

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Joshua RABINOWITZ et al.) Group Art Unit: Not Yet Assigned
Application No.: Not Yet Assigned) Examiner: Not Yet Assigned
Filed: May 21, 2014) Confirmation No.: Not Yet Assigned
For: COMPOSITIONS, DEVICES, AND) **VIA EFS-WEB**
METHODS FOR NICOTINE)
AEROSOL DELIVERY)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

TRANSMITTAL OF NEW NONPROVISIONAL PATENT APPLICATION

Enclosed is a new application, including the following:

1. Application including a specification (78 pages, including a cover page, claims, and a one-page abstract) and drawings (16 sheets – including Figs. 1A, 1B, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15).
2. Application Data Sheet (ADS) in accordance with 37 C.F.R. § 1.76 (7 pages).

Please accord this application an application number and filing date.

Applicant will submit an executed Declaration for each of the inventors at such time as required by the Patent Office.

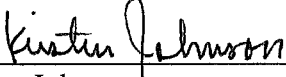
This application is filed without filing fees under the provisions of 37 C.F.R. § 1.53(f). Applicant awaits notification from the U.S. Patent and Trademark Office of the time set for paying the filing fees.

With the exception of the filing, search, examination, and claims fees, the Commissioner is hereby authorized to charge any additional fees due and any other fees due under 37 C.F.R. § 1.16 or § 1.17 during the pendency of this application to Deposit Account No. 50-5906.

Please address all correspondence with respect to this application to: **NJOY, Inc./Bookoff McAndrews, PLLC, Customer Number 118,647.**

Respectfully submitted,
BOOKOFF MCANDREWS, PLLC

Dated: May 21, 2014

By: 
Kirsten Johnson
Reg. No. 67,135

Electronic Acknowledgement Receipt

EFS ID:	19097159
Application Number:	14284194
International Application Number:	
Confirmation Number:	4034
Title of Invention:	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY
First Named Inventor/Applicant Name:	Joshua Rabinowitz
Customer Number:	118647
Filer:	Kirsten S. Johnson/Monique Blakey
Filer Authorized By:	Kirsten S. Johnson
Attorney Docket Number:	00028-0009-01000
Receipt Date:	21-MAY-2014
Filing Date:	
Time Stamp:	18:33:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	ADS.pdf	1566129 f6f06d358ea7bdb886fb909a5816c933c88e22a2	no	7

Warnings:

Information:

2	Transmittal of New Application	transmittal.pdf	55085 3195e555c152a3f7ca90e4c3063e70fae2c9bdf6	no	2
Warnings:					
Information:					
3		spec_drawings.pdf	4009005 0f692f25857f78d20d10135e7f6b50d9e81aa4d4	yes	94
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	67	
	Claims		68	77	
	Abstract		78	78	
	Drawings-only black and white line drawings		79	94	
Warnings:					
Information:					
Total Files Size (in bytes):			5630219		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	00028-0009-01000
		Application Number	
Title of Invention	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY		
<p>The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.</p> <p>This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.</p>			

Secrecy Order 37 CFR 5.2

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
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Inventor Information:

Inventor 1					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Joshua		RABINOWITZ			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Princeton	State/Province	NJ	Country of Residence i	US	
Mailing Address of Inventor:						
Address 1		2 Greenholm Street				
Address 2						
City	Princeton	State/Province	NJ			
Postal Code	08540	Country i	US			
Inventor 2					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Mark		SCATTERDAY			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Scottsdale	State/Province	AZ	Country of Residence i	US	
Mailing Address of Inventor:						
Address 1		4831 N. 67th Street				
Address 2						
City	Scottsdale	State/Province	AZ			
Postal Code	85251	Country i	US			
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.						
Add						

Correspondence Information:

<p>Enter either Customer Number or complete the Correspondence Information section below.</p> <p>For further information see 37 CFR 1.33(a).</p>
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	00028-0009-01000
		Application Number	
Title of Invention	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY		

☐ An Address is being provided for the correspondence information of this application.

Customer Number	118647		
Email Address		<input type="button" value="Add Email"/>	<input type="button" value="Remove Email"/>

Application Information:

Title of the Invention	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY		
Attorney Docket Number	00028-0009-01000	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	16	Suggested Figure for Publication (if any)	

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	118647		

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	00028-0009-01000
		Application Number	
Title of Invention	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/826318	2013-05-22
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/856374	2013-07-19
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/969650	2014-03-24
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	61/971340	2014-03-27
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) ⁱthe information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove			
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ^j (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	00028-0009-01000
		Application Number	
Title of Invention	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY		

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

<p>This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.</p> <p>☐ NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.</p>
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Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices
<p>If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.</p> <p>In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.</p> <p>In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.</p>

Applicant Information:

<p>Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.</p>
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	00028-0009-01000
		Application Number	
Title of Invention	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY		

Applicant 1				Remove	
<p>If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.</p>					
Clear					
☒ Assignee		☐ Legal Representative under 35 U.S.C. 117		☐ Joint Inventor	
☐ Person to whom the inventor is obligated to assign.			☐ Person who shows sufficient proprietary interest		
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:					
Name of the Deceased or Legally Incapacitated Inventor :					
If the Applicant is an Organization check here. ☒					
Organization Name		NJOY, Inc.			
Mailing Address Information:					
Address 1		15211 North Kierland Blvd.			
Address 2		Suite 200			
City		Scottsdale	State/Province		AZ
Country ⁱ		US	Postal Code		85254
Phone Number			Fax Number		
Email Address					
Additional Applicant Data may be generated within this form by selecting the Add button. Add					

Assignee Information including Non-Applicant Assignee Information:

<p>Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.</p>	
Assignee 1	
<p>Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.</p>	
Remove	
<p>If the Assignee or Non-Applicant Assignee is an Organization check here. ☐</p>	

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	00028-0009-01000
		Application Number	
Title of Invention	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY		

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		State/Province	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Add

Signature:

Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

Signature	/Kirsten Johnson/		Date (YYYY-MM-DD)	2014-05-21
First Name	Kirsten	Last Name	Johnson	Registration Number
			67135	

Additional Signature may be generated within this form by selecting the Add button.

Add

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
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.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/284,194	Filing Date 05/21/2014	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70
☒ SEARCH FEE (37 CFR 1.16(k), (j), or (m))	N/A	N/A	N/A	300
☒ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360
TOTAL CLAIMS (37 CFR 1.16(i))	23 minus 20 =	* 3	x \$40 =	120
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1	x \$210 =	210
☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1060

APPLICATION AS AMENDED – PART II

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE							

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE							

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
 The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LDRC
/EVA GILLIS/

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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.**
 If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Application Number</i>	14/284,194
				<i>Filing Date</i>	May 21, 2014
				<i>First Named Inventor</i>	Joshua Rabinowitz
				<i>Art Unit</i>	1747
				<i>Examiner Name</i>	Michael J. Felton
Sheet	1	of	1	<i>Attorney Docket Number</i>	00028-0009-01000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <i>(if known)</i>			
		US-8,381,739	02-26-2013	Gonda	
		US-2004/0002520 A1	01-01-2004	Soderlund et al.	
		US-2006/0018840 A1	01-26-2006	Lechuga-Ballesteros et al.	
		US-2012/0273589 A1	11-01-2012	Hon	
		US-2013/0255702 A1	10-03-2013	Griffith, Jr. et al.	
		US-2014/0096781 A1	04-10-2014	Sears et al.	
		US-2014/0271946 A1	09-18-2014	Kobal et al.	
		US-2016/0044968 A1	02-18-2016	Bowen et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
		Country Code Number Kind Code <i>(if known)</i>				
		WO 97/12639	04-10-1997	Slutsky et al.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶
		CALDWELL, B., et al., "A Systematic Review of Nicotine by Inhalation: Is There a Role for the Inhaled Route?," <i>Nicotine & Tobacco Research</i> , pp. 1-13 (2012).	
		TORRIE, B., "Nicotine inhaler gives instant 'hit'," 2 pages (2013), <i>available at</i> http://www.stuff.co.nz/national/health/8822875/Nicotine-inhaler-gives-instant-hit .	
		World Health Organization, "Health Effects of Interactions Between Tobacco Use and Exposure to Other Agents," <i>Environmental Health Criteria</i> 211, 83 pages (1999), <i>available at</i> http://www.inchem.org/documents/ehc/ehc/ehc211.htm .	
		"A Randomised Placebo-Controlled Trial of a Nicotine Inhaler and Nicotine Patches for Smoking Cessation," 5 pages, <i>available at</i> http://www.otago.ac.nz/wellington/otago047634.pdf .	

Examiner Signature		Date Considered
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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Electronic Acknowledgement Receipt

EFS ID:	30574340
Application Number:	14284194
International Application Number:	
Confirmation Number:	4034
Title of Invention:	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY
First Named Inventor/Applicant Name:	Joshua RABINOWITZ
Customer Number:	118647
Filer:	Christopher K. Agrawal/Monique Blakey
Filer Authorized By:	Christopher K. Agrawal
Attorney Docket Number:	00028-0009-01000
Receipt Date:	05-OCT-2017
Filing Date:	21-MAY-2014
Time Stamp:	13:01:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	IDS.pdf	81519	no	2
			03c9157ddd34f62a69ce9908654779fda91f83ba8		

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	sb08.pdf	97335	no	1
			88303f3fceed51df6df82d81c508db4b30ae96b		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	WO9712639.pdf	10573086	no	57
			9978e0d2178b8790a5f3686812f0712ca50ad633		
Warnings:					
Information:					
4	Non Patent Literature	torrie.pdf	101517	no	2
			74a5b7ed61353958f9bb3d87d1f3d27b4ab68232		
Warnings:					
Information:					
5	Non Patent Literature	WHO.pdf	867242	no	83
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Warnings:					
Information:					
6	Non Patent Literature	otago.pdf	198546	no	5
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Warnings:					
Information:					
7	Non Patent Literature	caldwell.pdf	218735	no	13
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Warnings:					
Information:					
Total Files Size (in bytes):			12137980		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No. 14/284,194	)	Examiner: Michael J. Felton
	)	
Filed: May 21, 2014	)	Confirmation No. 4034
	)	
For: COMPOSITIONS, DEVICES, AND	)	<u>VIA EFS WEB</u>
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents listed on the attached PTO/SB/08 Form. This Information Disclosure Statement is filed before the mailing of a first Office Action on the merits in this application. *See* M.P.E.P. § 609.04(b). Accordingly, no fee is required.

