

PATENT COOPERATION TREATY

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PCT

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

To:

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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/EP2016/069349

International filing date (day/month/year)
15.08.2016

Priority date (day/month/year)
25.08.2015

International Patent Classification (IPC) or both national classification and IPC
INV. B01L3/00

Applicant
ETH ZÜRICH

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

see form
PCT/ISA/210

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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	<u>3, 4, 6, 7, 9-11, 14, 15, 17</u>
	No: Claims	<u>1, 2, 5, 8, 12, 13, 16</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-17</u>
Industrial applicability (IA)	Yes: Claims	<u>1-17</u>
	No: Claims	

2. Citations and explanations

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

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 WO 2014/053237 A1 (ETH ZUERICH [CH]) 10 April 2014 (2014-04-10)

D2 US 2014/220606 A1 (PUNTAMBEKAR ANIRUDDHA [US] ET AL) 7 August 2014 (2014-08-07)

2 **Novelty**

The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claims 1, 2, 5, 13 and 16 is not new.

2.1 Document D1 discloses a device for analysing liquid samples, wherein the device comprises at least one sample layer (see nitrocellulose layer) comprising a plurality of liquid permeable test sites separated from each other by a liquid impermeable barrier region (see page 2 - lines 46-51, 61-64, page 4 - lines 164-166, page 5 - lines 208-209, page 6 - lines 220-222 and figure 1), wherein said device comprises an inlet part (see top mechanical clamping layer), wherein said inlet part comprises a plurality of inlet channels, and wherein said inlet channels lead to respective test sites of said at least one sample layer, such that a flow connection between said inlet channels and said respective test sites is established or can be established (see page 2 - lines 46-51, 78-84, page 5 - lines 211-213, page 6 - lines 224-225 and figure 1), wherein said inlet channels comprise first openings, which are positioned in a first plane, wherein said first openings are accessible from the outside of said inlet part, such that liquid samples are loadable into said inlet channels by means of said first openings (218), and wherein said inlet channels comprise second openings, which are positioned in a second plane adjacent to said test sites, such that liquid samples can flow from said inlet channels to respective test sites via said second openings, wherein a first surface area is defined by the positions of the first openings in said first plane, and a second surface area is defined by the positions of said second openings in said second plane, wherein said second surface area is smaller than said first surface area (see page 5 - lines 212-213, page 6 - lines 226-227 and figure 1).

Therefore, the subject-matter of independent claim 1 is not novel.

2.2 The additional features of claim 2 are also anticipated by D1, since it discloses that the device comprises at least a top sample layer and a second sample layer, and wherein said top sample layer and said second sample layer are positioned such that the test sites of said top sample layer overlap with respective test sites of said second sample layer, such that a liquid permeable sample channel extending through said top sample layer and said second sample layer is formed by the test sites (see page 2 - lines 51-52, page 5 - lines 209-210, page 6 - lines 223-224 and figures 1, 8).

Thus, the subject-matter of dependent claim 2 is also not novel.

2.3 D1 teaches also that said inlet channels comprise a reservoir section (see tapered section) and a connecting section (see straight section), wherein said connecting section leads to a respective test site (see page 5 - lines 211-212, page 6 - lines 226-227 and figure 1).

The subject-matter of claim 5 can therefore also not be considered as novel.

2.4 Moreover, document D1 discloses a method for analysing liquid samples by means of the device previously described, comprising the steps of:

- loading a liquid sample into a respective inlet channel of said inlet part in a loading step (see page 2 - lines 85-86),
- passing said liquid sample through a respective test site and/or sample channel, which is connected to said respective inlet channel, in an assay step (see page 3 - lines 87-88),
- analysing substances bound to a sample layer of the device in an analysis step (see page 3 - lines 95-98).

The subject-matter of claim 13 is therefore not novel.

2.5 For the sake of completeness, it is pointed out that the subject-matter of claims 1, 5 and 13 is also not new over the disclosure of D2 (see paragraphs [0064], [0065], [0067], [0097], [0098], [0118], [0120] and figures 1, 2, 3, 13, 14, 15).

