



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/594,637	10/25/2021	G. Marco Bommarito	81735US004	6502
200642	7590	09/05/2024	EXAMINER	
MRG/Solventum			YOUNG, NATASHA E	
c/o Mueting Raasch Group			ART UNIT	
111 WASHINGTON AVE. S., SUITE 700			PAPER NUMBER	
MINNEAPOLIS, MN 55401			1774	
			NOTIFICATION DATE	DELIVERY MODE
			09/05/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDocketing@Solventum.com
ptodocketing@mrgrs.com

Office Action Summary	Application No. 17/594,637	Applicant(s) Bommarito et al.	
	Examiner NATASHA E YOUNG	Art Unit 1774	AIA (FITF) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1,3,9,14,16-19,21,27,36,41,43-47,63 and 66-67 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 1,3,9,14,16-17,19,21,27,36,41,43-47,63 and 66-67 is/are allowed.
- 7) ☒ Claim(s) 18 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 25 October 2021 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date 12/20/2021 10/31/2022
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 18 recites the limitation "the two or more channels" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Allowable Subject Matter

Claims 1, 3, 9, 14, 16-17, 19, 21, 27, 36, 41, 43-47, 63, and 66-67 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

The closest prior art references are Witcher et al. (US 7,045,343 B2) and Franciskovich et al. (US 9,017,994 B2).

Regarding claim 1, Witcher et al. discloses **a sterilization test pack (80) comprising: a shell defining an indicator compartment (recess trough, 64) having a volume; a channel (lumen path, 70) extending between a compartment opening and an exterior opening, the channel (70) being in fluid communication with the indicator compartment (64) through the compartment opening and surrounding atmosphere being in fluid communication with the channel (70) through the exterior opening such that the indicator compartment (64) is in fluid communication with the surrounding atmosphere through the channel, the channel (70) having a length measured between the compartment opening and the exterior opening and a hydraulic radius (0.3125 cm) along the length; and an indicator (10) disposed in the indicator compartment (64)** (see Abstract; figures 9-10 and column 16, lines 4-67).

Witcher et al. fails to disclose or suggest a ratio of the compartment volume to the channel hydraulic radius ranging from 1000 cm² to 8000 cm².

Claims 3, 9, 14, and 16-17 depend on claim 1.

Regarding claim 19, Witcher et al. discloses **a sterilization test pack (80) comprising: a shell defining an indicator compartment (recess trough, 64) having a volume; a channel (lumen path, 70) extending between a compartment opening and an exterior opening, the channel (70) being in fluid communication with the indicator compartment (64) through the compartment opening and surrounding atmosphere being in fluid communication with the channel (70) through the exterior opening such that the indicator compartment is in fluid communication with the surrounding atmosphere through the channel (70), the channel (70) having a length measured between the compartment opening and the exterior opening and a hydraulic radius (0.3125 cm) along the length; and an indicator (10) disposed in the indicator compartment** (see Abstract; figures 9-10 and column 16, lines 4-67).

Witcher et al. fails to disclose or suggest that the sterilization test pack exhibiting a diffusivity (LD) of 0.02 cm to 50 cm.

Claims 21, 27, 36, 41, and 43-45 depend on claim 19.

Regarding claim 46, Franciskovich et al. discloses **a sterilization test pack** (10, 30, 50) **comprising: a shell defining an indicator compartment** (recessed compartments, 14 and 16) **having a volume; a channel** (20, 32, 34) **extending between a compartment opening and an exterior opening, the channel** (20, 32, 34) **being in fluid communication with the indicator compartment** (14, 16) **through the compartment opening and surrounding atmosphere being in fluid communication with the channel** (20, 32, 34) **through the exterior opening such that the indicator compartment** (14, 16) **is in fluid communication with the surrounding atmosphere through the channel** (20, 32, 34), the channel (20, 32, 34) **having a length of 1 mm to 25 mm measured between the compartment opening and the exterior opening and a maximum hydraulic radius of 1.0 mm or less** (1 mm, the shortest length) **at any selected location along the length; and an indicator** (chemical or biological) **disposed in the indicator compartment** (14, 16) (see Abstract; figures 1-5 and column 5, lines 32 through column 9, line 55).

Franciskovich et al. fails to disclose a sterilization test pack comprising: a shell defining an indicator compartment having a volume of 15 cm³ to 300 cm³; and the channel having a length of 30 mm to 1000 mm measured between the compartment opening and the exterior opening and a maximum hydraulic radius of 1.0 mm or less at any selected location along the length.

Claims 47, 63 and 66-67 depend on claim 46.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATASHA E YOUNG whose telephone number is (571)270-3163. The examiner can normally be reached M-F 6:30 am - 6:00 pm.



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.