Copies of the listed U.S. patent and published applications are not provided. Copies of the listed foreign patent and non-patent literature documents are attached.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute “prior art.” If the Examiner applies any of the documents as prior art against any

claim in the application and Applicant determines that the cited documents do not constitute “prior art” under United States law, Applicant reserves the right to present to the U.S. Patent and Trademark Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to Deposit Account No. 50-5906.

Respectfully submitted,
BOOKOFF McANDREWS, PLLC

Dated: October 5, 2017

By: /Kirsten Johnson/
Kirsten Johnson
Reg. No. 67,135



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/284,194	05/21/2014	Joshua RABINOWITZ	00028-0009-01000	4034
118647	7590	12/08/2017		
Bookoff McAndrews, PLLC 2020 K Street, NW Suite 400 Washington, DC 20006			EXAMINER FELTON, MICHAEL J	
			ART UNIT	PAPER NUMBER
			1747	
			NOTIFICATION DATE	DELIVERY MODE
			12/08/2017	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):

usptomail@bomcip.com
Kross@bomcip.com

Notice of Pre-AIA or AIA Status

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

Election/Restrictions

2. Applicant's election of Group I (claims 1-14 and 33-36) and the election of species of glycerol as the solvent, lactic acid as the ion pairing agent, and menthol as the agent in the reply filed on 9/29/2017 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.01(a)).
3. Claims, 15-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse as noted above.

Claim Rejections - 35 USC § 112

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.

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.

5. Claim **1-14** 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.

6. Claim 1-14 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: composition or structure essential for forming an aerosol wherein at least 85% of the nicotine by weight with respect to the total weight of the composition is in a particulate phase of an aerosol.

7. Claims 1-14 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how a aerosol is formed with 85% of the nicotine by weight with respect to the total weight of the composition is in a particulate phase of an aerosol.

8. Claims 8-9 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: what element results in a pH of 7-8. It appears that the disclosed solvents (polyols, weakly acidic), nicotine, and ion pairing agents (i.e. organic acids) would not be able to produce a pH of 7-8 (i.e. basic) without additional elements that are not claimed.

Claim Rejections - 35 USC § 102

9. 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.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

11. Claim(s) **1, 3-7, 10, 12, 13, 33-36**, is/are rejected under 35 U.S.C. 102(a)(2) as being anticipated by Sebastian et al. (US 2014/0000638).

12. Regarding claims **1, 3-7, 10, 12, 13, 33-36**, Sebastian et al. disclose an electronic cigarette that forms an aerosol from a composition composed of a solvent such as glycerol, tobacco material (containing nicotine), and flavor such as menthol (see 0055-0058).

13. Sebastian et al. further disclose that:

Organic acids particularly can be incorporated into the aerosol precursor to affect the flavor, sensation, or organoleptic properties of medicaments, such as nicotine, that can be combined with the aerosol precursor. For example, organic acids, such as levulinic acid, lactic acid, and pyruvic acid, can be included in the aerosol precursor with nicotine in amounts up to being equimolar (based on total organic acid content) with the nicotine. Any combination of organic acids can be used. For example, the aerosol precursor can include about 0.1 to about 0.5 moles of levulinic acid per one mole of nicotine, about 0.1 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine, or combinations thereof, up to a concentration wherein the total amount of organic acid present is equimolar to the total amount of nicotine present in the aerosol precursor. (0059)

14. Although Sebastian et al. disclose the use of the composition for vaporizing the term condensation is not used and the amount of 85% of the nicotine by weight is in a particulate phase of the aerosol.

15. First, Claim 1 recites the functional language “wherein vaporization and condensation of the composition produces and aerosol”. A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). The composition of Sebastian et al. meets all the structural limitations of the claim and is capable of being vaporized and undergo condensation. It would have been inherent that under some conditions (process limitations) a majority of the nicotine could be condensed into a particle phase.

16. Second, Sebastian et al. disclose that the composition is used to make an inhalable substance that is either in the form of a vapor (i.e. a substance that is in the gas phase at a temperature lower than its critical point) or an aerosol (i.e. a suspension of fine solid particles or liquid droplets in a gas). Therefore, the composition of Sebastian et al. is capable of being used to form an aerosol where all the composition (including at least 85% of the nicotine) is in the form of liquid droplets (i.e. particulate phase). Furthermore, Sebastian et al. disclose that the composition is present in the final form as “wet total particulate matter” in the aerosol.

17. Regarding claim 2, Sebastian et al. do not disclose that nicotine is in the free-base form and expressly disclose the combination of nicotine and an organic acid, which would result in the nicotine not being in a free base form.

Claim Rejections - 35 USC § 103

18. 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.

19. 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.

20. 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 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.

21. Claims **8, 9, 11 and 14** is/are rejected under 35 U.S.C. 103 as being unpatentable over Sebastian et al. (US 2014/0000638) as applied to claim 1 above.

22. Regarding claims **8 and 9**, Sebastian et al. do not disclose the pH of the composition or the aerosol that is intended to be produced from the composition. However, it would have been obvious to one of ordinary skill in the art at the time of filing that because the acid or basic nature of the solution is not discussed, a pH neutral solution (i.e. around pH 7) would be assumed.

23. Regarding claims **11 and 14**, Sebastian et al. disclose that the composition can contain 2-3% nicotine, 0.1%-0.5% of flavor (0061) and should include up to 98% polyol and that, "This total amount can be split in any combination between two or more different polyols," (0060). Glycerol and propylene glycol are both expressly disclosed but about 44-48% of each is not expressly disclosed. However, it would have been obvious to one of ordinary skill in the art at the time of invention to split the 98% as indicated by Sebastian et al., in half between two polyols, such as glycerol and propylene glycol as disclosed. This would result in less than 49% of each, which would have been considered to be "about 44 to about 48%".

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J FELTON whose telephone number is (571)272-4805. The examiner can normally be reached on Monday, Thursday-Friday 7:00-4:30, Wednesday 7:00-1:00.

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, Michael H Wilson can be reached on 571-270-3882. 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 <http://pair-direct.uspto.gov>. 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.

***/Michael J Felton/
Primary Examiner, Art Unit 1747***

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	14/284,194
				Filing Date	May 21, 2014
				First Named Inventor	Joshua RABINOWITZ
				Art Unit	1747
Examiner Name	Michael J. FELTON				
Attorney Docket Number	15058.0002-00000				
Sheet	1	of	1		

U.S. PATENTS					
Examiner Initials*	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² <i>(if known)</i>			
		US-2008/0138398	06-12-2008	Aradigm Corporation	
		US-			
		US-			
		US-			

U.S. PUBLISHED PATENT APPLICATIONS					
Examiner Initials*	Cite No. ³	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ⁴ <i>(if known)</i>			
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		US-			

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ⁵ Number ⁶ Kind Code ⁷ <i>(if known)</i>				
		WO 2014/151434	09-25-2014	Altria Client Services Inc.		

NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶
		Third Party Observations filed in European Patent Office for corresponding European Patent Application No. 14732735.7 on December 5, 2018	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

³ Applicant's unique citation designation number (optional).

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⁷ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

⁸ Applicant is to place a check mark here if English language Translation is attached.

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 CFR 1.14. This collection is estimated to take 2 hours 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.**

Electronic Patent Application Fee Transmittal

Application Number:	14284194			
Filing Date:	21-May-2014			
Title of Invention:	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY			
First Named Inventor/Applicant Name:	Joshua RABINOWITZ			
Filer:	Huimin Chen/Susan Benesh			
Attorney Docket Number:	15058.0002-00000			
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 3 months with \$0 paid	2253	1	700	700
Miscellaneous:				
RCE- 1ST REQUEST	2801	1	650	650
Total in USD (\$)				1350

Electronic Acknowledgement Receipt

EFS ID:	35213278
Application Number:	14284194
International Application Number:	
Confirmation Number:	4034
Title of Invention:	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY
First Named Inventor/Applicant Name:	Joshua RABINOWITZ
Customer Number:	22852
Filer:	Huimin Chen/Susan Benesh
Filer Authorized By:	Huimin Chen
Attorney Docket Number:	15058.0002-00000
Receipt Date:	21-FEB-2019
Filing Date:	21-MAY-2014
Time Stamp:	14:28:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 1350
RAM confirmation Number	022219INTEFSW14310100
Deposit Account	
Authorized User	

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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment Submitted/Entered with Filing of CPA/RCE	15058_0002_00_Amendment_as_filed.pdf	69828	no	17
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Warnings:					
Information:					
2	Request for Continued Examination (RCE)	15058_0002_00_RCE_Form_as_filed.pdf	180636	no	3
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Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	15058_0002_00_SB08_as_filed.pdf	30647	no	2
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Warnings:					
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7	Foreign Reference	15058_0002_00_WO2014151434A2_as_filed.pdf	2395375 f89cfd1cfd39c08b1c2240bd6e796a30c0e654e3	no	29
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	32438 4e88862638051d49d3250d7be1e8402b28ee4a6b	no	2
Warnings:					
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Total Files Size (in bytes):			3936583		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No.: 14/284,194	)	Examiner: Michael J. FELTON
	)	
Filed: May 21, 2014	)	Confirmation No.: 4034
	)	
For: COMPOSITIONS, DEVICES, AND	)	
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	

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Commissioner:

AMENDMENT WITH REQUEST FOR CONTINUED EXAMINATION

This Amendment accompanies a Request for Continued Examination, fulfills the requirement for a submission under 37 C.F.R. § 1.114, and responds to the Final Office Action mailed on September 10, 2018, the period for response having been extended to March 11, 2019 (March 10, 2019 being a Sunday) by a request for extension of three months and fee payment filed concurrently herewith.

Applicant proposes that this application be amended as follows:

Amendments to the Claims are reflected in the listing of claims in this paper.

Remarks/Arguments follow the amendment sections of this paper.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid;

wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1 [[7:8]]; and

wherein vaporization and condensation of the composition with a vaporizing device produces an aerosol having a gas phase and a particulate phase; and

wherein the lactic acid is present in an amount sufficient for at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase.

2. (Original) The composition of claim 1, wherein the nicotine is not in free base form.

