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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Act. 444 RESPUESTAREQUE Folios: 7

Re: Expediente No. 13-124838

**Solicitud de Patente de Invención titulado: "INDICADOR VAGINAL PARA
DETECTAR BIOMARCADORES DE UNA BUENA SALUD"**

Solicitante: KIMBERLY-CLARK WORLDWIDE, INC.

Nuestra Ref.: P2013/000008

(MEMORIAL DE ALCANCE)

J. IAN RAISBECK, mayor de edad y vecino de Bogotá, identificado tal como aparece al pie de mi firma, en mi carácter de apoderado de la sociedad en referencia, me permito adjuntar al presente memorial una copia del Reporte Preliminar Internacional de Patentabilidad, expedido por la OMPI.

Atentamente,

J. IAN RAISBECK
CC. No. 79.376.996 de Bogotá
T.P. 135.799 CSJ

Anexo: Reporte Preliminar Internacional de Patentabilidad.

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JUN 10 2013

PATENT COOPERATION TREATY

PCT/IB2011/054598

From the INTERNATIONAL BUREAU

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DORITY AND MANNING PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)
(PCT Rule 44bis.1(c))

To:

BATAVIA, Neil, M.
Dority & Manning, P.A.
PO Box 1449
Greenville, SC 29602-1449
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

30 May 2013 (30.05.2013)

CCX-1688-PCT

Applicant's or agent's file reference
64675900PC02

IMPORTANT NOTICE

International application No.
PCT/IB2011/054598

International filing date (day/month/year)
17 October 2011 (17.10.2011)

Priority date (day/month/year)
22 November 2010 (22.11.2010)

Applicant

KIMBERLY-CLARK WORLDWIDE, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Cécile Chatel

Facsimile No. +41 22 338 82 70

e-mail: ro.ib@wipo.int

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

DORITY AND MANNING(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 64675900PC02	FOR FURTHER ACTION See item 4 below	
International application No. PCT/IB2011/054598	International filing date (<i>day/month/year</i>) 17 October 2011 (17.10.2011)	Priority date (<i>day/month/year</i>) 22 November 2010 (22.11.2010)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KIMBERLY-CLARK WORLDWIDE, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒ Box No. I

Basis of the report

☐ 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 Article 35(2) with regard to novelty, inventive step or 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

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Date of issuance of this report 22 May 2013 (22.05.2013)
	Authorized officer Cécile Chatel e-mail: ro.ib@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

BATAVIA, Neil, M.

DORTY & MANNING, P.A. P O BOX 1449 GREENVILLE
South Carolina 29602-1449 USA

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) 26 JUNE 2012 (26.06.2012)

Applicant's or agent's file reference
64675900PC02

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/IB2011/054598

International filing date (day/month/year)

17 OCTOBER 2011 (17.10.2011)

Priority date(day/month/year)

22 NOVEMBER 2010 (22.11.2010)

International Patent Classification (IPC) or both national classification and IPC

C12Q 1/32(2006.01)i, C12Q 1/28(2006.01)i, G01N 33/68(2006.01)i

Applicant

KIMBERLY-CLARK WORLDWIDE, INC. et al

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 or 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
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

26 JUNE 2012 (26.06.2012)

Authorized officer

Lee Hyojin

Telephone No. 82-42-481-8743



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IB2011/054598

Box No. I 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 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. a sequence listing filed or furnished

- ☐ on paper
- ☐ in electronic form

b. time of filing or furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

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 in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2011/054598

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	1-20	YES
	Claims	NONE	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: GARG, K.B. et. al., Metabolic properties of lactobacilli in women experiencing recurring episodes of bacterial vaginosis with vaginal pH5, Eur J Clin Microbiol Infect Dis, vol.29, pp.123-125 (January 2010)

D2: BOSKEY, E.R. et. al., Origins of vaginal acidity: high D/L lactate ratio is consistent with bacteria being the primary source, Human Reproduction, vol.16, no.9, pp.1809-1813 (September 2001)

D3: RABE, L.K. and HILLIER, S.L., Optimization of Media for Detection of Hydrogen Peroxide Production by Lactobacillus Species, Journal of Clinical Microbiology, vol.41, no.7, pp.3260-3264 (July 2003)

D4: SHOPOVA, E., Determination of hydrogen peroxide production by vaginal strains of Lactobacillus spp. isolated from healthy women, Akush Ginekol(Sofia), vol.40, no.3, pp.23-24 (2001)

D1 discloses that Lactobacillus strains from women suffering from bacterial vaginosis produce much less D-lactic acid than those from women with healthy vagina.

D2 discloses that vaginal acidity, which is important for the maintenance of vaginal health, is primarily produced by bacteria making D-lactic acid.

D3 is related to an optimization of media for detection of hydrogen peroxide production by *Lactobacillus* species. D3 describes that women who are colonized with H₂O₂-producing lactobacilli are more likely to maintain a normal vaginal flora than women with lactobacilli that do not produce H₂O₂ and discloses a method for detecting H₂O₂ in a vaginal sample using TMB-Plus medium comprising 3,3',5,5'-tetramethylbenzidine and radish peroxidase.

D4 discloses a method for determination of hydrogen peroxide production by vaginal strains of Lactobacillus spp. and suggests that hydrogen peroxide producing lactobacillus spp. may play the main role for the homeostasis of the vaginal ecosystem.

1. Novelty

1.1. Claim 1 is directed to a diagnostic kit for biomarkers of beneficial vaginal health comprising: a first detecting zone for a D-lactic acid detection signal and a second detection zone for a hydrogen peroxide detection signal.

(Continued on Supplemental Box)

6

Supplemental Box

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

(Box V)

None of D1 to D4 discloses a diagnostic kit comprising two detecting zones for both D-lactic acid and hydrogen peroxide. Accordingly, claim 1 is not anticipated by any of D1 to D4. Therefore, claim 1 complies with PCT Article 33(2).

1.2. Since claims 2-12 are dependent on claim 1, they are also considered to be novel under PCT Article 33(2).

1.3. The same arguments as under point 1.1. hold *mutatis mutandis* for the independent claim 13, which comprises all the technical features of claim 1, and which therefore also meets the requirement of the PCT Article 33(2) with respect to novelty.

1.4. Since claims 14-20 are dependent on claim 13, they satisfy the criteria of novelty set forth in PCT Article 33(2).

2. Inventive step

2.1. Claim 1 is different from D1 in that claim 1 further comprising a second detection zone within which a hydrogen peroxide detection signal is capable of being generated, wherein the presence or quantity of hydrogen peroxide, is determinable from the hydrogen peroxide detection signal.

However, D3 discloses that hydrogen peroxide production by *Lactobacillus* species can be used as an indicative for vaginal health. Therefore, it would be obvious to a person skilled in the art to apply this feature in D3 to D-lactic acid detection in D1, thereby arriving at the diagnostic kit for comprising two detecting zones for both D-lactic acid and hydrogen peroxide of claim 1. Therefore, claim 1 lacks an inventive step under PCT Article 33(3).

2.2. The same arguments as under point 2.1. hold *mutatis mutandis* for the independent claim 13, which comprises all the technical features of claim 1, and which therefore also does not meet the requirement of the PCT Article 33(3) with an inventive step.

2.3. All the additional features of claims 2-12 and 14-20, depending on claims 1 and 13 respectively, fall within the general knowledge in the art. Therefore, The subject-matter of claims 2-12 and 14-20 is considered to lack an inventive step under PCT Article 33(3).

3. Industrial Applicability

The subject matter of claims 1-20 is industrially applicable and meets the requirement of PCT Article 33(4).