PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

<table>
<thead>
<tr>
<th>FOR FURTHER ACTION</th>
<th>See item 4 below</th>
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<tbody>
<tr>
<td>Applicant’s or agent’s file reference</td>
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<tr>
<td>683537JGS</td>
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<tr>
<td>International application No.</td>
<td>International filling date (day/month/year)</td>
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<tr>
<td>PCT/NZ2014/000040</td>
<td>14 March 2014 (14.03.2014)</td>
</tr>
<tr>
<td>International Patent Classification (8th edition unless older edition indicated)</td>
<td>See relevant information in Form PCT/ISA/237</td>
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<tr>
<td>Applicant</td>
<td>FISHER &amp; PAYKEL HEALTHCARE LIMITED</td>
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</table>

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 10 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).

Date of issuance of this report:
15 September 2015 (15.09.2015)

Authorized officer
Athina Nickitas-Etienne
e-mail: pt04.pct@wipo.int

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
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Form PCT/IB/373 (January 2004)
PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:
A J PARK
PO Box 949
6140 Wellington
New Zealand

PCT
WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year)
25 June 2014

Applicant's or agent's file reference
683537JGS

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/NZ2014/000040
International filing date (day/month/year)
14 March 2014
Priority date (day/month/year)
15 March 2013

International Patent Classification (IPC) or both national classification and IPC
A61M16/0666 INVALID A61M 16/00 (2006.01) A61M16/0672 INVALID A61M2016/00 INVALID A61M 16/06 (2006.01)

Applicant
FISHER & PAYKEL HEALTHCARE LIMITED (et al).

1. This opinion contains indications relating to the following items:
   - [X] 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
   - [X] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Rule 43bis.1(a)(ii) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI Certain documents cited
   - [X] 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
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606,
AUSTRALIA
Email address: pct@ipaustralia.gov.au

Date of completion of this opinion
25 June 2014

Authorised Officer
Ariane Le Guen
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No. 0262832060

Form PCT/ISA/237 (Cover sheet) (July 2011)
1. With regard to the **language**, this opinion has been established on the basis of:

   - [X] 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 (under 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 filed or furnished:
   
   a. (means)
      
      - [ ] on paper
      - [ ] in electronic form

   b. (time)
      
      - [ ] in the international application as filed
      - [ ] together with the international application in electronic form
      - [ ] 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:
<table>
<thead>
<tr>
<th>Box No. IV</th>
<th>Lack of unity of invention</th>
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<tr>
<td>1. ☒</td>
<td>In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:</td>
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<tr>
<td></td>
<td>☐ paid additional fees</td>
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<td>☐ paid additional fees under protest and, where applicable, the protest fee</td>
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<td>☐ not paid additional fees</td>
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<tr>
<td>2. ☐</td>
<td>This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.</td>
</tr>
<tr>
<td>3. ☒</td>
<td>This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is</td>
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<tr>
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<td>☐ complied with</td>
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<td>☒ not complied with for the following reasons:</td>
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**See Supplemental Box for Details**

4. Consequently, this opinion has been established in respect of the following parts of the international application:
   - ☒ all parts
   - ☐ the parts relating to claims Nos.
WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

INTERNATIONAL APPLICATION NO.
PCT/NZ2014/000040

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 15, 28, 33-34, 39, 41-47
Claims 1-14, 16-27, 29-32, 35-38, 40
Inventive step (IS) Claims NONE
Claims 1-47
Industrial applicability (IA) Claims 1-47
Claims NONE

2. CITATIONS AND EXPLANATIONS:

CITATIONS
D5: WO 2011/110961 A1 (KONINKLIJKE PHILIPS ELECTRONICS N.V.) 15 September 2011

NOVELTY (N)
Claims 1-39:

Document D1: D1 discloses a nasal cannula for administering a breathable gas to a patient (or user) (abstract), the nasal cannula comprising: a first section formed from a first material (cannula body 60, page 25, lines 6-7; Fig. 6A); and a second section formed from a second material (frame 31, page 26 lines 3-8; Fig. 6A); wherein the first section is relatively softer than the second section (page 28 lines 24-26; Fig. 6A). Therefore, D1 discloses all of the features of claim 1.