3. (Original) The composition of claim 1, wherein the at least one solvent comprises at least one alcohol chosen from glycerol, propylene glycol, polyethylene glycol, or any combination thereof.

4-7. (Canceled)

8. (Original) The composition of claim 1, wherein a pH of the composition is within a range of about pH 7 to about pH 8.

9. (Original) The composition of claim 8, wherein a pH of the aerosol is ± 0.3 pH of the pH of the composition.

10. (Previously Presented) The composition of claim 1, further comprising at least one agent chosen from menthol, a tobacco alkaloid compound, a preservative, or a combination thereof, wherein the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2.

11. (Original) The composition of claim 1, comprising from about 1.5% to about 6.0% nicotine, from about 44% to about 48% glycerol, and from about 44% to about 48% propylene glycol, by weight with respect to the total weight of the composition.

12. (Canceled)

13. (Canceled)

14. (Original) The composition of claim 11, further comprising from about 0.1% to about 3.0% of at least one agent chosen from menthol, a tobacco alkaloid

compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.

15-32. (Canceled)

33. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid, wherein the lactic acid has a molar ratio with respect to nicotine of about 5:6, wherein vaporization and condensation of the composition with a vaporizing device produces an aerosol having a gas phase and a particulate phase, and wherein the lactic acid ~~has a molar ratio with respect to nicotine of about 5:6~~ is present in an amount sufficient for at least 85% of the nicotine by weight in the aerosol to be partitioned in to the particulate phase.

34. (Canceled)

35. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, at least one ion pairing agent comprising lactic acid, and at least one agent chosen from chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof;

wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1 ~~[[7:8]]~~, and the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2;

and wherein the lactic acid is present in an amount sufficient for at least 85% of the nicotine by weight in the aerosol to be partitioned in to the particulate phase.

36-69. (Canceled)

70. (Currently Amended) The composition of claim 1, wherein the vaporizing device is an electronic cigarette that comprises a heating element and a battery, ~~and the aerosol produced by vaporization and condensation of the composition comprises at least 85% of the nicotine by weight with respect to the total weight of the composition in a particulate phase of the aerosol.~~

71. (Previously Presented) The composition of claim 1, wherein the composition comprises about 6.0% nicotine by weight with respect to the total weight of the composition.

72. (Withdrawn) The composition of claim 10, wherein the at least one agent comprises a first agent and a second agent, and the molar ratio of the first agent relative to nicotine is greater than the molar ratio of the second agent relative to nicotine.

73. (Previously Presented) The composition of claim 10, wherein the composition comprises less than about 2% by weight of the at least one agent.

74. (Previously Presented) The composition of claim 33, further comprising about 0.1% to about 3.0% of at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.

75. (Previously Presented) The composition of claim 33, wherein the composition comprises about 4.5% or about 6.0% nicotine by weight with respect to the total weight of the composition.

76. (Previously Presented) The composition of claim 33, wherein the composition comprises about 1.0% or about 1.5% nicotine by weight with respect to the total weight of the composition.

77. (Previously Presented) The composition of claim 33, wherein the at least one solvent comprises glycerol and propylene glycol.

78. (Previously Presented) The composition of claim 35, wherein the at least one agent comprises menthol, at least one tobacco alkaloid chosen from nornicotine, myosmine, anabasine, nicotyrine, metanicotine, anatabine, nornicotyrine, or continine, or a combination thereof.

79. (Currently Amended) The composition of claim 35, wherein the at least one agent comprises menthol, and the molar ratio of menthol to nicotine is about 1:100 ~~[[or]]~~ to about 1:50.

80. (Previously Presented) The composition of claim 35, wherein the molar ratio of lactic acid to nicotine ranges from about 3:4 to about 5:6.

81. (Previously Presented) The composition of claim 35, wherein a pH of the composition is within a range of about pH 7 to about pH 8.

82. (Currently Amended) A composition comprising:
from about 1.5% to about 6.0% nicotine by weight with respect to the total weight of the composition;

lactic acid, wherein a molar ratio of the lactic acid with respect to nicotine ranges from about 2:3 to about 1:1 ~~[[7:8]]~~;

at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, the at least one agent having a molar ratio relative to nicotine of about 1:50 to about 1:400, ~~about 1:300, about 1:200, about 1:100, or about 1:50~~; and

at least one solvent;

wherein vaporization and condensation of the composition with an electronic cigarette or other vaporizing device produces an aerosol having a gas phase and a particulate phase; and

wherein the lactic acid is present in an amount sufficient for at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase.

REMARKS

I. Status of Claims

In the Non-Final Office Action dated September 10, 2018 (“the Office Action”), the Examiner:

- i. withdrew claim 72 from further consideration as being drawn to a nonelected species;
- ii. rejected claims 70, 79 and 82 under 35 U.S.C. § 112(b) as allegedly being indefinite and failing to particularly point out and distinctly claim the subject matter regarded as the invention;
- ii. rejected claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 under 35 U.S.C. § 103 as allegedly unpatentable over US Patent Publication No. US2014/000638 (“Sebastian”).

Applicant has amended claims 1, 33, 35, 70, 79 and 82. Upon entry of this amendment, claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 will remain pending and under examination. Support for amendments to claims 1, 33, and 35 can be found in the as-filed specification, for example, at [0003] and Example 1. Support for amendments to claims 79 and 82 can be found in the as-filed specification, for example at [0053] - [0054]. Support for amendments to claim 82 can be found in the as-filed specification, for example, at [0003], [0053] - [0054], and Example 1. No new matter is introduced.

II. Rejection under 35 U.S.C. § 112

The Office alleges that claim 70 is “incomplete for omitting essential steps, such omission amounting to a gap between the steps.” Office Action at p. 2. In particular, the Office states that the “omitted steps are: how aerosol is formed with 85% of the nicotine

by weight with respect to the total weight of the composition is in a particulate phase of an aerosol.” *Id.* at 2. Applicant deletes the limitation that “the aerosol produced by vaporization and condensation of the composition comprises at least 85% of the nicotine by weight with respect to the total weight of the composition in a particulate phase of the aerosol” from claim 70, and amends independent claim 1 to incorporate this limitation. Furthermore, Applicant amends claim 1 for clarity, to recite “wherein vaporization and condensation of the composition with a vaporizing device produces an aerosol having a gas phase and a particulate phase” and “wherein the lactic acid is present in an amount sufficient for at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase.” Support for these amendments can be found, for example, in [0003] and Example 1 of the as-filed specification. Applicant submits that the rejection is obviated by these amendments.

The Office alleges that the metes and bounds of claims 79 and 82 are unclear because it “is unclear if a range is being claimed or if two discrete values are being claimed.” *Id.* at 3. Applicant amends claim 79 to recite that “the molar ratio of menthol to nicotine is about 1:100 to about 1:50.” Applicant also amends claim 82 to recite “the at least one agent having a molar ratio relative to nicotine of about 1:50 to about 1:400.” Support for these amendments can be found, for example, in paragraphs [0053] - [0054] of the as-filed specification. Applicant submits that the rejection is obviated by these amendments.

II. Rejection under 35 U.S.C. § 103

Applicant respectfully traverses the Office's rejection of claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 under 35 U.S.C. § 103 as allegedly unpatentable over Sebastian.

"The key to supporting any rejection under 35 U.S.C. § 103(a) is the clear articulation of the reason(s) why the claimed invention would have been obvious.... [R]ejections on obviousness cannot be sustained with mere conclusory statements." MPEP § 2142. "[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. § 103(a) is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).... The factual inquiries ... [include determining the scope and content of the prior art and] ... [a]scertaining the differences between the claimed invention and the prior art." MPEP § 2141(II). In rejecting a claim, "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art." MPEP § 2141(III). Here, no *prima facie* case of obviousness has been established, for at least the reason that the Office has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claimed invention.

Without acquiescing to the rejection, and solely to expedite prosecution, Applicant has amended independent claims 1, 33, 35, and 82 to further define the invention. For example, amended independent claim 1 recites:

A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid;
wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1; and
wherein vaporization and condensation of the composition with a vaporizing device produces an aerosol having a gas phase and a particulate phase; and

wherein the lactic acid is present in an amount sufficient for at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase.

Applicant's specification supports the amended claim at, for example, Example 1 of the as-filed specification.

The Office alleges that while Sebastian does not specifically disclose a lactic acid to nicotine ratio of about 2:3 to 7:8, "this somewhat narrower range is within the range disclosed by Sebastian et al. of about 0.1 to about 0.5 moles of lactic acid per mole of Nicotine(0.1:1 or 1/10, 0.5:1 or 1:2) up to equimolar (1:1)." *Id.* at 7. Applicant respectfully disagrees with the Office's characterization of Sebastian. Specifically, Sebastian teaches that:

"For example, the aerosol precursor can include about 0.1 to about 0.5 moles of levulinic acid per one mole of nicotine, about 0.1 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine, or combinations thereof, up to a concentration wherein the total amount of organic acid present is equimolar to the total amount of nicotine present in the aerosol precursor." Sebastian at [0059].

Applicant submits that Sebastian does not teach that the amount of lactic acid *alone* can range from about 0.1 to about 0.5 moles per one mole of nicotine up to an equimolar concentration. Rather, Sebastian teaches that the amount of lactic acid can range *only* from about 0.1 to about 0.5 moles per one mole of nicotine, but together in combination with other organic acids (i.e., levulinic acid or pyruvic acid), the total amount of organic acid present can be up to equimolar to the total amount of nicotine. Thus, Sebastian does not teach "the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1," as required by amended claim 1.

Furthermore, Sebastian also does not teach that “the lactic acid is present in an amount sufficient for at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase,” as required in amended claim 1. Accordingly, Sebastian fails to disclose each and every element of amended claim 1. For at least the above reasons, the rejection of claim 1 under 35 U.S.C. § 103 is improper and should be withdrawn. Amended independent claims 33, 35, and 82 are directed to compositions that also require lactic acid to nicotine molar ratios of greater than 2:3 and at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase. Thus, for at least the same reasons, the rejections of claims 33, 35, and 82 under 35 U.S.C. § 103 are also improper and should be withdrawn. Dependent claims 2, 3, 8-11, 14, 70, 71 and 73-81 are similarly allowable over Sebastian, at least due to their dependence from one of allowable independent claims 1, 33, 35, and 82.

