PATENT COOPERATION TREATY

PCT

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

(PCT Article 36 and Rule 70)

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<th>Applicant's or agent's file reference</th>
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International Patent Classification (IPC) or national classification and IPC
INV. A61M3/02

Applicant
Coloplast AS

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. (sent to the applicant and to the International Bureau) a total of 6 sheets, as follows:
      ☑ sheets of the description, claims and/or drawings which have been amended and/or sheets containing
        rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any
        accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative
        Instructions).
      ☐ sheets containing rectifications, where the decision was made by this Authority not to take them into account
        because they were not authorized by or notified to this Authority at the time when this Authority began to
draw up this report, and any accompanying letters (Rules 66.4bis, 70.2(e), 70.16 and 91.2).
      ☐ superseding sheets and any accompanying letters, where this Authority either considers that the
        superseding sheets contain an amendment that goes beyond the disclosure in the international application
        as filed, or the superseding sheets were not accompanied by a letter indicating the basis for the
        amendments in the application as filed, as indicated in Item 4 of Box No. 1 and the Supplemental Box (see
        Rule 70.16(b)).
   b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)), containing a
      sequence listing, in the form of an Annex CST.25 text file, as indicated in the Supplemental Box Relating to
      Sequence Listing (see paragraph 3ter of Annex C of the Administrative Instructions).

4. 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

Date of submission of the demand: 24.06.2016
Date of completion of this report: 13.09.2016

Name and mailing address of the international preliminary examining authority:
European Patent Office P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel: +31 70 340 - 2040
Fax: +31 70 340 - 3016

Authorized officer
Kempeneers, Johanna
Telephone No. +31 70 340-4502
Box No. 1  Basis of the report

1. With regard to the **language**, this report is based on

- ☒ 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))
  - ☐ publication of the international application (under Rule 12.4(a))
  - ☐ international preliminary examination (under Rules 55.2(a) and 55.3(a) and (b))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as “originally filed” and are not annexed to this report)*:

**Description, Pages**

1-6  as originally filed

**Claims, Numbers**

1-4  as amended (together with any statement) under Art. 19 PCT

**Drawings, Sheets**

1-33  as originally filed

☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify)*:

4. ☐ This report has been established as if *(some of)* the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify)*:

5. ☐ This report has been established:

- ☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
- ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.4bis and 70.2(e)).
6. ☑ With regard to top-up searches (Rules 66.1ter and 70.2(f)):
   ☑ A top-up search was carried out by this Authority on 23.08.2016 (all discovered documents are listed in the Supplemental Box Relating to Top-up Search).
   ☐ Additional relevant documents have been discovered during the top-up search.
   ☐ No top-up search was carried out by this Authority because it would serve no useful purpose.

7. ☐ Supplementary international search report(s) from Authority(ies) has/have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked “superseded”.

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**Box No. V**
**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

   **Novelty (N)**
   - Yes: Claims 1-4
   - No: Claims

   **Inventive step (IS)**
   - Yes: Claims 2, 4
   - No: Claims 1, 3

   **Industrial applicability (IA)**
   - Yes: Claims 1-4
   - No: Claims

2. Citations and explanations (Rule 70.7):

   **see separate sheet**

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**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**
Re Item V

Reference is made to the following document:


1 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

1.1 D1 is regarded as being the prior art closest to the subject-matter of claim 1, and discloses (see figure 11a):

an irrigation system comprising a container (implicit, to store the medical fluid to be dispensed via tube 12 through openings 5a), tubes (2, 12, 13, 14, 15, 18, 22), an anal probe (at end 10), an electrical pump, and (i) a control unit (54), one of the tubes being an external tube (2: see figure 1b) connecting the container with the control unit (54) (ii) and the anal probe (at end 10), the control unit (54) being connected to the external tube (2) through an extension cord (electric cable 53, to provide motor 51 with electricity for driving rotor 52: see also figure 11b) so that the control unit (54) extends transversely to the external tube (2), the extension cord (53) including only the electrical wiring, the extension cord (53) allowing for pivoting (iii) of the extension cord (53) with respect to the external tube (2).

