

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: SULLIVAN, MICHAEL J. KIMBERLY-CLARK WORLDWIDE, INC. 2300 WINCHESTER ROAD NEENAH WI 54956 USA

Date of mailing (day/month/year)	29 May 2015 (29.05.2015)
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Applicant's or agent's file reference 64937264PC01	FOR FURTHER ACTION See paragraph 2 below
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International application No. PCT/US2014/058369	International filing date (day/month/year) 30 September 2014 (30.09.2014)	Priority date(day/month/year)
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International Patent Classification (IPC) or both national classification and IPC A61K 9/08(2006.01)i, A61K 9/06(2006.01)i, A61K 31/194(2006.01)i, A61K 31/185(2006.01)i
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Applicant KIMBERLY-CLARK WORLDWIDE, INC.
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1. This opinion contains indications relating to the following items:

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|-------------------------------------|--------------|---|
| ☒ | 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 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. +82-42-472-7140	Date of completion of this opinion 28 May 2015 (28.05.2015)	Authorized officer LEE, Jeong A Telephone No. +82-42-481-8740
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2014/058369

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:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2014/058369

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	7-20	YES
	Claims	1-6	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: US 2012-0058181 A1 (CURRIE, J. et al.) 08 March 2012

D2: CN 102871921 A (GOLD HONG YE PAPER CO., LTD.) 16 January 2013

1. Novelty and Inventive Step

1.1. Independent Claim 1

D1, which is considered to represent the most relevant state of the art, discloses a liquid prebiotic filling for soft gels comprising 36.47 w/w% of propylene glycol; 46.40 w/w% of polyethylene glycol 1450; 5.50 w/w% of polyethylene glycol 400 NF; 0.03 w/w% of lactic acid; and 2.00 w/w% of fructo-oligosaccharide powder (see paragraph [0064]).

As all of the features of claim 1 are disclosed in D1, this claim is anticipated by D1. Therefore, claim 1 lacks novelty under PCT Article 33(2).

1.2. Dependent Claims 2-6

The additional features of claims 2-6 dependent on claim 1 are identical to D1 considering the liquid prebiotic filling for soft gels comprising 36.47 w/w% of propylene glycol; 46.40 w/w% of polyethylene glycol 1450; 5.50 w/w% of polyethylene glycol 400 NF; 0.03 w/w% of lactic acid; and 2.00 w/w% of fructo-oligosaccharide powder, wherein the lactic acid may be added to adjust the pH to a pH>4.0 (see paragraphs [0029], [0064]). Therefore, claims 2-6 lack novelty under PCT Article 33(2).

1.3. Dependent Claim 7

The additional feature of claim 7 dependent on claim 1 differs from D1 in water. However, said feature is easily modified or optimized by a person skilled in the art from

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D1 and no unexpected effects or properties are indicated in the application. Therefore, claim 7 lacks an inventive step under PCT Article 33(3).

1.4. Independent Claims 8 and 13

D2, which is also considered to represent the most relevant state of the art, discloses a hand-washing composition comprising saccharide prebiotics such as galacto-oligosaccharide, lactulose or inulin; water; pH regulator such as citric acid; surfactants such as sodium lauryl sulfate; and skin conditioners such as mineral oil (see abstract; claims 1-2, 10-13; and tables 1-2). In addition, the hand-washing composition can be applied to other materials or evenly distributed in the materials such as insoles, dry paper towel, non-woven fabrics etc., so that the establishment of a protective layer, keeping long-term isolation avoids recontamination fungi microorganisms (see paragraph [0041]).

*The phrase "the ratio of alpha-hydroxy acid" of claim 8 is considered to be a typo for "the weight ratio of alpha-hydroxy acid".

Claim 8 differs from D2 in the weight percentage of a prebiotic agent; the weight ratio of alpha-hydroxy acid to prebiotic agent; and the pH of a formulation.

Claim 13 differs from D2 in the weight percentage of the prebiotic agent.

However, said features are easily modified or optimized by a person skilled in the art from D2 and no unexpected effects or properties are indicated in the application. Therefore, claims 8 and 13 lack an inventive step under PCT Article 33(3).

1.5. Dependent Claims 9-12, 14-20

The additional features of claims 9-10 dependent on claim 8 differ from D2 in that the formulation is a liquid or a gel. However, said features are easily modified or optimized by a person skilled in the art from D2 and no unexpected effects or properties are indicated in the application.

The additional feature of claim 11 dependent on claim 8 differs from D2 in that the formulation is liquid and further comprises a fatty acids, fatty alcohols, polyethylene glycol, glyceryl behenate, mineral oil, paraffines, hydrogenated vegetable oil, leucine, and

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polyethylene glycols (PEG). However, said features are easily modified or optimized by a person skilled in the art from D2 and no unexpected effects or properties are indicated in the application.

The additional feature of claim 12 dependent on claim 8 differs from D2 in i) the weight percentage of water and inulin; ii) the formulation comprising lactic acid; and iii) a pH of the liquid. However, said features are easily modified or optimized by a person skilled in the art from D2 and no unexpected effects or properties are indicated in the application.

※The phrase "of the composition" of claim 14 is considered to be a typo for "of the prebiotic composition".

The additional feature of claim 14 dependent on claim 13 differs from D2 in i) the weight ratio of alpha-hydroxy acid to prebiotic agent; and ii) the pH of the prebiotic composition. However, said features are easily modified or optimized by a person skilled in the art from D2 and no unexpected effects or properties are indicated in the application.

The additional features of claims 15-16 dependent on claim 13 correspond to D2 considering the saccharide prebiotics such as galacto-oligosaccharide, lactulose or inulin; and the pH regulator such as citric acid (see abstract; claims 1, 13; and tables 1-2).

The additional feature of claim 17 dependent on claim 13 differs from D2 in a digestible saccharide selected from the group consisting of lactose, glucose and galactose. However, said feature is easily modified or optimized by a person skilled in the art from D2 and no unexpected effects or properties are indicated in the application.

※The phrases "composition" and "the composition" of claim 18 are considered to be a typo for "the prebiotic composition".

The additional feature of claim 18 dependent on claim 13 differs from D2 in i) the weight percentage of the prebiotic agent and alpha-hydroxy acid and water; and ii) the pH of the prebiotic composition. However, said features are easily modified or optimized by a person skilled in the art from D2 and no unexpected effects or properties are indicated in the application.

The additional feature of claim 19 dependent on claim 13 differs from D2 in a kind of a

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nonwoven material. However, said feature is merely one of several straightforward possibilities from which the skilled person would select, if necessary, without the exercise of inventive skill, in order to solve the problem posed.

The additional feature of claim 20 dependent on claim 13 differs from D2 in that a wiping substrate is a tissue web having a basis weight greater than about 10 grams per square meter and a bulk greater than about 3 cubic centimeters per gram. However, said feature is merely one of several straightforward possibilities from which the skilled person would select, if necessary, without the exercise of inventive skill, in order to solve the problem posed.

Therefore, claims 9-12, 14-20 lack an inventive step under PCT Article 33(3).

2. Industrial Applicability

Claims 1-20 are industrially applicable under PCT Article 33(4).