Additionally, Applicant submits that a person of ordinary skill in the art would not have had motivation to modify the teachings of Sebastian to achieve the claimed subject matter. A proper obviousness analysis requires, *inter alia*, consideration of two factors:

- (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and
- (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1164 (Fed. Cir. 2006) (quoting *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003)). “Both the suggestion and

the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

The Office alleges that with regard to claim 1, while Sebastian does not specifically disclose a lactic acid to nicotine ratio of about 2:3 to 7:8, it "would have been obvious to one of ordinary skill in the art at the time of invention to use molar ratios in the range of Sebastian et al., including ratios of 2:3 (0.66:1) and 7:8 (0.875:1)." Office Action at p. 7. Applicant submits that a person of ordinary skill in the art seeking to increase the amount of nicotine partitioning into the particulate phase relative to the gas phase when aerosolized, would not have been motivated by the teachings of Sebastian to modify the amount of lactic acid. Sebastian is entirely silent on this point. Instead, Sebastian teaches that "[o]rganic acids particularly can be incorporated into the aerosol precursor to affect the flavor, sensation, or organoleptic properties of medicaments, such as nicotine, that can be combined with the aerosol precursor." Sebastian at [0059]. That is, Sebastian does not teach that lactic acid can be used to change the amount of nicotine partitioning into the particulate phase of the aerosol. Accordingly, Sebastian does not provide suggest or motivation to modify the amount of lactic acid in order to achieve at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase, as required in amended claim 1.

Furthermore, for the reasons already described above, Applicant respectfully disagrees with the Office's characterization of the range of molar ratios of lactic acid as taught by Sebastian. Applicant submits that a person of ordinary skill in the art would understand Sebastian teaches that the amount of lactic acid can range *only* from about 0.1 to about 0.5 moles per one mole of nicotine, Applicant submits that Sebastian

actually teaches away from using lactic acid to nicotine ratio of about 2:3 to 1:1, as required by amended claim 1. Thus, the rejection of claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 should be withdrawn, for at least the reason that Sebastian does not provide teaching or suggestion to modify the lactic acid to nicotine ratio to achieve a higher partitioning of nicotine into the particulate phase.

With regard to claim 1, the Office also contends that “[t]he composition of Sebastian et al. meets all the structural limitations of the claim and is capable of being vaporized and undergo condensation. It would have been inherent that under some conditions (process limitations) a majority of the nicotine could be condensed into a particle phase.” Office Action at p. 4. Further, the Office posits that “Sebastian et al. disclose that the composition is used to make an inhalable substance that is either in the form of a vapor (i.e. a substance that is in the gas phase at a temperature lower than its critical point) or an aerosol (i.e. a suspension of fine solid particles or liquid droplets in a gas) Therefore, the composition of Sebastian et al. is capable of being used to form an aerosol where all the composition (including at least 85% of the nicotine) is in the form of liquid droplets (i.e. particulate phase).” *Id.* at 5. Applicant respectfully disagrees.

“[T]he limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art” to be inherently disclosed by the reference. *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1194-95 (Fed. Cir. 2014). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). “In relying upon

the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Applicant submits that the Sebastian does not explicitly disclose the lactic acid to nicotine molar ratios of 2:3 to 1:1. Nor has the Office provided evidence or sound reasoning to establish that the allegedly inherent feature necessarily is present in the Sebastian’s compositions. Thus, the Office has not shown how the limitations of amended claim 1 are inherently disclosed by Sebastian.

With this amendment and for the reasons argued above, Applicant submits that a *prima facie* case of obviousness has not been established. Accordingly, Applicant respectfully requests that the Office withdraw this rejection of claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82.

CONCLUSION

In view of the foregoing remarks, Applicant requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 21, 2019

By: /Huimin Chen/
Huimin Chen
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	14/284,194
Filing Date	May 21, 2014
First Named Inventor	Joshua RABINOWITZ
Art Unit	1747
Examiner Name	Michael J. FELTON
Attorney Docket Number	15058.0002-00000

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

ii. ☐ Other _____

b. ☒ Enclosed

i. ☒ Amendment/Reply

iii. ☒ Information Disclosure Statement (IDS)

ii. ☐ Affidavit(s)/ Declaration(s)

iv. ☐ Other _____

2. Miscellaneous

a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

b. ☐ Other _____

3. Fees

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 06-0916.

i. ☒ RCE fee required under 37 CFR 1.17(e)

ii. ☒ Extension of time fee (37 CFR 1.136 and 1.17)

iii. ☐ Other _____

b. ☐ Check in the amount of \$ _____ enclosed

c. ☒ Payment by credit card (~~XXXXXX-XXXX-XXXX-XXXX~~)

d. ☐ Payment by EFS-Web

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/Huimin Chen/	Date	February 21, 2019
Name (Print/Type)	Huimin Chen	Registration No.	76,845

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being EFS-Web transmitted to the United States Patent and Trademark Office (USPTO), deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the USPTO on the date shown below.

Signature			
Name (Print/Type)		Date	

This collection of information is required by 37 CFR 1.114. 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 1.11 and 1.14. This collection is estimated to take 12 minutes 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: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Instruction Sheet for RCEs

(not to be submitted to the USPTO)

NOTES:

An RCE is not a new application, and filing an RCE will not result in an application being accorded a new filing date.

Filing Qualifications:

The application must be a utility or plant application filed on or after June 8, 1995. The application cannot be a provisional application, a utility or plant application filed before June 8, 1995, a design application, or a patent under reexamination. See 37 CFR 1.114(e).

Filing Requirements:

Prosecution in the application must be closed. Prosecution is closed if the application is under appeal, or the last Office action is a final action, a notice of allowance, or an action that otherwise closes prosecution in the application (e.g., an Office action under *Ex parte Quayle*). See 37 CFR 1.114(b).

A submission and a fee are required at the time the RCE is filed. If reply to an Office action under 35 U.S.C. 132 is outstanding (e.g., the application is under final rejection), the submission must meet the reply requirements of 37 CFR 1.111. If there is no outstanding Office action, the submission can be an information disclosure statement, an amendment, new arguments, or new evidence. See 37 CFR 1.114(c). The submission may be a previously filed amendment (e.g., an amendment after final rejection).

WARNINGS:

Request for Suspension of Action:

All RCE filing requirements must be met before suspension of action is granted. A request for a suspension of action under 37 CFR 1.103(c) does not satisfy the submission requirement and does not permit the filing of the required submission to be suspended.

Improper RCE will NOT toll Any Time Period:

Before Appeal - If the RCE is improper (e.g., prosecution in the application is not closed or the submission or fee has not been filed) and the application is not under appeal, the time period set forth in the last Office action will continue to run and the application will be abandoned after the statutory time period has expired if a reply to the Office action is not timely filed. No additional time will be given to correct the improper RCE.

Under Appeal - If the RCE is improper (e.g., the submission or the fee has not been filed) and the application is under appeal, the improper RCE is effective to withdraw the appeal. Withdrawal of the appeal results in the allowance or abandonment of the application depending on the status of the claims. If there are no allowed claims, the application is abandoned. If there is at least one allowed claim, the application will be passed to issue on the allowed claim(s). See MPEP 1215.01.

See MPEP 706.07(h) for further information on the RCE practice.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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 inspection 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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No.: 14/284,194	)	Examiner: Michael J. FELTON
	)	
Filed: May 21, 2014	)	
	)	
For: COMPOSITIONS, DEVICES, AND	)	Confirmation No.: 4034
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

PETITION FOR EXTENSION OF TIME

Applicant petitions for a three-month extension of time to file a reply to the Office
Action of September 10, 2018. A small entity fee of \$700.00 is enclosed.

Please grant any additional extensions of time required to enter the attached
reply and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 21, 2019

By: /Huimin Chen/
Huimin Chen
Reg. No. 76,845
(202) 408-4000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No.: 14/284,194	)	Examiner: Michael J. FELTON
	)	
Filed: May 21, 2014	)	
	)	
For: COMPOSITIONS, DEVICES, AND	)	Confirmation No.: 4034
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed before the mailing date of a first Office Action after the filing of a Request for Continued Examination in the above-referenced application.

Copies of the U.S. patents and U.S. published patent applications are not included pursuant to 37 C.F.R. § 1.98(a)(2)(ii).

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed

documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the U.S. Patent and Trademark Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 21, 2019

By: /Huimin Chen/
Huimin Chen
Reg. No. 76,845
(202) 408-4000

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 14/284,194		Filing Date 05/21/2014		☐ To be Mailed		
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO										
APPLICATION AS FILED - PART I										
		(Column 1)	(Column 2)							
FOR		NUMBER FILED	NUMBER EXTRA	RATE (\$)		FEE (\$)				
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A	N/A	N/A						
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))		N/A	N/A	N/A						
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A	N/A	N/A						
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *		x \$40 =						
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *		x \$210 =						
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL						
APPLICATION AS AMENDED - PART II										
		(Column 1)	(Column 2)	(Column 3)						
AMENDMENT	02/21/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	* 23	Minus	** 23	= 0	x \$50 =		0		
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 4	= 0	x \$230 =		0		
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
							TOTAL ADD'L FEE		0	
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =				
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =				
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
							TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.							SLIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".							/ALA H HUNTER/			
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 14/284,194		Filing Date 05/21/2014		☐ To be Mailed		
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO										
APPLICATION AS FILED - PART I										
		(Column 1)	(Column 2)							
FOR		NUMBER FILED	NUMBER EXTRA	RATE (\$)		FEE (\$)				
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A	N/A	N/A						
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))		N/A	N/A	N/A						
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A	N/A	N/A						
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *		x \$40 =						
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *		x \$210 =						
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL						
APPLICATION AS AMENDED - PART II										
		(Column 1)	(Column 2)	(Column 3)						
AMENDMENT	10/15/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	* 22	Minus	** 23	= 0	x \$50 =		0		
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 4	= 0	x \$230 =		0		
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
							TOTAL ADD'L FEE		0	
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =				
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =				
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
							TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.							SLIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".							/TONYA Q MCBRIDE/			
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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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For: COMPOSITIONS, DEVICES, AND	)	
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

DECLARATION OF WALTON SUMNER II, M.D., UNDER 37 C.F.R. § 1.132

I, Walton Sumner II, M.D., hereby declare and state as follows:

1. I am a retired physician. I received a B.A. in biochemistry from Rice University in 1981 and an M.D. in 1985 from the University of Texas Health Science Center at Dallas. From 2001 until I retired in 2017, I held the position of associate professor in the Department of Internal Medicine Washington University in St. Louis.
2. I have served on several editorial boards, including guest co-editor of a special issue of International Journal of Environmental Research and Public Health directed to "Electronic Cigarette Use and Public Health." I have been the recipient of several invited professorships and lectureships directed to smoking cessation. Over the course of my career I have published over 60 peer-reviewed articles and over 40 abstracts, including:

Sumner W. Estimating the health consequences of replacing cigarettes with nicotine inhalers. Tob Control 2003 Jun; 12(2):124-132. PMID: 12773720
PMCID: PMC1747720

Sumner W. Permissive nicotine regulation as a complement to traditional tobacco control. BMC Public Health 2005 Feb 24; 5(1):18. PMCID: PMC554785

McQueen A, Tower S, Sumner W. Interviews with “vapers”: Implications for future research with electronic cigarettes. *Nicotine Tob Res*, 2011; 13(9): 860-7.

