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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/215,698		06/28/2023	Yiming Zhao	135975-57003	6465
197394	7590	12/02/2025	EXAMINER		
BakerHostetler / Regeneron			WHEELER, THURMAN MICHAEL		
1735 Market Street			ART UNIT	PAPER NUMBER	
Suite 3300					
Philadelphia, PA 19103-7501			1619		
			NOTIFICATION DATE	DELIVERY MODE	
			12/02/2025	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):

cofficevaluator@bakerlaw.com

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.

DETAILED ACTION

1. Claims 1-24, 28-37, 43-49 and 51 are pending 8/20/2025.
2. Claims 1-4, 13, 16, 21, 28, 30, 31-33, 37, 45, 49 and 51 have been amended.
3. Claims 2, 15 and 23 are withdrawn.
4. Claims 25-27, 38-42, 50 and 52 are cancelled.
5. Claims 1, 3-14, 16-22, 24, 28-37, 43-49 and 51 are for examination.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 6/20/2025 has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

Withdrawn Rejections

The rejection of claim 3 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a joint inventor, or for pre-AIA the applicant regards as the invention directed to 'the at least one microparticle' is withdrawn in view of the claim amendments.

The rejection of claim 32 is withdrawn in view of the claim amendments.

The rejection of claim 50 is withdrawn because claim 50 has been cancelled.

The rejection of claims 1, 2, 4-14, 16-22, 24, 28-37 and 43-51 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the claim amendments.

The rejection of claims 1, 2, 4-14, 16-22, 24, 28-37 and 43-51 under 35 U.S.C. 103(a) as being unpatentable over Mama et al (Oil-in-oil microencapsulation technique with an external perfluorohexane phase, International Journal of Pharmaceutics, Vol. 338, no. 1-2, 23 May 2007, cited in IDS) [Mana] in view of Chen et al (US 20130129830) [Chen], Tang et al (USP 11135586, 1, 2, 4-14, 16-22, 24, 28-37 and 43-51) and Dangla et al (WO2019077114A1, cited in IDS) is withdrawn in view of the claim amendments. Applicant's arguments are moot in view thereof.

The rejection of claims 1, 2, 4-16, 18-24, 28-37, and 43-52 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 5-9, 12-14, 16, 17 and 19 of U.S. Patent No. 12,239,687 (herein '687) because a Terminal Disclaimer was filed 8/20/2025 (Approved).

Claim Objections

Claims 1, 28 and 31 are objected to because of the following informalities.

Claims 1, 28 and 31 recite 'the microparticle'.

For claim consistency, this limitation: 'the microparticle' should be preceded with the phrase 'encapsulated protein, e.g., encapsulated protein microparticles.

For example:

It is recommended to amend the claims, e.g., claim 1, to recite:

A method of producing encapsulated protein microparticles comprising:

combining spray-dried protein powder and a polymer into a hydrocarbon solvent to form a non-aqueous first solution;

adding the first solution to a second solution, wherein the second solution comprises a fluorocarbon liquid and a fluorosurfactant;

agitating the combined solutions to form a non-aqueous emulsion comprising multiple emulsion hydrocarbon droplets in the fluorocarbon liquid;

removing the hydrocarbon solvent; and removing the fluorocarbon liquid to isolate the encapsulated protein microparticles, wherein the encapsulated protein microparticles comprise protein encapsulated within a matrix of polymer, wherein the encapsulated protein microparticles are sustained release encapsulated protein microparticles, and wherein the encapsulated protein microparticles comprise a polymer cortex devoid of pores or channels.

Appropriate correction of claim consistency is required.

Rejections reformulated in view of the claim amendments

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.

Claims 13, 14 and 33 are 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 pre-AIA the applicant regards as the invention. These rejections have been reformulated in view of the claim amendments.

Claims 13 is indefinite because it is unclear whether a fragment or a truncated version of the protein applies to the 'antigen binding fragment', since antigen binding fragment is itself a fragment of the protein (i.e., antibody).