2.6 Document D2 also discloses a method for functionalising a sample layer, comprising the steps of:

- providing a sample layer, wherein said sample layer comprises a plurality of liquid permeable test sites (see microchannels + absorbents) separated by a liquid impermeable barrier region (see paragraphs [0118], [0164], [0165] and figures 1, 2, 3, 13, 14, 15),
- providing a reagent, which is able to bind to said test sites (see paragraphs [0144] [0188], [0223] and figures 1, 2, 3, 13, 14, 15),

- providing an inlet part comprising a plurality of inlet channels (see well structure + through hole), wherein said inlet channels comprise first openings, which are positioned in a first plane, wherein said first openings are accessible from the outside of said inlet part, such that liquid samples are loadable into the inlet channels by means of said first openings, and wherein said inlet channels comprise second openings, which are positioned in a second plane, wherein a first surface area is defined by the positions of said first openings in said first plane, and a second surface area is defined by the positions of said second openings in said second plane, wherein the second surface area is smaller than the first surface area (see paragraphs [0097], [0098] and figures 1, 2, 3, 13, 14, 15),
- assembling said inlet part and said sample layer, such that said test sites of said sample layer are aligned with respective second openings, such that liquid samples can flow from said inlet channels of said inlet part to said respective test sites via said second openings (see paragraphs [0144], [0185], [0222] and figures 1, 2, 3, 13, 14, 15),
- loading said reagent into at least one inlet channel (see paragraphs [0144], [0188], [0223] and figures 1, 2, 3, 13, 14, 15), and
- passing said reagent through said respective test site, which is in flow connection with said at least one inlet channel (see paragraphs [0064], [0065], [0118], [0120], [0144] and figures 1, 2, 3, 13, 14, 15).

Thus, the subject-matter of claim 16 is not novel.

3 Inventive step

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 17 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1 Document D1 discloses

- a sample layer (see nitrocellulose layer), wherein the sample layer comprises a plurality of liquid permeable test sites separated by a liquid impermeable barrier region (see page 2 - lines 46-51, 61-64, page 4 - lines 164-166, page 5 - lines 208-209, page 6 - lines 220-222 and figures 1,8),
- a reagent, which is able to bind to said test sites (see page 5 - line 192) and
- an inlet part (see top mechanical clamping layer) comprising a plurality of inlet channels, wherein said inlet channels lead to respective test sites of said sample layer, such that a flow connection between said inlet channels and said respective test sites is established or can be established (see page 2 - lines 46-51, 78-84, page 5 - lines 211-213, page 6 - lines 224-225 and figures

1,8), wherein said inlet channels comprise first openings, which are positioned in a first plane, wherein said first openings are accessible from the outside of said inlet part, such that liquid samples are loadable into the inlet channels by means of said first openings, and wherein said inlet channels comprise second openings, which are positioned in a second plane, such that liquid samples can flow from said inlet channels to respective test sites via said second openings, wherein a first surface area is defined by the positions of said first openings in said first plane, and a second surface area is defined by the positions of said second openings in said second plane, wherein said second surface area is smaller than said first surface area (see page 5 - lines 212-213, page 6 - lines 226-227 and figure 1).

The skilled person would regard it a normal procedure to combine all these features to make a kit. Thus, the subject-matter of claim 17 does not involve an inventive step (Article 33(3) PCT).

- 3.2 Dependent claims 3, 4, 6-12, 14 and 15 do not appear to contain any additional features which, in combination with the features of any claim to which it refers, meet the requirements of the PCT in respect of novelty and/or inventive step (see documents as cited in the European Search Report).

Re Item VIII

Certain observations on the international application

4 Clarity

The application does not meet the requirements of Article 6 PCT, because claims 1, 16 and 17 are not clear.

- 4.1 The term "a first/second area is defined by the positions of the first/second openings" used in claim 1 is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.

- 4.2 The same applies, mutatis mutandis, to claims 16 and 17.