Furthermore, the features added in dependent claims 3-10, 12-13, 16, 18-26, 29-32, 35 are also disclosed in D1 (where the second material that is different from the first material, page 26 lines 3-8, where the sections are assembled through the use of one or more mechanical fasteners, page 27 lines 9-18, wherein the first section provides for a user-friendly or comfort contacting component part of a nasal cannula, page 28 line 25-26, wherein the second section provides for a structural or support or shape-defining component part, of a nasal cannula, frame 31; Fig. 6A, wherein the first section is at least an arm or a pair of arms extending outwards from a central body portion that comprises at least one (or preferably a pair of) nasal prong(s), Fig. 6A, wherein the first section (60) is adapted to receive a manifold connection for delivery of a source of gases to the nasal cannula (45) or a body of the nasal cannula in fluid communication with a delivery system for delivery of gases to the user, Fig. 6B, wherein the first section comprises one or more surface relief portions, the surface relief portion(s) of the first section engageable with an associated one or more commensurately or complimentarily shaped or configured surface relief portions of the second section, frame 31 slots onto body 60, Fig. 6B, wherein the first section comprises a cannula body portion defining at least in part an open cavity receivable of a supply of gases directed thereto via a manifold, the open cavity in fluid communication with one or a pair of nasal prongs, Fig. 16, wherein the first section and second section are commensurately or complimentarily shaped or configured to communally receive a manifold connection for delivery of a source of gases to be delivered to a user, Fig. 7, wherein the first section is at least in part a nasal cannula body defining an open cavity, first section-cannula body 61 having nasal prongs 62 defining a cavity to 45 Fig. 6B, wherein the second section at least in part surrounds a nasal cannula body defining an open cavity, second section-frame 31 surrounds nasal cannula body (cannula body 61); Fig. 6A, 16, wherein the second section supports the first section in a predetermined configuration, Fig. 6B, wherein the second section extends: substantially to a longer length than the nasal cannula defined by a first section, frame 32 extends along further than cannula body 61; Fig. 6B, wherein a nasal cannula includes a pair of side arms extending outwardly from a cannula body defining at least in part an open cavity receivable of a source of gases, such as via a manifold connection, side arms 65; Fig. 6B, wherein located substantially toward each end of the side arms is a connection system for connecting a headgear, the headgear in-use, to be worn by a user, connecting head gear 50a/50b to side arms 54; fig. 6B, wherein the connection system is a part of the second section, 36; Fig. 6A, wherein a nasal cannula comprises a body defining an open cavity engageable by a manifold Fig. 7, a rear portion of said body being, in-use, substantially adjacent to a user's septum region marked by line C, the rear portion being substantially compliant or deformable in response to a pressure applied by a user to said rear portion, page 25 lines 6-7, wherein the rear portion is a substantially thinned wall section of the body, a thin wall can be
seen behind prongs 62; Fig. 16, wherein the rear portion is defined by a hollow section of the body, with the open cavity being a separate distinct region of the body. Fig. 16, wherein the body comprises a hollowed enclosure substantially adjacent to the user's septum region. Fig. 16).

Therefore, D1 discloses all of the features of claims 1, 3-10, 12-13, 16, 18-26, 29-32 & 35.

Document D2: D2 discloses a nasal cannula for administering a breathable gas to a patient (or user) (abstract), the nasal cannula comprising: a first section formed from a first material (para 47, items 21, 22, & 23); and a second section formed from a second material (para 47, item 24); wherein the first section is relatively softer than the second section (para 47). Therefore, D2 discloses all of the features of claim 1.