Caldwell B, Sumner W, Crane J. A systematic review of nicotine by inhalation: Is there a role for the inhaled route? *Nicotine Tob Res*. 2012, 14(10): 1127-1139.

Zhang Y, Sumner W, Chen D. In vitro particle size distributions in electronic and conventional cigarette aerosols suggest comparable deposition patterns. *Nicotine Tob Res* 2013, 15(2):501-8.

McQueen A, Shacham E, Sumner W, Overton ET. Beliefs, Experience, and Interest in Pharmacotherapy among Smokers with HIV. *Am J Health Behav*. 2014;38(2):284-296. PMID:PMC3964360

Sumner HM, McQueen A, Scott MJ, Sumner W. Analysis of Comments in a Petition Defending Electronic Cigarettes. *Nicotine & Tobacco Research*. 2014, 16(11):1503-11.

Martinez RE, Dhawan S, Sumner W, Williams BJ. On-line chemical composition analysis of refillable electronic cigarette aerosol - measurement of nicotine and nicotine. *Nicotine Tob Res* 2015 Oct; 17(10):1263-1269. PMID: 25542921

Abramovitz A, McQueen A, Martinez RE, Williams BJ, Sumner W. Electronic cigarettes: the nicotine hypothesis. *Medical Hypotheses*, 2015, 85(3):305-10. PMID: 26100465

3. My work in tobacco control was originally focused on reducing smoking, but by 2003 had shifted to harm reduction. Inhaled nicotine aerosols were conceptually appealing before e-cigs appeared, and I developed some harm reduction models to estimate the health consequences of widespread use. I subsequently worked with e-cig users to understand their experience in switching products, and with an aerosol laboratory to characterize e-cig aerosols. I eventually realized that nicotine in stored e-liquids undergoes oxidation to nicotine that could be interfering with nicotine clearance in a way that facilitated smoking cessation, at least for some users.
4. My *curriculum vitae* is attached to this Declaration as Exhibit A.
5. I have been engaged by the law firm Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. on behalf of Njoy Inc. (“Njoy”) to provide my opinion regarding what a “hypothetical person of ordinary skill in the art” (as defined below) would have understood or thought in May 22, 2013 about certain issues relevant to the

claims of U.S. patent application no. 14/284,194, published as US 2014/0345635 A1 on November 27, 2014 ("the present application"). I understand that Njoy is the owner this application. I have been engaged at my customary hourly consulting rate, receive no other compensation for this engagement, and my compensation for this engagement is not contingent on the outcome

6. For this assessment, I have reviewed:

U.S. patent application no. 14/284,194, published as US 2014/0345635 A1 on November 27, 2014 ("the present application");

the final Office Action dated September 10, 2018, with respect to the present application;

the Amendment with Request for Continued Examination dated February 21, 2019, with respect to the present application;

the Interview Summary dated April 29, 2019, with respect to the present application;

the non-final Office Action dated June 19, 2019, with respect to the present application (the "Office Action"); and

US 2014/0000638 A1 of Andries Don Sebastian et al., for "Reservoir and Heater System for Controllable Delivery of Multiple Aerosolizable Materials in an Electronic Smoking Article," published on January 2, 2014; "Sebastian").

7. I have been asked to consider several questions and to provide my opinions from the perspective of a person having "ordinary skill in the art" relevant to the present invention, as of May 22, 2013.

8. I understand the claims under examination that are being filed concurrently with this Declaration recite as follows:

1. A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid;

wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1; and

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element, produces an aerosol having a gas phase and a particulate phase; and

wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase.

2. The composition of claim 1, wherein the nicotine is not in free base form.
3. The composition of claim 1, wherein the at least one solvent comprises at least one alcohol chosen from glycerol, propylene glycol, polyethylene glycol, or any combination thereof.
8. The composition of claim 1, wherein a pH of the composition is within a range of about pH 7 to about pH 8.
9. The composition of claim 8, wherein a pH of the aerosol is ± 0.3 pH of the pH of the composition.
10. The composition of claim 1, further comprising at least one agent chosen from menthol, a tobacco alkaloid compound, a preservative, or a combination thereof, wherein the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2.
11. The composition of claim 1, comprising from about 1.5% to about 6.0% nicotine, from about 44% to about 48% glycerol, and from about 44% to about 48% propylene glycol, by weight with respect to the total weight of the composition.
14. The composition of claim 11, further comprising from about 0.1% to about 3.0% of at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.
33. A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid, wherein the lactic acid has a molar ratio with respect to nicotine of about 5:6, wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase, and wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase.

35. A liquid composition comprising nicotine, at least one solvent, at least one ion pairing agent comprising lactic acid, and at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof;

wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1, and the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2;

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase,

and wherein at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase.

71. The composition of claim 1, wherein the composition comprises about 6.0% nicotine by weight with respect to the total weight of the composition.

73. The composition of claim 10, wherein the composition comprises less than about 2% by weight of the at least one agent.

74. The composition of claim 33, further comprising about 0.1% to about 3.0% of at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.

75. The composition of claim 33, wherein the composition comprises about 4.5% or about 6.0% nicotine by weight with respect to the total weight of the composition.

76. The composition of claim 33, wherein the composition comprises about 1.0% or about 1.5% nicotine by weight with respect to the total weight of the composition.

77. The composition of claim 33, wherein the at least one solvent comprises glycerol and propylene glycol.

78. The composition of claim 35, wherein the at least one agent comprises menthol, at least one tobacco alkaloid chosen from nornicotine, myosmine, anabasine, nicotyrine, metanicotine, anatabine, nornicotyrine, or continine, or a combination thereof.

79. The composition of claim 35, wherein the at least one agent comprises menthol, and the molar ratio of menthol to nicotine is about 1:100 to about 1:50.

80. The composition of claim 35, wherein the molar ratio of lactic acid to nicotine ranges from about 3:4 to about 5:6.

81. The composition of claim 35, wherein a pH of the composition is within a range of about pH 7 to about pH 8.

82. A composition comprising:

from about 1.5% to about 6.0% nicotine by weight with respect to the total weight of the composition;

lactic acid, wherein a molar ratio of the lactic acid with respect to nicotine ranges from about 2:3 to about 1:1;

at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, the at least one agent having a molar ratio relative to nicotine of about 1:50 to about 1:400; and at least one solvent;

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase; and

wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase.

9. Back in May 2013, the development of nicotine-containing formulations for use in devices such as electronic cigarettes to produce aerosols with attributes such as, but not limited to, pH comparable with the parent formulation, nicotine in a specified state of ionization, nicotine partitioned in a specified ratio between liquid and gas phase, or including compounds such as non-nicotine tobacco alkaloids, would have required the skills of a scientist or medical doctor having some training in chemistry, with experience in formulating liquid compositions containing nicotine, and evaluating such formulations following vaporization/aerosolization by, for example, heating in a device such as an e-cigarette.
10. I was asked to consider whether a hypothetical person of ordinary skill in the art would have agreed in May 2013 with the Examiner's characterizations of

paragraph [0059] of Sebastian, as set forth on page 6 of the Office Action and reproduced below:

14. The applicant argues that Sebastian et al. does not teach the amount of lactic acid *alone* can range from about 0.1 to about 0.5 moles per one mole of nicotine up to an equimolar concentration. The examiner disagrees. The examiner maintains that Sebastian et al. broadly discloses that organic acids, including lactic acid, can be used up to equimolar concentration. Sebastian et al. state:

For example, organic acids, such as levulinic acid, lactic acid, and pyruvic acid, can be included in the aerosol precursor with nicotine in amounts up to being equimolar (based on total organic acid content) with the nicotine.

Although the parenthetical phrase “(based on total organic acid content)” indicates that a combination of acids may be used, the broad disclosure is that any of the organic acids can be used “up to” equimolar. It appears that the phrase is meant to indicate that the amount of acid should not exceed a 1:1 ratio.

