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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/777,657	07/19/2024	Lewis HANNA	37151-701.303	1929

21971 7590 11/18/2026

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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
11/18/2026	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):

patentdocket@wsgr.com

Office Action Summary	Application No. 18/777,657	Applicant(s) HANNA et al.	
	Examiner Christine J Saoud	Art Unit 1645	AIA (First Inventor to File) Status No

-- 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 2 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 _____.

☐ 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) 203-224 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☐ Claim(s) _____ is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☑ Claim(s) 203-224 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 is being examined under the pre-AIA first to invent provisions.

Nucleotide and/or Amino Acid Sequence Disclosures

REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Items 1) and 2) provide general guidance related to requirements for sequence disclosures.

1) 37 CFR 1.821(c) requires that patent applications which contain disclosures of nucleotide and/or amino acid sequences that fall within the definitions of 37 CFR 1.821(a) must contain a "Sequence Listing," as a separate part of the disclosure, which presents the nucleotide and/or amino acid sequences and associated information using the symbols and format in accordance with the requirements of 37 CFR 1.821 - 1.825. This "Sequence Listing" part of the disclosure may be submitted:
   a) In accordance with 37 CFR 1.821(c)(1) via the USPTO patent electronic filing system (see Section I.1 of the Legal Framework for Patent Electronic System (https://www.uspto.gov/PatentLegalFramework), hereinafter "Legal Framework") as an ASCII text file, together with an incorporation-by-reference of the material in the ASCII text file in a separate paragraph of the specification as required by 37 CFR 1.823(b)(1) identifying:
      i) the name of the ASCII text file;
      ii) the date of creation; and
      iii) the size of the ASCII text file in bytes;
   b) In accordance with 37 CFR 1.821(c)(1) on read-only optical disc(s) as permitted by 37 CFR 1.52(e)(1)(ii), labeled according to 37 CFR 1.52(e)(5), with an incorporation-by-reference of the material in the ASCII text file according to 37 CFR 1.52(e)(8) and 37 CFR 1.823(b)(1) in a separate paragraph of the specification identifying:

i) the name of the ASCII text file;

ii) the date of creation; and

iii) the size of the ASCII text file in bytes;

c) In accordance with 37 CFR 1.821(c)(2) via the USPTO patent electronic filing system as a PDF file (not recommended); or

d) In accordance with 37 CFR 1.821(c)(3) on physical sheets of paper (not recommended).

2) When a "Sequence Listing" has been submitted as a PDF file as in 1(c) above (37 CFR 1.821(c)(2)) or on physical sheets of paper as in 1(d) above (37 CFR 1.821(c)(3)), 37 CFR 1.821(e)(1) requires a computer readable form (CRF) of the "Sequence Listing" in accordance with the requirements of 37 CFR 1.824.

a) If the "Sequence Listing" required by 37 CFR 1.821(c) is filed via the USPTO patent electronic filing system as a PDF, then 37 CFR 1.821(e)(1)(ii) or 1.821(e)(2)(ii) requires submission of a statement that the "Sequence Listing" content of the PDF copy and the CRF copy (the ASCII text file copy) are identical.

b) If the "Sequence Listing" required by 37 CFR 1.821(c) is filed on paper or read-only optical disc, then 37 CFR 1.821(e)(1)(ii) or 1.821(e)(2)(ii) requires submission of a statement that the "Sequence Listing" content of the paper or read-only optical disc copy and the CRF are identical.

Specific deficiencies and the required response to this Office Action are as follows:

Specific deficiency - The Incorporation by Reference paragraph required by 37 CFR 1.821(c)(1) defective. See item 1) a) or 1) b) above.

The incorporation statement must include the name of the file, the file size in bytes and the date the file was created. The incorporation statement at [002.1] recites the following information:

July 16, 2024, is named 37151-701_303_SL.xml and is 116,972 bytes in size.

However, the file information of record in the PTO systems is:

Application Number: 18777657

Version Number	Num of Sequences	Receipt Date	Load Date	File Size	File Name
1.0	76	07-19-2024	07-19-2024	116972 B	37151_701_303_SL.xml

NOTE: the file names do not match. The incorporation statement in the specification has a dash between "37151" and "701" while the file that was submitted to the PTO has an underscore between "37151" and "701". Therefore, the file names do not match.

Required response – Applicant must provide:

- A substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3) and 1.125 inserting the required incorporation-by-reference paragraph, consisting of:
    - A copy of the previously-submitted specification, with deletions shown with strikethrough or brackets and insertions shown with underlining (marked-up version);
    - A copy of the amended specification without markings (clean version); and
    - A statement that the substitute specification contains no new matter.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 203, drawn to a method of treating a disease or condition in a subject by administering a therapeutically effective amount of a composition comprising alpha-2-macroglobulin polypeptide, classified in A61K 38/1722.

II. Claims 204-224, drawn to a method of making a composition comprising: (a) centrifuging a blood sample and passing the sample from a mammal through a filter, thereby separating the sample into a filtrate and a retentate; and (b) collecting the retentate, wherein the retentate comprises: (i) a concentration of A2M that is at least 1.1 times higher than the concentration of A2M present in the biological sample, and (ii) plasma, BMA, or another body fluid from the biological sample, classified in C07K 1/36.

The inventions are independent or distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to distinct methods. Group I is directed to a method of treatment by administering a composition. Group II is directed to a method of making a composition. The methods have different designs, modes of operation and effects. One group makes a particular composition and the other group utilizes the composition which is made in a method of treatment.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancelation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J Saoud whose telephone number is (571)272-0891. The examiner can normally be reached M-F, 8am-4pm.

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, Julie Z Wu can be reached at 571-272-5205. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1645