i: It is true that it does not seem uniquely derivable from D1 that there is an electrical pump for pumping the inflating gas towards the balloons (3, 4, 20) or for pumping medical fluid towards openings (5a). Some of the specific embodiments provide syringes for the flow of gas or medical fluid: see air syringe (34) in the embodiment of figure 3 and irrigation syringe (36) in the embodiments of figures 4 and 8. There seems to be no disclosure of an electrical pump.
ii: In the irrigation system of present application, an extension cord (9) connects control unit (2) to external tube (4) somewhere in between a first end of the external tube (4) connected to the container (1) and a second end of the external tube (4) connected to the probe (3). Control unit (2) is thus connected to the container (1) via the extension cord and the external tube (4). The external tube (4) therefore only forms a part of the connection between the container (1) and the control unit (2) (the rest of the connection being formed by the extension cord 9). The expression in claim 1 regarding the external tube connecting the container with the control unit, is therefore to be interpreted in the sense that the external tube forms part of the connection between the container and the control unit. Similarly, in the irrigation system of present application, external tube (2) forms (at least) part of the connection between the container and the control unit (the rest of the connection being formed by the extension cord 53, and possibly also any other tube connecting external tube (2) with the container for supply of medical fluid).

iii: In the irrigation system of present application, it is the flexible nature of the extension cord (9) that allows it to be "pivoted" with respect to the external tube (2). The term "pivoting" should therefore be interpreted in that sense, and not as for instance implying the existence of a dedicated hinge or pivot element connecting a rather rigid extension cord. Similarly, in the irrigation system of present application, extension cord (53) is flexible, allowing "pivoting" of the extension cord with respect to the external tube (2).

1.2 The subject-matter of claim 1 therefore differs from this known irrigation system in that it comprises

an electrical pump.

1.3 It is not specified in claim 1 what the purpose of the "electrical pump" is. Starting from document D1, one could imagine an electrical pump for pumping the medical fluid via tube (12) through openings (5a), or an electrical pump for inflating balloons (3, 4, 20) via tubes (14, 15, 18 and 22).

The problem to be solved by the present invention may therefore be regarded as

providing means to pump medical fluid

or as
providing means to pump balloon inflating fluid.

1.4 It is however common practice for the person skilled in the art to provide an electrical pump for pumping the inflating gas towards balloons at an anal probe of an irrigation system or for pumping medical fluid towards such an anal probe. The subject-matter of independent claim 1 therefore does not involve an inventive step in the sense of Article 33(3) PCT.

1.5 It is noted that none of the available prior art documents reveals an irrigation system such as defined in present claim 1, wherein the control unit is a control unit for controlling an electrical pump for pumping irrigation fluid towards the anal probe. Independent claim 1 however does not specify that the control unit is a control unit for controlling the electrical pump.

2 DEPENDENT CLAIMS 2-4

2.1 Dependent claim 3 does not meet the requirements of the PCT in respect of inventive step. It is common practice to foresee a container for medical fluid with a lid and that the cavity of such a medical fluid container is sufficiently large to be able to house a control unit (54).

2.2 The combinations of the features of dependent claims 2 and 4 are neither known from, nor rendered obvious by, the available prior art.

Re Item VIII

The application does not meet the requirements of Article 6 PCT, because the scope of claim 1 is broader than justified by the description and drawings. Indeed, independent claim 1 is formulated such that its scope also covers irrigations systems in which the extension cord connects the external tube to a control unit that for instance controls an electrical stirrer at the anal probe (such as the one disclosed in D1), or that controls a pump for pumping inflating fluid towards balloons at the anal probe. Such irrigation systems have not been disclosed in the description and drawings.
Moreover, according to page 1, lines 5-7, the invention is explicitly directed to an anal irrigation system in which the control unit is specifically a control unit for controlling an electrical pump, which, in view of the rest of the disclosure of present application, is an electrical pump for pumping liquid to the probe.
European Patent Office
D-80298 München
Germany

Your ref: PCT/DK2015/050285
Our ref.: 2014096-WO

Demand in respect of international application no. PCT/DK2015/050285

Dear Sirs,

We enclose a Demand to the effect that the above-mentioned application becomes subject to an international preliminary examination.

