# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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# 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/US2017/068213 | 22.12.2017 | 28.12.2016 |

International Patent Classification (IPC) or both national classification and IPC
INV. C12M1/12 C12Q1/04

Applicant
3M INNOVATIVE PROPERTIES COMPANY

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<br>P.B. 5818 Patentlaan 2<br>NL-2280 HV Rijswijk - Pays Bas<br>Tel. +31 70 340 - 2040<br>Fax: +31 70 340 - 3016 | see form PCT/ISA/210 | Adida, Anne<br><br>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. 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 | 1-17 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-17 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-17 |
| | No: | Claims | |

2. Citations and explanations

**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 US 5 409 838 A (WICKERT PETER D [US]) 25 April 1995

D2 US 5 232 838 A (NELSON ROBERT L [US] ET AL) 3 August 1993

D3 US 2013/084624 A1 (WAKU SHIN-ICHI [JP] ET AL) 4 April 2013

1.2 **Novelty and inventive step**

As far as clear and sufficiently supported (see point VIII below), the subject-matter of claims 1-17 is new in the sense of Article 33(2) PCT and involves an inventive step in the sense of Article 33(3) PCT.

1.2.1 **D1** (column 3, line 49 - column 4, line 62; figure 1; examples 1,9) is the closest prior art to the subject-matter of claim 1 and discloses a microbial detection device comprising:
a body member comprising a substrate ("substrate 12") having a first major surface and a second major surface;
a first adhesive composition ("adhesive 14") adhered to the first major surface of the substrate, the adhesive being in particular isooctyl acrylate/acrylamide in a weight ratio of 96/4,
a dry powder comprising a cold-water-soluble hydrogel-forming composition and a microbial growth nutrient composition ("dry powder 16") adhered to the adhesive; and
a cover sheet ("cover sheet 20") attached to the body member, wherein the cover sheet comprises a first major surface facing the body member.

1.2.2 As far as clear and sufficiently supported in the description (see point VIII below), the subject-matter of claim 1 differs from this known device in that the device comprises the following layers:
- a dry microbial growth nutrient composition disposed on the substrate;
- an adhesive composition being isooctyl acrylate/acrylamide in a weight ratio of 98/2 adhered to the first microbial growth nutrient composition;
- a cold-water-soluble hydrogel-forming composition adhered to the first adhesive composition.

1.2.3 The subject-matter of claim 1 is thus new (Article 33(2) PCT).

1.2.4 The technical effect resulting from this difference is an improved growth of certain organisms (see Table 3 of the application).
The problem to be solved by the present invention may therefore be regarded as: how to modify the device of D1 to improve the growth of certain organisms?

1.2.5 The solution proposed in claim 1, as far as clear and sufficiently supported by the description, is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
No document of the prior art discloses or suggests to cover the dry nutrient composition with an adhesive and then add a cold-water-soluble hydrogel-forming composition in order to improve microbial growth.
**D2** (column 3, line 1 - line 31; column 5, line 43 - column 6, line 21; figures 1, 3) discloses a microbial detection device having on the substrate a water-based adhesive composition comprising dry nutrients. A cold-water-soluble powder comprising a gelling agent is adhered to the adhesive layer. D2 does not suggest to have first a dry nutrient layer and then an adhesive layer.
**D3** (abstract; figure 1-7) discloses the use of an adhesive layer on the cover of a micro-organisms culture sheet in order to collect environmental microorganisms. The adhesive layer is covering the nutrient layer after a gelling solution was added to the dry nutrient layer (i.e. the nutrient is not dry and the adhesive layer does not comprise a gelling agent adhered to it).

1.2.6 Independent claims 10, 14, 15 and 16 refer to the device of claim 1 or comprise the same new and inventive general concept of having first a dry microbial growth nutrient composition, then an adhesive composition made of isooctyl acrylate/acrylic acid, 98/2 weight ratio and a cold-water-soluble first hydrogel-forming composition adhered to the adhesive composition.
Consequently, claims 10, 14, 15 and 16, as far as clear and sufficiently supported (see point VIII below), also meet the requirements of Articles 33(2) and (3) PCT.

1.2.7 Claims 2-9, 11-13, 17 are dependent on claim 1, 10 or 16 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

1.3 **Industrial applicability**
The subject-matter of claims 1-17 is industrially applicable, as required by Article 33(4) PCT.

2 **Re Item VIII**

**Certain observations on the international application**

2.1 Claims 1-17 are not supported by the description as required by Article 6 PCT, as their scope is broader than justified by the description and drawings.

2.1.1 The description of the application teaches that "It has been unexpectedly discovered that despite the lack of compatibility between the materials of the microbial growth nutrient composition (e.g. being water soluble) and the adhesive composition (e.g. being water insoluble), a sufficient amount of nutrients are able to traverse through the layer of adhesive composition to be available for microorganism consumption in the device" (page 7, lines 3-7; page 15, lines 7-11).
The three examples of the application are made with isooctyl acrylate/acrylic acid, 98/2 weight ratio as adhesive. No other adhesive has been tested.
*A priori*, what was "unexpectedly discovered" in the examples for an adhesive comprising isooctyl acrylate/acrylic acid, 98/2 weight ratio in the examples of the present application can not be extrapolated to all kinds of adhesive compositions.

2.1.2 The attention of the applicant is also drawn to D2. D2 teaches an adhesive layer comprising dry nutrients for growing microorganisms. D2 illustrates in Table I (columns 5-6) and Table II (columns 5-6) that using a conventional isooctyl acrylate/acrylic acid (95:5 ratio) adhesive did not allow the growth of *Staphylococcus* bacteria whereas an adhesive comprising isooctyl acrylate/ acrylamide (98:2 ratio) or isooctyl acrylate/N-vinylpyrrolidone (98:2 ratio) allows *Staphylococcus* bacteria growth. This confirms that observations made with one kind of adhesive are not *a priori* applicable to other adhesives. Consequently, there are serious reasons to believe that the skilled person could not perform the invention over the whole scope of the claims (any kind of adhesive). The claims are not fully supported by the description, contrary to the requirements of Article 6 PCT.
*This objection may be overcome by restricting the adhesive in all independent claims to the adhesive used in the examples.*

2.2 The application does not meet the requirements of Article 6 PCT because claims 1, 10, 14 and 16 are not clear:

2.2.1 The term "substantially" used in claims 1, 10 and 16 is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.
*This objection may be overcome by deleting the term "substantially" in the claims.*

2.2.2 Claim 14 mentions "the first layer" and "the second layer" but does not define these layers. The device of claims 1 to 9 to which claim 14 refers do not mention a "first layer" nor a "second layer". Consequently, claim 14 is not clear (Article 6 PCT).
*It appears from page 22, lines 27-31 that the first layer corresponds to the substrate of claim 1 and that the second layer corresponds to the cover sheet of claim 1.*
*To overcome this objection, claim 14 may be amended to refer to the substrate and cover sheet instead of the first and second layer.*

3 *It is noted that the suggestions are only for assisting the applicant in his decision on how to proceed. It in no way precludes consideration of alternative solutions submitted by the applicant. The responsibility for determining the text of the application and in particular for defining the subject-matter for which protection is sought remains with the applicant.*