Furthermore, the features added in dependent claims 4-5, 9, 12-14, 16-22, 24-25, 29-32, 35 are also disclosed in D2 (where the sections are assembled through the use of one or more mechanical fasteners, Fig. 4 & 12, items 31 and 53, wherein the first section provides for a user-friendly or comfort contacting component part of a nasal cannula, face mount and prongs 21, 22 & 23, wherein the first section forms a patient contacting surface (21), and the second section forms a frame upon which the first section is attached (24), Fig. 2 & 3, wherein the first section is at least an arm or a pair of arms extending outwards from a central body portion that comprises at least one (or preferably a pair of) nasal prong(s), 31 Fig. 4, wherein the first section is adapted to receive a manifold connection for delivery of a source of gases to the nasal cannula or a body of the nasal cannula in fluid communication with a delivery system for delivery of gases to the user, Fig. 2, wherein the second section is adapted to receive a manifold connection for delivery of a source of gases to the nasal cannula or a body of the nasal cannula in fluid communication with a delivery system for delivery of gases to the user, such as via at least one nasal prong (or preferably a pair of nasal prongs) to, in-use, the nare or nares of the user, Fig. 2, wherein the first section comprises one or more surface relief portions, the surface relief portion(s) of the first section engageable with an associated one or more commensurately or complimentarily shaped or configured surface relief portions of the second section, Fig. 4 para 57, wherein the first section comprises at least one raised region receivable by an associated aperture or detent region of the second section, raised region 38 receives part 35, para 57, wherein the first section comprises a cannula body portion defining at least in part an open cavity receivable of a supply of gases directed thereto via a manifold, the open cavity in fluid communication with one or a pair of nasal prongs, Fig. 2, wherein the first section and second section are commensurately or complimentarily shaped or configured to communally receive a manifold connection for delivery of a source of gases to be delivered to a user, Fig. 2, wherein the second section at least in part surrounds a nasal cannula body defining an open cavity, Fig. 2, wherein a nasal cannula includes a pair of side arms extending outwardly from a cannula body defining at least in part an open cavity receivable of a source of gases, such as via a manifold connection, side arms 31 Fig. 4, wherein located substantially toward each end of the side arms is a connection system for connecting a headgear, the headgear in-use, to be worn by a user, Fig. 12, wherein a nasal cannula comprises a body defining an open cavity engageable by a manifold, a rear portion of said body being, in-use, substantially adjacent to a user's septum region marked by line C, the rear portion being substantially compliant or deformable in response to a pressure applied by a user to said rear portion, Fig. 2, wherein the rear portion is a substantially thinned wall section of the body, Fig. 2, wherein the rear portion is defined by a hollow section of the body, with the open cavity being a separate distinct region of the body, Fig. 3).

Therefore, D2 discloses all of the features of claims 1, 4-5, 9, 12-14, 16-22, 24-25, 29-32, 35.

Document D3: D3 discloses a nasal cannula for administering a breathable gas to a patient (or user) (abstract), the nasal cannula comprising: a first section formed from a first material (Flexible base 6; Fig. 4); and a second section formed from a second material (connectors 50; Fig. 4); wherein the first section is relatively softer than the second section (para 190). Therefore, D3 discloses all of the features of claim 1.

Furthermore, the features added in dependent claims 2-8, 11-13, 18, 20, 24-27, 29-32, 35-38 are also disclosed in D3 (where the second material that is the same as the first material and where the second material is different from the first material, para 190, where the sections are assembled through the use of one or more mechanical fasteners, connectors 50, wherein the first section provides for a user-friendly or comfort contacting component part of a nasal cannula, para 182, wherein the second section is at least in part over-moulded by the first section, Fig. 8b, wherein the first section is at least an arm or a pair of arms extending outwards from a central body portion that comprises at least one (or preferably a pair of) nasal prong(s), item 64 Fig. 8d, wherein the first section comprises a cannula body portion defining at least in part an open cavity receivable of a supply of gases directed thereto via a manifold, the open cavity in fluid communication with one or a pair of nasal prongs, Fig. 8a, wherein the first section is adapted to receive a manifold connection for delivery of a source of gases to the nasal cannula or a body of the nasal cannula in fluid communication with a delivery system for delivery of gases to the user, such as via at least one nasal prong (or preferably a pair of nasal prongs) to, in-use, the nare or nares of the user, 46 Fig. 8a, wherein the first section is at least in part a nasal cannula body defining an open cavity, Fig. 4, wherein a nasal cannula includes a pair of side arms extending outwardly from a cannula body
defining at least in part an open cavity receivable of a source of gases, such as via a manifold connection, Fig. 8b, wherein located substantially toward each end of the side arms is a connection system for connecting a headgear, the headgear in-use, to be worn by a user, Fig. 7a, wherein the connection system is a part of the second section, connectors 50, wherein the first section provides for a manifold receivable by at least a part of the first section, such as that defining an open cavity of a cannula body, Fig. 8b, wherein a nasal cannula comprises a body defining an open cavity engageable by a manifold, a rear portion of said body being, in-use, substantially adjacent to a user's septum region, the rear portion being substantially compliant or deformable in response to a pressure applied by a user to said rear portion, para 182 Fig. 8b, wherein the rear portion is a substantially thinned wall section of the body, 47 Fig. 8a, wherein the rear portion is defined by a hollow section of the body, with the open cavity being a separate distinct region of the body, Fig. 8b, wherein the body comprises a pillow section substantially adjacent to the user's septum region, nasal pillows 4, wherein the pillow section is a hollow region, the hollow region bounded by walls of the body, and separate to an open chamber, and having a relatively thin wall in the region substantially adjacent to, in use, the user's septum, Fig. 8b).

