

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

To:

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|--|--|--|--|
| Date of mailing (<i>day/month/year</i>) 31 May 2018 (31.05.2018) | | FOR FURTHER ACTION See paragraph 2 below | |
| Applicant's or agent's file reference 84634781 | | | |
| International application No. PCT/US 2017/048835 | International filing date (<i>day/month/year</i>) 28 August 2017 (28.08.2017) | Priority date (<i>day/month/year</i>) | |
| International Patent Classification (IPC) or both national classification and IPC C12M1/34 (2006.01) B81B1/00 (2006.01) B01L3/00 (2006.01) G01N33/50 (2006.01) | | | |
| Applicant HEWLETT-PACKARD DEVELOPMENT COMPANY, L. P. | | | |

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 43*bis*.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 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 66.1*bis*(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.

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|---|--|--|
| Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37 | Date of completion of this opinion 08 May 2018 (08.05.2018) | Authorized officer A.Kubasov Telephone No. (8-495) 531-65-15 |
|---|--|--|

Box No. I Basis of this 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 43*bis*.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. 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 13*ter*.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 13*ter*.1(a)).
 - on paper or in the form of an image file (Rule 13*ter*.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 in 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 and industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|--------------------|-----|
| Novelty (N) | Claims | 1-15 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | 2, 6, 9-11, 14-15 | YES |
| | Claims | 1, 3-5, 7-8, 12-13 | NO |
| Industrial applicability (IA) | Claims | 1-15 | YES |
| | Claims | | NO |

2. Citations and explanations:

D1: US 6653136 B1, 25.11.2003;
D2: US 9248230 B2, 02.02.2016;
D3: US 8728025 B2, 20.05.2014;
D4: US 9091656 B2, 28.07.2015.

From D1 (abstract, col. 2-3, 5-6, 8, claim 10, fig. 1-3) a fluid device is known, comprising: a substrate including a sense region; a microfluidic channel structure formed in the substrate and including a first channel; a sensor disposed in the sense region to lie above the microfluidic channel structure and adjacent to the first channel; and a deformable cover disposed on the substrate.

The invention of independent claim 1 differs from this known in D1 in that the deformable cover is made to seal the sensor from contact with a fluid in the microfluidic channel structure and ambient conditions, the fluid to be fluidly coupled to the sensor when the deformable cover is deformed.

Therefore, the invention of independent claim 1 and dependent claims 2-6 meets the criterion of novelty.

However, D2 (abstract, col. 9-10, fig. 1-2) discloses a sensor device for use in a medical fluid delivery system comprising the deformable cover to seal the sensor from contact with a fluid in the microfluidic channel structure and ambient conditions, wherein the fluid to be fluidly coupled to the sensor when the deformable cover is deformed.

Therefore, the invention of independent claim 1 does not meet the criterion of inventive step.

From D1 (abstract, col. 2-3, 5-8, claim 10, fig. 1-4) a fluid device is known, comprising: a substrate; a sensor coupled to the substrate; a reservoir formed in the substrate adjacent to the sensor; and a deformable cover disposed on the substrate.

The invention of independent claim 7 differs from this known in D1 in that the deformable cover is made to seal the sensor and the reservoir.

Therefore, the invention of independent claim 7 and dependent claims 8-13 meets the criterion of novelty.

However, D2 (abstract, col. 9-10, fig. 1-2) discloses a sensor device for use in a medical fluid delivery system comprising the deformable cover to seal the sensor and the reservoir.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of V:

Therefore, the invention of independent claim 7 does not meet the criterion of inventive step.

Features of dependent claims 3-4, 12, relating to a transparent region of the substrate and a sensor, are known from D3 (col. 15, 31, claim 15).

Features of dependent claims 5, 13, relating to a SERS substrate, are known from D4 (abstract).

Features of dependent claim 8, characterizing that the reservoir and the sensor are disposed in separate compartments formed by the deformable cover, are known from D2 (abstract, col. 9-10, fig. 1-2).

Therefore, the inventions of dependent claims 3-5, 8, 12-13 do not meet the criterion of inventive step.

Features of dependent claims 2, 6, 9-11 are not known from the prior art and are not obvious to a person skilled in the art for improving the accuracy and reliability of detection.

Therefore, the inventions of dependent claims 2, 6, 9-11 meet the criterion of inventive step.

From D1 (abstract, col. 2-3, 5-8, fig. 1-4) a device is known, comprising: a substrate; a fluid reservoir formed in the substrate; and a deformable cover disposed on the substrate.

The invention of independent claim 14 differs from this known in D1 in that the device also comprises a SERS substrate disposed at least partially in the transparent region; the substrate includes a transparent region; the fluid reservoir is formed to be fluidly coupled to the SERS substrate; the deformable cover is made to seal the SERS substrate from the fluid reservoir in a gastight compartment.

Therefore, the invention of independent claim 14 and dependent claim 15 meets the criterion of novelty.

The above mentioned distinguishing features of independent claim 14 are not known from the prior art and the invention in whole is not obvious to a person skilled in the art for improving the accuracy and reliability of detection.

Therefore, the invention of independent claim 14 and dependent claim 15 meets the criterion of inventive step.

The inventions of the claims 1-15 meet the criterion of industrial applicability.