11. In my opinion, a person of ordinary skill in the art would not have understood Sebastian to teach or suggest that the lactic acid may be included in a molar ratio up to 1:1 with nicotine.
12. The relevant part of paragraph [0059] of Sebastian (emphasis added) states:

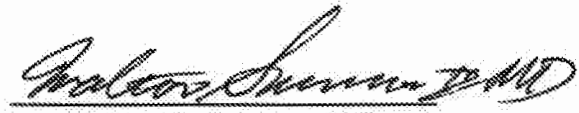
Any of the materials, such as flavorings, casings, and the like that can be useful in combination with a tobacco material to affect sensory properties thereof, including organoleptic properties, such as already described herein, can be combined with the aerosol precursor composition. Organic acids particularly can be incorporated into the aerosol precursor to affect the flavor, sensation, or organoleptic properties of medicaments, such as nicotine, that can be combined with the aerosol precursor. For example, organic acids, such as levulinic acid, lactic acid, **and** pyruvic acid, can be included in the aerosol precursor with nicotine in **amounts up to being equimolar (based on total organic acid content)** with the nicotine. **Any combination of organic acids can be used. For example, the aerosol precursor can include about 0.1 to about 0.5 moles of levulinic acid per one mole of nicotine, about 0.1 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine, or combinations thereof, up to a concentration wherein the total amount of organic acid present is equimolar to the total amount of nicotine present in the aerosol precursor.**

13. This passage is directed to adding combinations of organic acids to aerosol precursors containing a medicament, which can be nicotine. For example, it states in the plural form that “organic acids ... can be combined with the aerosol precursor” instead of indicating that one or more organic acids may be incorporated.
14. The next sentence “[f]or example, organic acids, such as levulinic acid, lactic acid, and pyruvic acid, can be included in the aerosol precursor with nicotine in amounts up to being equimolar (based on total organic acid content) with the nicotine[,]” is consistent. Again, “organic acids” are referred to in the plural form followed by identification of “levulinic acid, lactic acid, and pyruvic acid” instead of referring to the acids as alternatives. Had Sebastian intended to teach equimolar content of lactic acid and nicotine, the passage could have used one or more statements like: (a) “levulinic acid, lactic acid, or pyruvic acid;” (b) “at least one of levulinic acid, lactic acid, and pyruvic acid;” or (c) “... about 0.0 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 1.0 moles of lactic acid per one mole of nicotine, or combinations thereof...” The absence of any of these constructs in the Sebastian patent is conspicuous, suggesting that it intends to teach something else.
15. Sebastian primarily teaches separation of components for vaporization at different temperatures by a multiplicity of heating elements, not combination of components in a solution to optimize features of an aerosol produced with a single heating element. By changing nicotine ionization and therefore wicking properties, Sebastian teaches that acidification can change which heating element vaporizes nicotine, maximizing volatilization while minimizing unwanted high temperature reactions. Furthermore, Sebastian emphasizes that the organoleptic effects of the formulations taught are sensory, and does not address nicotine partitioning in aerosols, deposition in the respiratory system, or absorption by users. There is little or no chance that a person of ordinary skill would understand from Sebastian that any one or more organic acids in any concentration would favorably affect nicotine partitioning, deposition, or absorption. In contrast, the current application is explicit about these details.
16. I disagree with the Examiner’s conclusion that this passage from Sebastian would be understood by a person of ordinary skill in the art as meaning that lactic acid *alone* may be present in the aerosol precursor in an amount that is equimolar with the nicotine present, that is, in a molar ratio of lactic acid to nicotine of 1:1. In my opinion, a person of ordinary skill in the art would understand this passage as teaching one to include in the aerosol precursor a combination of organic acids that may be present in an amount that is equimolar

with the amount of nicotine present. Because the combination of organic acids is limited to an equimolar amount, no single organic acid, for example, lactic acid, may be present in an amount that is equimolar with the amount of nicotine. Therefore, Sebastian would not be understood by the person of ordinary skill as teaching that lactic acid may be present in a 1:1 molar ratio with nicotine.

17. I declare further that all statements made in this declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and the such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: October 8, 2019


Walton Sumner II, M.D.

Attachment: *Curriculum vitae*

Curriculum Vitae - Walton Sumner II, M.D.

August, 2018



Personal Information

Sex: Male
Date of birth: July 21, 1959
Place of birth: Fort Lee, Virginia

Citizenship

United States of America

Address and Telephone Numbers

St. Louis, MO
Mobile: (314) 704-6688
Email: wsumner@wustl.edu

Education

1981 B.A., Biochemistry, Rice University, Houston, Texas
1985 M.D., University of Texas Health Science Center at Dallas
1985-1988 Residency, Family Practice, The Medical Center
1989-1990 Fellowship, Family Practice Faculty Development, Family Medicine Department, Baylor College of Medicine, Houston, Texas
1990-1992 Fellowship, Medical informatics, Pathology Department, Dartmouth Medical School, Hanover, New Hampshire

Academic Positions/Employment

1979 (06-08) Research Assistant, University of Texas Health Science Center at Houston, Houston, Texas
1980-1981 Research Assistant, Rice University, Houston, Texas
1986 (11) Visiting Physician to Tenwek Hospital, Kenya
1987 (12) Visiting Physician to the Public Health Service Hospital, Kotzebue, Alaska
1986-1988 Part-time emergency room staff at:
Meriwether Memorial Hospital, Warm Springs, Georgia
Donalsonville Hospital, Donalsonville, Georgia
The Medical Center, Columbus, Georgia
Sumter County Hospital, Americus, Georgia
1986-1988 Part time physician, Alchemy drug rehabilitation center, Columbus, Georgia
1988-1989 Part time physician, PRIMUS clinic, Columbus, Georgia
1988-1989 Part time faculty, Columbus Family Medicine Associates, Columbus, Georgia
1991-1992 Part time faculty, Hitchcock clinic, Hanover, New Hampshire
1992-1996 Assistant Professor, Department of Family Practice, Kentucky Clinic, University of Kentucky, Lexington, Kentucky
1996-2000 Assistant Professor, Department of Internal Medicine, Division of General Medical Sciences, Washington University, St. Louis, Missouri
2001-2017 Associate Professor, Department of Internal Medicine, Division of General Medical Sciences, Washington University, St. Louis
2017-present Co-Owner, Sumner's Farm, LLC

Medical Licensure and Board Certification

Licensure

DEA Licensure since 1986
New Hampshire Medical Licensure from 1991 to 1992
Georgia Medical Licensure from 1986 to 1995
Kentucky Licensure from 1992 to 1997
Missouri Licensure since 1996
ABMS Board Certifications
American Board of Family Medicine since 1988
American Board of Preventive Medicine/Clinical Informatics since 2013

Military Service - none

Honors and Awards

Phi Beta Kappa, Rice University
"Recapping the accidental needlestick problem," Third place, Georgia Family Medicine Research Day, Research category, 1986
Family practice teachers' award, 1987, 1988
Magna Cum Laude, Rice University
"Family Practice Faculty Recognition Award," 1994

Editorial Responsibilities

Editorial Review Board, Medical Decision Making, 1999 – 2001
Scientific Program Committee, American Medical Informatics Association 2003 Symposium
Family Medicine Digital Resources Library, 2006 – 2009
International Journal of Environmental Research and Public Health, guest co-editor, special issue "Electronic Cigarette Use and Public Health" 2017

Professional Societies and Organizations

American Academy of Family Physicians
American Medical Informatics Association
Amaranth Institute
St. Louis County Medical Reserve Corps

Major Invited Professorships and Lectureships

1. *Smoking Cessation in Primary Care*, 2001, Missouri Baptist Department of Medicine Grand Rounds, October 17, 2001, St. Louis, Missouri.
2. *Smoking Cessation*, 2002 Leske Primary Care Symposium, March 1, 2002, St. John Medical Center, Tulsa, Oklahoma.
3. *Computer Assisted Medical Decision Making*, 2002 Leske Primary Care Symposium, March 1, 2002, St. John Medical Center, Tulsa, Oklahoma.
4. *Smoking cessation and Otolaryngology*, Otolaryngology Grand Rounds, October 31, 2007, Washington University School of Medicine, St. Louis, Missouri
5. Statistics and Quality Measurement: Why and how we are under surveillance." Missouri Baptist Grand Rounds, January 26, 2011

Consulting Relationships and Board Memberships

1. Board Member, St. Louis Academy of Family Physicians, 2006 –
2. Secretary, St. Louis Academy of Family Physicians, 2007-8
3. President, St. Louis Academy of Family Physicians, 2008-9
4. Treasurer, St. Louis Academy of Family Physicians, 2010-11
5. Treasurer, Amaranth Institute, 2018 – present

Research Support

Governmental Completed

R03 (McQueen) 04/01/13 - 06/30/16

NIH - 5R03CA175571

Usability Testing of a Web-based Tool to Help Smokers Select Cessation Aids

The aims of this study are to: (1) assess the face validity of the tool for selecting cessation aids with smokers and healthcare providers, (2) examine the process of selecting cessation aids using a cross-over trial (tool vs. print information), and (3) explore smokers' use of the web-based tool prior to an appointment with a provider via field testing. (3051-79041)

0123090001 (Sumner) 09/01/12 – 08/31/13

Global Health Economic Projects, LLC

Chronic Wound Care Patient Time-Trade-Off

This project shall be the development of an interview protocol to be used with an adapted version of the X-Trade software for the purpose of eliciting preference from patients with extremity ulcers.

Role: PI (3051-49650) \$15,250

1 R01 HL083067-01 (Yusen, PI) 01/01/06 – 12/31/10

National Heart, Lung, and Blood Institute

Lung Transplantation for COPD: Outcomes/Technology Assessment

Role: Co-Investigator

1 R03 EY017862-01 (Kymes, PI) 04/01/07 – 03/31/09

NIH/NEI

Development of a Vision-Specific Utilities Elicitation Method

Role: Co-Investigator \$150,000

R01 DP000098 09/30/04 – 9/29/08

Centers for Disease Control

Worksite Phone Counseling for Smoking Cessation

Role: Principal Investigator

Total \$1,274,655

R21 DK067172 (Schoutman, PI) 08/01/05 – 07/31/07

National Institute of Diabetes & Digestive & Kidney Diseases/NIH

Geography of Amputations Among African Americans

Role: Co-Investigator

#DAMD17-98-1-8498 (Smith, PI)

Department of Defense

Patient Preference for Outcomes Associated with Surgical Management of Prostate Cancer
Role: Co-Investigator
\$29,202

Non-Governmental Ongoing

Non-Governmental Completed

004130-0002J (Sumner)	01/01/96 – 12/31/16
ABFM	\$1,640,100
Computer Based Assessment Examination for Family Practice	
The goal of this project was to develop virtual patients and related software tools to facilitate evaluation and training of family physicians.	
Role: Co-Investigator	

American Heart Association grant # 9970162N	1999-2000
Carotid Ultrasound Report Enhancement	\$225,041
Role: Principal Investigator	

Clinical Title and Responsibilities

Medical Director, Adult triage advisory board (BJC), 2000 – 2002

Teaching Title and Responsibilities

Predoctoral

Family Practice Clerkship (MS-III) Coursemaster 1998 – 2012
Aerosol Laboratory PhD candidate medical advisor, 2012 - present

Postdoctoral

Family Practice Resident Precepting, 15% FTE, 1993 – 1996
Fellowship advisor, Medical Decision Making 1995 – 1999
Medical Resident Precepting, 15% FTE, 1996 – 2017
Fellowship advisor, Pulmonary research on nicotine, 2014
Fellowship mentor, Clinical Informatics, 2014 – 2017

