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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/336,024	03/22/2019	Raymond MCCAGUE	3663-0111PUS1	3794
2292 7590 08/07/2020 BIRCH STEWART KOLASCH & BIRCH, LLP 8110 Gatehouse Road Suite 100 East Falls Church, VA 22042-1248			EXAMINER SHIAO, REI TSANG	
			ART UNIT 1629	PAPER NUMBER
			NOTIFICATION DATE 08/07/2020	DELIVERY MODE 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):

mailroom@bskb.com

Office Action Summary**Application No.**

16/336,024

Applicant(s)

MCCAGUE et al.

Examiner

REI TSANG SHIAO

Art Unit

1629

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 3/22/2019.

☐ 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) 1-20 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) 1-20 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)

3) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date ____.

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

4) ☐ Other: ____.

Paper No(s)/Mail Date 3/22/19.

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

Priority and Status of the Claims

1. This application is a 371 of PCT/EP2019/056194 with a filing date 03/12/2019, which claim benefit of the foreign application: EUROPEAN PATENT OFFICE (EPO) 18206826.2 with a filing date 11/16/2018. However, the foreign priority document EUROPEAN PATENT OFFICE (EPO) 18206826.2 has not been filed to the Office.
2. Claims 1-20 are pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Claim 1 is rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112, first paragraph (pre-AIA), because the specification does not reasonably provide enablement for the instant “methylating the (S)-nornicotine” without limitation (i.e., no named compounds), see line 4 in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention is a process of making (S)-nicotine using a step “methylating the (S)-nornicotine”, wherein the “methylating the (S)-nornicotine” is without limitation (i.e., no named compounds), see claim 1.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art Weber et al. CAS: 171: 128332, 2019. Weber et al. '332 discloses a process of making nicotine by methylating nornicotine using formaldehyde or paraformaldehyde.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the description of the instant “methylating the (S)-nornicotine”, representing a number of methylating compounds on page 8 of the specification. There is no data present in the instant specification for the instant “methylating the (S)-nornicotine” without limitation (i.e., no named compounds).

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant “methylating the (S)-nornicotine” is without limitation (i.e., no named compounds).

The quantity or experimentation needed and the level of skill in the art

While the level of the skill in the chemical arts is high, it would require undue experimentation of one of ordinary skill in the art to resolve any methylating compounds without limitation. There is no guidance or working examples present for constitutional any methylating the (S)-nornicotine” without limitation for the instant invention. Incorporation of the limitation of the “methylating the (S)-nornicotine” (i.e., claim 5) supported by the specification into claim 1 would overcome this rejection.

4. 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.

Claim 15 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 15 provides for the use of compounds of uric acid, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

5. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Claim Rejections - 35 USC § 103

6. 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.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being obvious over Arnold's US 2016/0115150 in view of Flora et al. *Regulatory Toxicology and Pharmacology*, 2016, 74:1-11.

Applicant claim a process of making (S)-nicotine comprising the steps of:

- (i) reducing myosmine with an enzyme with imine reductase activity to form (S)-nomicotine; and

(ii) methylating the (S)-nomicotine formed from step (i) to form (S)-nicotine, see claim

1. Dependent claims 2-20 further limit the scope of processes, i.e., the methylation step using formaldehyde, formic acid in claims 2-10 and 15-20, a process of making a pharmaceutical composition for electronic cigarette in claims 11-14.

Determination of the scope and content of the prior art (MPEP §2141.01)

Arnold's '150 disclose a process of making nicotine by reducing myosamine with a reducing agent selected from hydrogenation catalyst (e.g. enzyme) to form nornicotine, then methylating the nornicotine with formaldehyde and formic acid, see columns 5-6.

Flora et al. disclose a pharmaceutical composition or formulation comprising nicotine (e.g. (S)-nicotine) for electronic cigarette. The impurity of degradation products in electronic cigarette has been characterized.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between instant claims and Arnold's '150 is that the instant claims are silent on the scope of methylating agents.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the claims 1-20 prima facie obvious because one would be motivated to employ the processes of Arnold's '150 in view of Flora et al. to obtain the instant invention.

The motivation to make the claimed processes derived from the known processes of Arnold's '150 in view of Flora et al. would possess similar yields or activity to that which is claimed in the reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REI TSANG SHIAO whose telephone number is (571)272-0707. The examiner can normally be reached on 8:30 am-5:00 pm.

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, Jeffrey Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access

to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI TSANG SHIAO/

Rei-tsang Shiao, Ph.D.
Primary Examiner, Art Unit 1629

August 04, 2020

Notice of References Cited	Application/Control No. 16/336,024		Applicant(s)/Patent Under Reexamination MCCAGUE et al.	
	Examiner REI TSANG SHIAO		Art Unit 1629	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20160115150-A1	04-2016	Arnold; Michael	C07D401/04	546/279.4
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Weber et al. CAS: 171: 128332, 2019.
	V	Flora et al. Regulatory Toxicology and Pharmacology, 2016, 74:1-11.
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 16/336,024	Applicant(s)/Patent Under Reexamination MCCAGUE et al.
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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	07/14/2020								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
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	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								

<i>Search Notes</i> 	Application/Control No. 16/336,024	Applicant(s)/Patent Under Reexamination MCCAGUE et al.
	Examiner REI TSANG SHIAO	Art Unit 1629

CPC - Searched*		
Symbol	Date	Examiner
C07D401/04	07/14/2020	RS

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
STN, structure, inventors, text	07/10/2020	RS
EAST class/subclass	07/14/2020	RS
PALM inventors	07/14/2020	RS

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/REI TSANG SHIAO/ Primary Examiner, Art Unit 1629	
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	121,172	C07D401/04	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/07/14 15:31

EAST Search History (Interference)

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