

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

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

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2018/072849

International filing date (day/month/year)
24.08.2018

Priority date (day/month/year)
11.09.2017

International Patent Classification (IPC) or both national classification and IPC
INV. A61M39/28 F16K7/00

Applicant
FRESENIUS VIAL SAS

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 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 usually 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:



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Date of completion of this opinion

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Box No. I 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

Novelty (N)	Yes: Claims	
	No: Claims	<u>1-14</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-14</u>
Industrial applicability (IA)	Yes: Claims	<u>1-14</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

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 documents; the numbering will be adhered to in the rest of the procedure.

- D1 US 5 810 323 A (WINTERER SEAN [US] ET AL) 22 September 1998 (1998-09-22)
- D2 US 2 858 095 A (HARRIS EDWARD P ET AL) 28 October 1958 (1958-10-28)
- D3 WO 2010/101783 A2 (DEKA PRODUCTS LP [US]; KAMEN DEAN [US]; KENLEY RODNEY S [US]; VIOLETTE) 10 September 2010 (2010-09-10)
- D4 GB 2 448 374 A (HOWARD PETER LYNTON [GB]) 15 October 2008 (2008-10-15)
- D5 EP 1 466 646 A1 (NUTRICIA HEALTHCARE S A [CH]) 13 October 2004 (2004-10-13)

- 1 The severe clarity deficiencies detailed in Re Item VIII notwithstanding, the subject-matter of claim 1 is also not novel (Article 33(2) PCT).
- 1.1 Document D1 discloses a pinch clamp device for a flexible tube (86), comprising a first part (30) and a second part (16,12) that are movable with respect to each other, wherein the first part comprises a first conduit (obvious) for housing a flexible tube and the second part comprises a second conduit (16) for housing the same flexible tube, wherein the first part and the second part are arranged in an interacting manner such that the pinch clamp device can be present in a first position or in a second position, wherein a flow of a fluid within a flexible tube arranged inside the first conduit and the second conduit is enabled in the first position (fig. 3B), and wherein a flow of a fluid within a flexible tube arranged inside the first conduit and the second conduit is prevented in the second position (fig. 3A), and wherein the first part and the second part are designed axisymmetrically (obvious).
- 1.2 Document D2, fig. 1-5, shows a pinch clamp device for a flexible tube (38), comprising a first part (20) and a second part (32, 58 etc.) that are movable with respect to each other, wherein the first part comprises a first conduit (obvious) for housing a flexible tube and the second part comprises a second

conduit (32) for housing the same flexible tube, wherein the first part and the second part are arranged in an interacting manner such that the pinch clamp device can be present in a first position or in a second position, wherein a flow of a fluid within a flexible tube arranged inside the first conduit and the second conduit is enabled in the first position (fig. 2), and wherein a flow of a fluid within a flexible tube arranged inside the first conduit and the second conduit is prevented in the second position (fig. 1), and wherein the first part and the second part are designed axisymmetrically (obvious).

- 1.3 Also the documents D3, cf. fig. 4 and 5, and D4, cf. fig. 9 and 10, disclose a pinch clamp which anticipates the definition of claim 1 in an obvious manner.
- 2 The additional features of the dependent claims 2-6, 10, 12 are also already known from at least one of the documents D1 to D4, thus **not novel**.
I.e. the prior art pinch clamps have first and second parts with respective axis of symmetries along the first and second conduit (claim 2), the first and second parts are all separate parts (claim 5) which can be translationally moved with respect to each other, and wherein the second part is nested within the first part (claim 6), and both parts have a different outer design (claim 10). All these features are readily obvious from the figures of D1 to D4.

The features of claim 11-14 are trivial design features, i.e. it is logical that these automatic pinch clamps are to be installed in an infusion pump (claim 12), and that a cover of the pump is normally used to actuate the pinch clamp such that free flow of the liquid is avoided in any case if the door of the peristaltic pump is opened (claim 13). Therefore, the subject-matter of these claims is **not inventive** (Article 33(3) PCT).

- 3 In general, it appears that the concept of a telescopic pinch clamp comprising two axisymmetric parts, wherein a first part is translationally received inside a second part has been extensively described in the prior art, cf. D1 to D4. Therefore, it seems that the present application is reflecting mere prior art rather than presenting the solution of an objective technical problem over the prior art in a non-obvious way.

Re Item VII

- 4 The independent claim should have been cast in the **two-part form** (Rule 6.3(b) PCT) with the **preamble** containing those features known in combination from the document the applicant considers as the closest prior art (**D1 to D4**) (Rule 6.3(b)(i) PCT).
- 5 The features of **all the claims** should have been provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).
- 6 Documents D1 to D4 should have been briefly discussed in the description (Rule 5.1(a)(ii) PCT).

Re Item VIII

- 7 The subject-matter of claim 1 does not comply with Article 6 PCT.
- 7.1 The formulation of claim 1 is broad and unclear and does not enable the skilled person to understand the working principle of the "invention". I.e. from the definition of claim 1 the skilled person cannot understand in which way the pinch clamp defined is supposed to function. Clarity in the sense of Article 6 PCT means that any independent claim has to be clear in itself and in a way as to enable the skilled man to understand it without having to consult the description.
- 7.2 Claim 1 seeks to define the "invention" by mere results to be achieved ("arranged in an interacting manner such that the pinch clamp device can be present in a first position or in a second position ... is enabled in the first position, ... is prevented in the second position ...") without defining, however, the technical features necessary for achieving said result, cf. PCT Guidelines 5.35. This is not allowable.
- 7.3 Moreover, the description and the figures disclose a single embodiment of a very particular pinch clamp having very specific interacting technical features. These features appear to be defined in present dependent claims 2, 4 and 6-8, and it is obvious from the entire application that **at least** the combination of these features is essential for the functioning of the pinch clamp as disclosed (cf. PCT Guidelines 5.33). Therefore, these features should have been defined in the independent claim.
- 7.4 Moreover, the applicant is also not entitled to the present broad definition of claim 1 in the light of the possible contribution to the prior art cited in the search report. I.e. the scope of protection sought is not commensurate with the applicant's possible contribution over the prior art.