



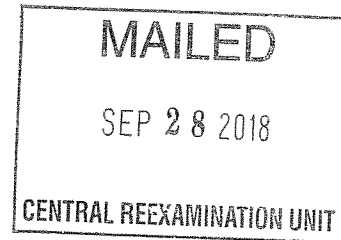
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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

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**EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/014,043.

PATENT NO. 8304193.

ART UNIT 3991.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Elizabeth L McKane

Primary Examiner, Art Unit: 3991

<b>Notice of Intent to Issue Ex Parte Reexamination Certificate</b>	Control No. 90/014,043	Patent Under Reexamination 8304193	
	Examiner ELIZABETH MCKANE	Art Unit 3991	AIA (First Inventor to File) Status No

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

1. ☒ Prosecution on the merits is (or remains) closed in this *ex parte* reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of
  - (a) ☒ Patent owner's communication(s) filed: 12 June 2018.
  - (b) ☐ Patent owner's failure to file an appropriate timely response to the Office action mailed: \_\_\_\_\_.
  - (c) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 41.31).
  - (d) ☐ The decision on appeal by the ☐ Board of Patent Appeals and Interferences ☐ Court dated \_\_\_\_\_
  - (e) ☐ Other: \_\_\_\_\_.
2. The Reexamination Certificate will indicate the following:
  - (a) Change in the Specification: ☐ Yes ☒ No
  - (b) Change in the Drawing(s): ☐ Yes ☒ No
  - (c) Status of the Claim(s):
    - (1) Patent claim(s) confirmed: 1-14.
    - (2) Patent claim(s) amended (including dependent on amended claim(s)): \_\_\_\_\_
    - (3) Patent claim(s) canceled: \_\_\_\_\_.
    - (4) Newly presented claim(s) patentable: \_\_\_\_\_.
    - (5) Newly presented canceled claims: \_\_\_\_\_.
    - (6) Patent claim(s) ☐ previously ☐ currently disclaimed: \_\_\_\_\_
    - (7) Patent claim(s) not subject to reexamination: \_\_\_\_\_.
3. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.
4. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."
5. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).
6. ☐ Note attached LIST OF REFERENCES CITED (PTO/SB/08 or PTO/SB/08 substitute).
7. ☐ The drawing correction request filed on \_\_\_\_\_ is: ☐ approved ☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the certified copies have
    - ☐ been received.
    - ☐ not been received.
    - ☐ been filed in Application No. \_\_\_\_\_.
    - ☐ been filed in reexamination Control No. \_\_\_\_\_.
    - ☐ been received by the International Bureau in PCT Application No. \_\_\_\_\_.

\* Certified copies not received: \_\_\_\_\_.
9. ☐ Note attached Examiner's Amendment.
10. ☐ Note attached Interview Summary (PTO-474).
11. ☐ Other: \_\_\_\_\_.

**All correspondence** relating to this reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

/ELIZABETH MCKANE/ Primary Examiner, Art Unit 3991	/K. Jastrzab/ Primary Examiner, AU 3991	/Jean Witz/ Supervisory Patent Examiner Art Unit 3991
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cc: Requester (if third party requester)

Claims 1-14 are confirmed.

### REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Claim 1 is the sole independent claim.

*1. A method for conducting an autocatalytic reaction in plugs in a microfluidic system, comprising the steps of:*

*providing the microfluidic system comprising at least two channels having at least one junction;*

*flowing an aqueous fluid containing at least one substrate molecule and reagents for conducting an autocatalytic reaction through a first channel of the at least two channels;*

*flowing an oil through the second channel of the at least two channels;*

*forming at least one plug of the aqueous fluid containing the at least one substrate molecule and reagents by partitioning the aqueous fluid with the flowing oil at the junction of the at least two channels, the plug being substantially surrounded by an oil flowing through the channel, wherein the at least one plug comprises at least one substrate molecule and reagents for conducting an autocatalytic reaction with the at least one substrate molecule;*

*and providing conditions suitable for the autocatalytic reaction in the at least one plug such that the at least one substrate molecule is amplified.*

Importantly, claim 1 requires *providing conditions suitable for the autocatalytic reaction in the at least one plug such that the at least one substrate molecule is amplified.*

The instant patent, US 8,304,193 sets forth certain conditions that must be addressed when conducting PCR in a microfluidic droplet, including unwanted adsorption of proteins on the surface of the droplet. See col.35, lines 59-66. These conditions require more than a single stimulus (such as heat) to induce a reaction such that the substrate molecule to be amplified in a microfluidic system, as claimed by the instant patent. The avoidance of protein adsorption specifically and control of surface chemistry in general in microfluidic reactions is achieved for example, through the use of perfluorocarbons as carrier-fluids. The instant patent discloses that surface chemistry "is preferably controlled through a careful selection of surfactants that are preferably designed to assemble at the interface between the plugs and the immiscible fluid that surrounds them." See col.12, lines 9-17. Additionally, the instant patent discloses introducing appropriate fluorosurfactants into the fluorinated carrier fluid will provide the plugs of aqueous fluid inertness towards protein adsorption, thus achieving biocompatibility and the conditions suitable for the autocatalytic reaction claimed. See col.36, lines 38-47.

The closest prior art of record is Quake PCT, Kopp, and Shaw Stewart, all cited by Requester and discussed in the Non-Final Rejection mailed 18 April 2018.

Quake, while teaching a microfluidic device, a carrier fluid, and an aqueous sample fluid, does not teach or suggest PCR or a carrier fluid/surfactant system that would provide conditions suitable for an autocatalytic reaction such that at least one substrate molecule is amplified. Instead of using biocompatible fluorinated oils and fluorosurfactants, Quake teaches traditional hydrocarbons which are not biocompatible

and will destroy proteins. See Quake, page 6, lines 8-10 and page 28, lines 7-29. See also, Sia Declaration ¶¶91-93. Thus, Quake neither teaches nor suggests any appropriate carrier fluid/surfactant combination that would create suitable conditions for PCR or an autocatalytic reaction such that at least one substrate molecule is amplified.

Kopp discloses a method of performing PCR within glass channels but does not teach a microfluidic droplet or system. Further, Kopp is silent with respect to oil as a carrier fluid. See Sia Declaration, ¶¶62-64.

Shaw-Stewart teaches a microfluidic device for conducting chemical reactions but does not teach or suggest providing the conditions suitable for an autocatalytic reaction such that at least one substrate molecule is amplified. See Sia Declaration, ¶¶55-59.

Thus, as supported by Patent Owner's arguments and the Sia Declaration, none of Quake, Kopp, or Shaw-Stewart, either alone or in combination, teach or suggest a method for conducting an autocatalytic reaction in plugs in a microfluidic system and providing conditions suitable for the autocatalytic reaction in at least one plug such that at least one substrate molecule is amplified.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

/Elizabeth L McKane/  
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