixture of the foregoing, wherein the oxy-polymer is (1) a poly-oxyalkylene polymer that is predominantly oxyethylene or (2) a polyvinyl alcohol, wherein the hydrophilicity promoting composition enhances the spreading in a space or seam of any of hydrophilic or aqueous fluid that breaches to a top elastomer or bottom elastomer layer. And this different feature is not disclosed in any of the other prior art documents D2-D6. Accordingly, claim 1 is not anticipated by any of the documents, nor is it obvious by the documents, taken alone or in combination. Therefore, claim 1 is novel and involves an inventive step under PCT Article 33(2) and (3).

Claims 2-4 are dependent on claim 1 and therefore meet the requirements of PCT Article 33(2) and (3).

2. Industrial Applicability

Claims 1-4 are industrially applicable under PCT Article 33(4).