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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/772,588	06/12/2020	Kelvin J. Witcher	79826US006	8117

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EXAMINER	
KANE, TREVOR LOGAN	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
03/14/2023	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):

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Office Action Summary	**Application No.** 16/772,588	**Applicant(s)** Witcher et al.	
	Examiner TREVOR L KANE	**Art Unit** 1657	**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 1/25/23.

☐ 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) 1-16 is/are pending in the application.

5a) Of the above claim(s) 8-15 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-7 and 16 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 _____ 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

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 § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Maintained rejection. **Claims 1-7 and 16** are rejected under 35 U.S.C. 103 as being unpatentable over **Lee** (Lee, I., *et al*. (2016). Antibacterial performance of various amine functional polymers coated silica nanoparticles. Polymer, 83, 223-229) in view of **Albert** (Albert, H., *et al* (1998). Biological indicators for steam sterilization: characterization of a rapid biological indicator utilizing *Bacillus stearothermophilus* spore-associated alpha-glucosidase

enzyme. Journal of applied microbiology, 85(5), 865-874.) and **Ghosh** (Ghosh, *et al* "Surface modification of nano-silica with amides and imides for use in polyester nanocomposites." Journal of Materials Chemistry A 1.19 (2013): 6073-6080).

Regarding claim 1, Lee teaches surface modification of silica nanoparticles with amines (abstract). Lee teaches tertiary amine-modified silica nanoparticles and using those nanoparticles in a liquid medium containing water to kill the bacteria (p 224 right column lines 4-19, p224 right column lines 32-39, and figure 1). Lee further teaches that the tertiary amine-modified silica nanoparticles are able to kill both gram positive and gram-negative bacteria (abstract, figure 5 and 6, p227 left column lines 5-10). Examiner notes claim 1 contains the limitation of an organic solvent, if present. Examiner has interpreted this to mean that organic solvent can be lacking from the composition. Lee teaches that the nanoparticles are in distilled water (liquid medium) which is inherently free of organic solvent and thus meets the limitation on an “organic solvent, if present” (p 224 right column lines 4-19).

Lee fails to teach an indicator compound or explicitly teach that the amine groups are covalently attached to the silica nanoparticle surface.

Albert teaches biological indicators for sterilization (title). Albert teaches that sterilization monitoring is important to ensure adequate sterilization and that biological indicators are the most effective method (p865 left column lines 14-16). Albert teaches using α-glucosidase for a spectrophotometric measurement using p-nitrophenyl-alpha-D-glucoside (PNPG) as an indicator compound as a read out for sterilization of spore forming bacteria (p866 left column lines 27-34, p867 left column lines 15-43). Albert teaches that α-glucosidase is a useful predictor of spore survival as it is present in both viable and vegetative cells and the

enzyme survives just longer than the spore following the sterilization (p872 right column lines 17-20).

Lee and Albert fail to teach that the amine groups are covalently attached to the silica nanoparticle surface.

Ghosh teaches surface modification of silica nanoparticles with primary amines (abstract). Ghosh teaches that there are different ways to bind APS (primary amine) to the silica nanoparticle and that a covalent bond is the strongest (p6075 left column lines 37-40, figure 1).

It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to modify the anti-bacterial composition containing tertiary amine silica nanoparticle of Lee by adding the indicator compound of Albert and generating the tertiary amine silica nanoparticle through covalent bonds as taught by Ghosh. One of ordinary skill in the art would be motivated to do so because Albert teaches the utility of using indicators for killing bacteria. One of ordinary skill would be further motivated to generate the tertiary amine silica nanoparticles using the covalent bond method of Ghosh as Ghosh teaches that a covalent bond results in the strongest amine modified silica nanoparticles. There would be a reasonable expectation of success as both Lee and Albert are in the same field of endeavor of killing bacteria and Lee and Ghosh are in the same field of endeavor of amine surface-modified silica nanoparticles.

Regarding claims 2 and 3, Lee teaches contacting tertiary amine-nanoparticles with the bacterial strains *E. coli* and *S. aureus* (bacteria) (p224 right column lines 33-39).

Regarding claim 4, while Lee teaches bacteria, Lee fails to teach spore forming bacteria. However, Albert teaches the use of the spore forming bacterium *Bacillus stearothermophilus* to measure sterilization (abstract, p866 left column lines 29-32).

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