Therefore D3 discloses all of the features of claims 1-8, 11-13, 18, 20, 24-27, 29-32, 35-38.

Therefore, the subject matter of claims 1-14, 16-27, 29-32, 35-38 is not new and does not meet the requirements of Article 33(2) of the PCT with regard to novelty.

Claims 15, 28, 33-34 & 39 meet the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose a manifold being of a relatively rigid material, relative to the first material; wherein the second section provides for a structure to which a manifold connection may be made, and the first section provides for a scaling, such as a fluid-type seal, of a manifold in making such a manifold connection; wherein the rear portion of cannula body is substantially elasticised; or wherein the cannula body comprises a pillow section formed of a material capable of deforming under application of a pressure by a user during use.

Claims 40-47

D4 discloses a headgear (600) comprising: a strap (602), each end of the strap adapted to be attached to a patient interface (Fig. 41) and extend around a patient's head to hold the patient interface in place on a patient's face (Fig. 39), wherein at least a portion of the strap is configured to bifurcate into more than one band to extend around the patient's head (Fig. 41). Therefore, D4 discloses all of the features of claim 40.

In addition, claim 40 also lacks novelty in light of any of D5-D6. In particular see Fig. 8, 9 & 14 in D5 and Fig. 1 & 2 in D6.

Therefore, the subject matter of claim 40 is not new and does not meet the requirements of Article 33(2) of the PCT with regard to novelty.

Claims 41-47 meet the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose a strap comprising a longitudinal frangible section with a hole at the end defining the end of the frangible section and at least a portion of the strap being coated with a polymer, the coating providing the frangible section between the bands, the coating adapted to be torn to separate the bands.

INVENTIVE STEP (IS)

Claims 1-39:

Claims 1-14, 16-27, 29-32, 35-38 lack novelty and therefore also lack an inventive step.

The feature added in claims 15, 33-34 is not inventive in light of anyone of D1-D3 with common technical knowledge as it is considered to represent routine design variation that a person skilled in the art would understand that a variety of materials could be used.
The feature added in claim 39 is not inventive in light of D3 with common technical knowledge as it is considered to represent routine design variation that a person skilled in the art would understand that a variety of materials could be used.

The feature added by claim 28 is considered to lack an inventive step in light of any D1-D3 because using a fluid-type seal for a manifold connection is well known in the art.

Therefore, the subject matter of claims 1-39 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

Claims 40-47:

Claim 40 lacks novelty and therefore also lacks an inventive step.

The features added in claims 41-47 are considered to represent technical equivalents, which do not contribute to a patentable invention. In particular, D4 discloses various head gear arrangements, notably Fig. 63a -65 & 67. The applicant advises the benefits of having these adjustable head straps is to increase patient comfort. As can be seen in the various figures and through pages 35-43, different variations of head straps are shown to allow different types of comfort for the user.

Therefore, the subject matter of claims 40-47 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

INDUSTRIAL APPLICABILITY (IA)

The invention defined in the claims 1-47 is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.
The following defects in the form or contents of the international application have been noted:

The figures do not comply with Rule 11.13 (k) because they are not numbered consecutively in Arabic numerals.
Continuation of: Box IV

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-39 are directed to a nasal cannula for administering a breathable gas to a patient (or user). The feature of a first section formed from a first material; and a second section formed from a second material; wherein the first section is relatively softer than the second section is specific to this group of claims.

- Claims 40-47 are directed to a headgear. The feature of at least a portion of the strap is configured to bifurcate into more than one band to extend around the patient's head is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied a priori.