Appointments and Committees

Curriculum Evaluation Committee – III, 1999
Primary Care Curriculum Task Force 2010 – 2016
Library Advisory Committee, 2002
Washington University Wellness Committee, 2007 – 2016
American Medical Informatics Association Practice Examination Item Writing Group, Masson Team, 2013 - present

Grant Review Panels

1. "Clinical Trials Data Collection Using Hand Held Technology" (Topic 181) Small Business Innovation Research, National Cancer Institute, Bethesda, MD, April 18-19, 2002
2. "Real-Time Cancer Communications Data Collection" (Topic 189), and "Technologies to promote best practices in data sharing" (Topic 188) Small Business Innovation Research, National Cancer Institute, Bethesda, MD, March 20-1, 2003
3. "Health Services Research and Development"
Veterans Administration

- Methodology section, San Diego, CA, January 20-1, 2004
 Methodology section, Washington, D.C. September 20-1, 2004
 Methodology section, San Antonio, TX. March 16-7, 2005
 Methodology section, General Health Services section, Washington, DC, August 31-September 1, 2005
4. "Health Research Council of New Zealand contestable funding round" February, 2009
 5. "Risk Prevention and Health Behavior Integrated Review Group", Bethesda, MD, Center for Scientific Review, National Institutes of Health. Special Emphasis Panel/Scientific Review Group 2010/01 ZRG1 RPHB-A (90) S
 6. Continuation of Consumer Assessment of Healthcare Providers and Systems (CAHPS IV) (U-18); Agency for Healthcare Research and Quality (AHRQ), May, 2012
 7. Special Emphasis Panel PCOR-DPHA 18, Agency for Healthcare Research and Quality, June, 2012
 8. Agency for Healthcare Research and Quality (AHRQ) RFA-HS-14-003, "Disseminating Patient Centered Outcomes Research To Improve Healthcare Delivery" January 15-17, 2014, Gaithersburg, MD.
 9. Agency for Healthcare Research and Quality (AHRQ) RFA-HS-14-007, "Deliberative Approaches: Patient and Consumer Input for Implementing Evidence-Based Health Care (R21)" May 15-16, 2014, Gaithersburg, MD.
 10. Agency for Healthcare Research and Quality (AHRQ) RFA-HS-14-008, "Accelerating the Dissemination and Implementation of PCOR Findings into Primary Care Practice (R18)" November 13-14, 2014, Gaithersburg, MD.
 11. Agency for Healthcare Research and Quality (AHRQ) Health Care Research Training (HCRT) Study Section, February 2016 to present. Rockville, MD.
 12. Agency for Healthcare Research and Quality (AHRQ) National Research Service Award (T32) ZHS1 Special Emphasis Panel Meeting. January 11-12, 2018. Rockville, MD

Bibliography

Peer-Reviewed Manuscripts

1. Sumner W, Bennett G. Anthramycin inhibition of restriction endonuclease cleavage and its use as a reversible blocking agent in DNA constructions. *Nucleic Acids Research* 1981; 9(9):2105-19. PMID: 6272225 PMCID: PMC326829
2. Rubacha A, Sumner W, Richter L, Beckingham K. Conserved 5' flank homologies in dipteran 5S RNA genes that would function on 'A' form DNA. *Nucleic Acids Res*, 1984. 12(21): p. 8193-8207. PMID: 6209610
3. Sumner W. Needlecaps to prevent needlestick injuries. *Infection Control* 1985 Dec; 6(12):495-7. PMID: 3852798
4. Huber K, Sumner W: Recapping the accidental needlestick problem. *American Journal of Infection Control* 1987 Jun; 15(3):127-30. PMID: 3113293
5. Sumner W. Needle disposal - what are we doing? *Journal of the Georgia Association of Family Practitioners* 1987; 9(4):16-18.
6. Sumner W. An evaluation of readable preventive health messages. *Family Medicine* 1991 Aug; 23(6):463-66. PMID: 1936723
7. Sumner W, Nease R, Littenberg B. U-titer: a utility assessment tool. *Proceedings of the Fifteenth Annual Symposium on Computer Applications in Medical Care* 1991:701-5. PMID: 1807694 PMCID: PMC2247621

8. Sumner W, Shultz E. Expert systems and expert behavior. *Journal of Medical Systems* 1992 Oct; 16(5):183-93. PMID: 1289466
9. Sumner W. A review of Iliad and Quick Medical Reference for primary care providers. Two diagnostic computer programs. *Archives of Family Medicine* 1993 Jan; 2(1):87-95. PMID: 8252140
10. Sumner W. Four proposals for market-based health care system reform. *Archives of Family Medicine* 1994 Aug; 3(8):660-4. PMID: 7952250
11. Zug KA, Littenberg B, Baughman RD, Kneeland T, Nease RF, Sumner W, O'Connor GT, Jones R, Morrison E, Cimis R. Assessing the preferences of patients with psoriasis: A quantitative, utility approach. *Archives of Dermatology* 1995 May; 131(5):561-568. PMID: 7741543
12. Nease RF, Kneeland T, O'Connor GT, Sumner W, Lumpkins C, Shaw L, Pryor D, Sox HC (for the Ischemic Heart Disease Patient Outcomes Research Team) Variation in patient utilities for outcomes of the management of chronic stable angina. *JAMA* 1995 Apr 19; 273(15):1185-90. PMID: 7707625
13. Sumner W, Dillman DG. A fist full of coupons: cigarette continuity programs. *Tobacco Control* 1995; 4:245-252.
14. Alexander NE, Ross J, Sumner W, Nease RF Jr, Littenberg B. The effect of an educational intervention on the perceived risk of breast cancer. *J Gen Intern Med* 1996 Feb; 11(2):92-7. PMID: 8833016
15. Sumner W, Truszczyński M, Marek VW. A formal model of family medicine. *Journal of the American Board of Family Practice* 1996 Jan-Feb; 9(1):41-52. PMID: 8770809
16. Marek VW, Sumner W. II, Truszczyński M. Creating Evolution Scenarios for Hybrid Systems. *Proceedings of IEEE-SMC Symposium on Control, Optimization and Supervision*, at CESA96, Lille 1996, pp. 512-516.
17. Sumner W, Dunaway M, Dillman DG. Cigarette continuity programs and social support for smoking. *Archives of Family Medicine* 1998 May-Jun; 7(3):264-268. PMID: 9596462
18. Sumner W, Truszczyński M, Marek VW. Simulating patients with Parallel Health State Networks. *Proc Am Med Inform Assoc Annual Symposium* 1998:438-42. PMID: 9929257 PMCID: PMC2232267
19. Bennett JE, Sumner W, Downs SM, Jaffe DM. Parent's utilities for outcomes of occult bacteremia. *Arch Pediatr Adolescent Med* 2000 Jan; 154(1):43-8. PMID: 10632249
20. Ganiats TG, Carson RT, Hamm RM, Cantor SB, Sumner W, Spann SJ, Hagen MD, Miller C: Population-based time preferences for future health outcomes. *Med Decis Making* 2000 Jul-Sep; 20(3):263-70. PMID: 10929848
21. Gage BF, Banet GA, Goldstein M, Sumner W. Development and implementation of a decision support system for carotid artery stenosis: The Carotid Ultrasound Report Enhancement (CURE). *Proc Am Med Inform Assoc Annual Symposium* 2000:280-4. PMID: 11079889 PMCID: PMC2243903
22. Marshall M, Sumner W. Family practice clerkship encounters documented with structured phrases on paper and hand-held computers. *Proc Am Med Inform Assoc Annual Symposium* 2000:547-50. PMID: 11079943 PMCID: PMC2243790
23. Merlino LA, Bagchi I, Taylor TN, Utrie P, Chrischilles E, Sumner W, Mudano A, Saag KG. Preferences for fractures and other glucocorticoid-associated adverse effects among rheumatoid arthritis patients. *Med Decis Making* 2001 Mar-Apr; 21(2):122-32. PMID: 11310945
24. Sumner W, Nease RF. Choice-matching preference reversals in health outcome assessments. *Med Decis Making* 2001 May-Jun; 21(3):208-18. PMID: 11386628

25. Sumner W. Student documentation of multiple diagnoses in family practice patients using a handheld student encounter log. *Proc Am Med Inform Assoc Annual Symposium* 2001:687-690. PMID: 11825273 PMCID: PMC2243664
26. Tosteson AN, Kneeland TS, Nease RF, Sumner W. Automated current health time-trade-off assessments in women's health. *Value in Health* 2002; 5(2):98-105. PMID: 11918825
27. Smith DS, Krygiel J, Nease RF, Sumner W, Catalona WJ. Patient preferences for outcomes associated with surgical management of prostate cancer. *J Urol* 2002 May; 167(5):2117-22. PMID: 11956454
28. Lee JS, Sineff SS, Sumner W. Validation of electronic student encounter logs in an emergency medicine clerkship. *Proc Am Med Inform Assoc Annual Symposium* 2002:425-9. PMID: 12463859 PMCID: PMC2244433
29. Sumner W, Xu J. Modeling fatigue. *Proc Am Med Inform Assoc Annual Symposium* 2002:747-51. PMID: 12463924 PMCID: PMC2244328
30. Bennett J, Nease RF, Sumner W. Evidence for the rapid construction of preference during utility assessments. *Proc Am Med Inform Assoc Annual Symposium* 2002:41-5. PMID: 12463783 PMCID: PMC2244275
31. Hagen MD, Sumner W, Roussel G, Rovinelli R, Xu J. Computer-based testing in family practice certification and recertification. *J Am Bd Fam Prac* 2003 May-Jun; 16(3):227-32. PMID: 12755250
32. Sumner W. Estimating the health consequences of replacing cigarettes with nicotine inhalers. *Tob Control* 2003 Jun; 12(2):124-132. PMID: 12773720 PMCID: PMC1747720
33. Schiffman RM, Walt JG, Jacobsen G, Doyle JJ, Lebovics G, Sumner W. Utility assessment among patients with dry eye disease. *Ophthalmology* 2003 Jul; 110(7):1412-9. PMID: 12867401
34. Krygiel JM, Smith DS, Homan SM, Sumner W 2nd, Nease RF Jr, Brownson RC, Catalona WJ. Intermediate term biochemical progression rates after radical prostatectomy and radiotherapy in patients with screen detected prostate cancer. *J Urol* 2005 Jul; 174(1):126-30. PMID: 15947596
35. Sumner W. Permissive nicotine regulation as a complement to traditional tobacco control. *BMC Public Health* 2005 Feb 24; 5(1):18. PMCID: PMC554785
36. Yusen RD, Brown KL, Habrock TE, Sumner W, Nease RF, Patterson GA, Trulock EP, Littenberg B. The impact of lung transplantation on quality of life in patients with COPD. *J Heart Lung Transpl* 2005; 24(2):S156-S157.
37. Hagen MD, Ivins DJ, Puffer JC, Rinaldo J, Roussel GH, Sumner W, Xu J. Maintenance of certification for family physicians (MC-FP) self assessment modules (SAMs): the first year. *J Am Board Fam Med* 2006 Jul-Aug; 19(4):398-403. PMID: 16809655
38. Sumner W, Campbell J, Irving SC. Developing an educational reminder system for a handheld encounter log. *Fam Med* 2006 Nov-Dec; 38(10):736-41. PMID: 17075748
39. Campbell J, DeFer T, Sumner W. Tapping trumps typing: how users enter data in an electronic student encounter log. *AMIA Annu Symp Proc* 2006: *Biomedical and Health Informatics* 2006:111-5. PMID: 17238313 PMCID: PMC1839468
40. Sumner W, Xu J, Roussel G, Hagen MD. Modeling relief. *Proc Am Med Inform Assoc Annual Symposium* 2007 Oct 11; 706-10. PMID: 18693928
41. Lee BS, Kymes SM, Nease RF, Jr., Sumner W, Siegfried CJ, Gordon MO. The impact of anchor point on utilities for 5 common ophthalmic diseases. *Ophthalmology* 2008 May; 115(5):898-903. e4. PMID: 17826833 PMCID: PMC2655778
42. Schootman M, Jeffe DB, Lian M, Deshpande AD, Gillanders WE, Aft R, Sumner W. Area-level poverty is associated with greater risk of ambulatory-care-sensitive hospitalizations