In response to the Written Opinion and International Search Report mailed on 16 November 2015, we have the following comments.

Amendments

Claim 4 has been amended so that it is dependent on claim 3.

Novelty, Art 33(2) PCT

The following document is cited in the ISR and WO:

D1: WO2009/153973

Claim 1 is novel over D1 at least because D1 does not disclose a container, an electrical pump, a control unit and an extension cord. The Examiner notes in the ISR and WO that a container is implicitly disclosed. We fail to see that. Other solutions, e.g. syringes, may be applied to the system in D1. Furthermore, the Examiner seems to find an electrical pump implicitly disclosed. Irrigation systems
have been known to have manually operated pumps – therefore, we fail to see that D1 implicitly discloses an electrical pump.

Furthermore, we fail to see a control unit in D1. From the drawing in figure 11a, we cannot deduce what reference number 54 is. Thus, figure 11a does not directly and clearly disclose a control unit. Moreover, and also in relation to what can be deducted from figure 11a and figure 11b, we do not know what reference numbers 53 or 52 are. Therefore, we cannot establish directly and clearly that these figures disclose an extension cord and an electrical pump – it is simply not derivable from these figures.

Finally, the claim specifies that the extension cord connects the control unit with an external tube. Figure 11a does not disclose any external tube, nor any extension cord connecting a control unit with an external tube.

Based on all of the above, claim 1 is novel over D1.

**Inventive Step, Art 33(3) PCT**

In the ISR and WO, lack of inventive step were only raised against dependent claim 3. Assuming that claim 1 is inventive, claim 3 is also inventive based on claim dependencies.

**Clarity, Art 6 PCT**

The amendment to claim 4 mentioned above should overcome the clarity objection raised in the ISR and WO.
Closing comments
Should the Examiner consider issuing a negative IPER, we respectfully request a telephone interview or a second written opinion prior to issuing the IPER.

Yours sincerely,
Lotte Vinggaard Andreasen
Senior Patent Counsel

Encl.:
Amended claims, marked and clean version
An anal irrigation system, WO2016/041564  2014096-WO amended claims Chapter II.docx
Coloplast A/S
24 June 2016

CLAIMS

1. An irrigation system comprising a container, tubes, an anal probe, an electrical pump and a control unit, one of the tubes being an external tube connecting the container with the control unit and the anal probe, the control unit being connected to the external tube through an extension cord so that the control unit extends transversely to the external tube, the extension cord including only the electrical wiring, the extension cord allowing for pivoting of the extension cord with respect to the external tube.

2. The irrigation system of claim 1, wherein the tube extending from the control unit to the container has three lumens, two for liquid and one for an electrical wire, and wherein the tube extending from the control unit to the catheter has two liquid lumens.

3. The irrigation system of any of the preceding claims, wherein the container further has a lid with a cavity with room for the control unit.

4. The irrigation system according to claim 3, wherein the cavity has a rim that cooperates with a cam on the extension cord.
International application no. PCT/DK2015/050285

Dear Sirs,

In response to the phone conversation between the Examiner and the undersigned, we hereby provide further arguments in favour of the patentability of the claims on file over D1 (WO2009153973)

We respectfully disagree with the Examiner in that all features of claim 1 is disclosed in D1, in particular in the embodiment disclosed in figure 11 and mentioned as Example 3.

In this particular embodiment there is no disclosure of a container. In a machine translation of the document, Example 3 includes a reference that other features may be as disclosed in Example 1. However, Example 1 does not mention a container either.

Furthermore, in the embodiment referred to by the Examiner, the cord 53 is specifically mentioned as extending from a proximal end of the catheter. Therefore, we fail to see that this cord should be able to fulfil the limitation of the claim with respect to the extension cord, because of two reasons:

i. The cord 53 does not connect the control unit to the external tube - but rather directly to the catheter
ii. The cord is not pivotable with respect to the external tube.

For the reasons mentioned above, we fail to see that D1 discloses all of the features of claim 1 – and in particular, we fail to see that the embodiment of figure 11
discloses all of the features of claim 1.

Yours sincerely,

Lotte V. Andreasen