Claim 14 recites "the protein is a VEGF Trap protein". It is unclear whether the VEGF Trap protein, as claimed, applies to the recombinant protein, the fusion protein, an antibody or antigen binding fragment, or a fragment or truncated version of the protein. Notably, it well established that a VEGF Trap protein is a recombinant fusion protein.

Claim 33 recites "the protein is a VEGF Trap protein or a truncated VEGF Trap protein". It is unclear whether the VEGF Trap protein or truncated version thereof applies to the recombinant protein, the fusion protein, or fragment thereof, of which are recited in claim 32 from which claim 33 directly depends.

Response to Arguments

Applicants argue that for clarity, applicant amends claims 13 and 32. Claims 14 and 15 are dependent of claim 13 and claim 33 is dependent of claim 32.

Applicant's arguments have been fully considered but they are not persuasive, because the rejection of claims 13, 14 and 33 have been reformulated. Therefore, claims 13, 14 and 33 are 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 pre-AIA the applicant regards as the invention remain rejected for reasons as set forth above.

Claim 51 is 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 pre-AIA the applicant regards as the invention.

Claim 50 is indefinite because it is dependent upon cancelled claim 50.

Therefore, it is unclear as to which claim that claim 51 depends from.

Conclusions

Claims 13, 14, 33 and 51 are rejected.

Claim 1, 28 and 31 are objected to.

Claims 3-12, 16-22, 24, 29-32, 34-37 and 43-49 are deemed allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any nonprovisional extension fee (37 CFR 1.17(a)) pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thurman Wheeler whose telephone number is (571)-270-1307. The examiner can normally be reached Monday-Friday 11:00am-5:00pm EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached on 571-272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 1619

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Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T.W./

Examiner, Art Unit 1619

/SARAH ALAWADI/

Primary Examiner, Art Unit 1619

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	18215698
	Filing Date	2023-06-28
	First Named Inventor	Yiming Zhao
	Art Unit	1619
	Examiner Name	T. M. Wheeler
	Attorney Docket Number	135975-57003

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Application Number	18215698
Filing Date	2023-06-28
First Named Inventor	Yiming Zhao
Art Unit	1619
Examiner Name	T. M. Wheeler
Attorney Docket Number	135975-57003

/T.W./	1	Singapore Office Action for Application No. 11202301581P, dated May 21, 2025, 8 pages.	☐
/T.W./	2	Singapore Office Action for Application No. 11202205117V, dated May 21, 2025, 9 pages.	☐

If you wish to add additional non-patent literature document citation information, please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/THURMAN WHEELER/	Date Considered	11/27/2025
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*EXAMINER: Initial if reference considered and whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	18215698
	Filing Date	2023-06-28
	First Named Inventor	Yiming Zhao
	Art Unit	1619
	Examiner Name	T. M. Wheeler
	Attorney Docket Number	135975-57003

TIMING STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached timing statement under 37 CFR 1.97(e).

☒ A timing statement under 37 CFR 1.97(e) is not submitted herewith.

TIMING FEE

☐ The fee set forth in 37 CFR 1.17(p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98(d)(1) is attached.

SIZE FEE ASSERTION

Please see 37 CFR 1.17(v) and the [IDS Auto-Load Instructions](#) for completing this form to make the appropriate selection of an assertion under 37 CFR 1.98. For the information disclosure statement (IDS) submitted herewith, the applicant or patent owner certifies the following with respect to the cumulative number of applicant-provided or patent-owner provided items of information submitted to date including those in the accompanying IDS (select only one):

☒ No IDS size fee is required under 37 CFR 1.17(v) at this time.

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(1).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(2).

☐ The IDS is accompanied by the IDS size fee under 37 CFR 1.17(v)(3).

SIGNATURE

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/John P. Isacson/	Date (YYYY-MM-DD)	2025-06-20
Name/Print	John P. Isacson	Registration Number	33,715

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	18215698
Filing Date	2023-06-28
First Named Inventor	Yiming Zhao
Art Unit	1619
Examiner Name	T. M. Wheeler
Attorney Docket Number	135975-57003

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.