PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA220

International application No.
PCT/DK2015/050285

International filing date (day/month/year)
21.09.2015

Priority date (day/month/year)
19.09.2014

International Patent Classification (IPC) or both national classification and IPC
INV. A61M3/02

Applicant
COLOPLAST A/S

<table>
<thead>
<tr>
<th>1. This opinion contains indications relating to the following items:</th>
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<tr>
<td>☑ Box No. I Basis of the opinion</td>
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<tr>
<td>☑ Box No. II Priority</td>
</tr>
<tr>
<td>☑ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td>
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<td>☑ Box No. IV Lack of unity of invention</td>
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<tr>
<td>☑ 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</td>
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<tr>
<td>☑ Box No. VI Certain documents cited</td>
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<td>☑ Box No. VII Certain defects in the international application</td>
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<td>☑ Box No. VIII Certain observations on the international application</td>
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<th>2. FURTHER ACTION</th>
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<tr>
<td>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 (&quot;IPEA&quot;) 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.</td>
</tr>
<tr>
<td>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/ISA220 or before the expiration of 22 months from the priority date, whichever expires later.</td>
</tr>
<tr>
<td>For further options, see Form PCT/ISA220.</td>
</tr>
</tbody>
</table>

Name and mailing address of the ISA:
European Patent Office
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Date of completion of this opinion
see form PCT/ISA210

Authorized Officer
Kempeneers, Johanna

Telephone No. +31 70 340-0

Form PCT/ISA237 (Cover Sheet) (January 2015)
Box No. 1  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 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:
   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 13ter.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 13ter.1(a)).
      ☐ on paper or in the form of an image file (Rule 13ter.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 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. **Statement**

<table>
<thead>
<tr>
<th></th>
<th>Yes: Claims</th>
<th>No: Claims</th>
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<tbody>
<tr>
<td>Novelty (N)</td>
<td>2-4</td>
<td>1</td>
</tr>
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<td>Inventive step (IS)</td>
<td>2, 4</td>
<td>1, 3</td>
</tr>
<tr>
<td>Industrial applicability (IA)</td>
<td>1-4</td>
<td></td>
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</tbody>
</table>

2. **Citations and explanations**

   *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(2) PCT, because the subject-matter of claim 1 is not new.

D1 discloses (see figure 11a):

an irrigation system comprising a container (implicit, to store the medical fluid to be dispensed through openings 5a), tubes (2, 12, 13, 14, 15, 18, 22), an anal probe (at end 10), an electrical pump (implicit, to pump the medical fluid to the openings 5a) and a control unit (54), one of the tubes being an external tube (2: see figure 1b) connecting the container with the control unit (54) 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 of the extension cord (53) with respect to the external tube (2).

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.
*: Claim 4 is unclear (Art. 6 PCT), because it refers to technical features ("the cavity") defined in claim 3, although there is no reference to this claim. It is considered that claim 4 is dependent on claim 3.