- in older breast cancer survivors. *J Am Geriatrics Soc* 2008 Dec; 56(12):2180-7. PMID: 19093916 PMCID: PMC2735731
43. Sumner W, Asaro P. An electronic encounter log's failure to scale. *Proc Am Med Inform Assoc Annual Symposium* 2008:707-11. PMID: 18998815 PMCID: PMC2655968
 44. Sumner W, Schootman M, Asaro P, Yan Y, Hagen MD. Using county level public health data to prioritize medical education topics. *J Continuing Education In The Health Professions* 2008 Fall; 28(4):197-204. PMID: 19058239
 45. Sumner II W. Health and life insurance as an alternative to malpractice tort law. *BMC Health Services Res* 2010; 10(1):150. PMID: 20525190 PMCID: PMC2902464
 46. McQueen A, Tower S, Sumner W. Interviews with "vapers": Implications for future research with electronic cigarettes. *Nicotine Tob Res*, 2011; 13(9): 860-7.
 47. Sumner W, 2nd, Hagen MD: Variation Over Time in Preventable Hospitalization Rates Across Counties. *J Am Board Fam Med* 2011, 24(6):639-646.
 48. Sumner W, O'Neill TR, Roussel G, Xu JZ, Fu H, Ivins D, Hagen MD: Family physicians' completion of scoring criteria in virtual patient encounters. *AMIA Annu Symp Proc* 2011:1355-1360. PMCID: PMC3243160.
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 53. Khoong EC, Gibbert WS, Garbutt JM, Sumner W, Brownson RC. Rural, Suburban, and Urban differences in factors that impact physician adherence to clinical preventive service guidelines. *J Rural Health*, 2014 Winter;30(1):7-16. PMCID:PMC3882340
 54. Kapp JM, Sumner W. Body Mass Index and Perception of Cancer Risk: An Opportunity for Behavioral Education? *Ann Behav Sci Med Educ*. 2013, 19(1):27-32.
 55. McQueen A, Shacham E, Sumner W, Overton ET. Beliefs, Experience, and Interest in Pharmacotherapy among Smokers with HIV. *Am J Health Behav*. 2014;38(2):284-296. PMCID:PMC3964360
 56. Sumner W, Ding E, Fischer ID, Hagen MD. Methods for Performing Survival Curve Quality of Life Assessments. *Medical Decision Making*. 2014, 34:787-99.
 57. Sumner HM, McQueen A, Scott MJ, Sumner W. Analysis of Comments in a Petition Defending Electronic Cigarettes. *Nicotine & Tobacco Research*. 2014, 16(11):1503-11.
 58. Sumner W, Stwalley DL, Asaro PV, Hagen MD, Olsen MA. Adding flexible temporal constraints to identify chronic comorbid conditions in ambulatory claims data. *AMIA, Annu Symp Proc* 2014, Nov 14; 2014:1088-97. eCollection 2014. PMICD: PMC4420007
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 60. Abramovitz A, McQueen A, Martinez RE, Williams BJ, Sumner W. Electronic cigarettes: the nicotine hypothesis. *Medical Hypotheses*, 2015, 85(3):305-10. PMID: 26100465
 61. Sumner W II, Walker MS, Highstein GR, Fischer I, Yan Y, McQueen A, Fisher EB. A randomized controlled trial of directive and nondirective smoking cessation coaching through an employee quitline. *BMC Public Health*, 2016, 16:550 PMID: 27400966

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63. Coppolino M, Avins AL, Callen A, Sumner W. Quantifying Worry in the Face of Uncertainty: Radiation Exposure from Medical Imaging. *J Med Imaging Radiat Sci*. 2017 Mar; 48(1):16-21
64. Kapp J, Sumner W. Kombucha: A Systematic Review of the Empirical Evidence of Human Health Benefit. *Ann Epidemiology* 2018. *In press*. Available online 10 November 2018. DOI: 10.1016/j.annepidem.2018.11.001

Invited Publications

1. Sumner W. Nicotine Addiction. In: Bope E, Cass A, Hagen M, editors. *Saunders Review of Family Practice*. 2 ed. Philadelphia, PA:W.B. Saunders Company; 1997.
2. Sumner W, Hagen MD, Rovinelli R. The item generation methodology of an empiric simulation project. *Advances in Health Sciences Education* 1999; 4(1):49-66. PMID: 16208435
3. Fisher E, Brownson R, Luke D, Sumner W, Heath A. Cigarette Smoking. In: *Health/Behavior handbook*. Washington, DC: *American Psychological Association* 2001.
4. Sumner W. The Integrated Health & Life Insurer: Harmonization of Patient's, Provider's, Insurer's and Public Health Perspectives. Longer Life Foundation White Paper, 2002.
5. McCord D, Xu W, Sumner W. Personal Health Records' Interoperability Between Public Health and Consumer Health Informatics. In: *Building a Roadmap for Health Information Systems Interoperability for Public Health*, White Paper of the Public Health Data Standards Consortium, 2008:54-56.

Editorials and Letters

1. Sumner W. Computer assisted patient education. *Family Medicine* 1990; 22(2):92-93. PMID: 2182363
2. Sumner W. Branded: Cigarette preferences in the medical record. *American Family Physician* 1995; 52(3):750-756. PMID: 7653414
3. Sumner W. "Thou dost protest too much" - Student reaction to the last ASPN convocation. (editorial) *Family Medicine* 2000; 32:422-423. PMID: 10879326
4. Sumner W. Argument for partial nicotine deregulation. *Lancet* 2003; 362(9397):1764. PMID: 14643135
5. Sumner W, Farsalinos K. Lessons and Guidance from the Special Issue on Electronic Cigarette Use and Public Health. *International Journal of Environmental Research and Public Health*. 2018; 15(7):1338

Abstracts

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2. Nease RF, Sumner W, Owens DK. "A methodology for estimating the cost-effectiveness of incorporating patient preferences into practice guidelines," *Medical Decision Making* 1992; 12:347.

3. Nease R, Kneeland T, O'Connor G, Sox H, Sumner W. "Variation in patient utilities for outcomes of the management of chronic stable angina. Implications for clinical practice guidelines." *Clinical Research* 1993; 41:181A.
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5. Sumner W, Nease RF, Littenberg B. Status report on automated utility assessment with U-Titer. *Medical Decision Making* 1993; 13:390.
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7. Nease R, Hynes L, Tosteson A, Littenberg B, Sumner W, Owens D. The cost-effectiveness of incorporating patient preferences into practice guidelines for mild hypertension. *Clinical Research* 1994; 42(2): 226A.
8. Tosteson ANA, Kneeland TS, Nease RF, Sumner W, Minshall M, Draper M. Feasibility of automated utility assessment in phase III clinical trials. U-Titer and a raloxifene osteoporosis prevention trial. *Medical Decision Making* 1995; 15(4):413.
9. Sumner W, Truszczynski M, Marek VW. Data Transformations for Patient Simulations. *Proceedings of the Nineteenth Annual Symposium on Computer Applications in Medical Care*, New Orleans, LA, 1995:970.
10. Sumner W, Nease RF, Foreman SE. Aligning patient and insurer incentives. *Medical Decision Making* 1995; 15(4):420.
11. Sumner W, Kang Y, Tacchi G, Stocker B, Nease R. Bisection preference search process reduces procedural variance. *Medical Decision Making* 1997; 17(4):537.
12. Sumner W, Kang Y, Tacchi G, Nease R. Flosequin is a defensible but unavailable heart failure therapy. *Medical Decision Making* 1997; 17(4):522.
13. Merlino L, Bagchi I, Taylor T, Sumner W, Nease R, Saag K. Preference values for corticosteroid associated adverse health states in 107 rheumatoid arthritis patients. *Medical Decision Making* 1998; 18(4):470.
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16. Sumner W, Hagen, MD. Using Bayesian Networks as a Scripting Language. *Proc Am Med Inform Assoc Annual Symposium* 1999:1171.
17. Sumner W, Gage B. Carotid Ultrasound Report Enhancement. American Heart Association Research symposium, May 6, 2000, Dallas, Texas.
18. Sumner W. A visual medical modeling language. *Proc Am Med Inform Assoc Annual Symposium* 2000; 1145.
19. Sumner W. RIME in a family practice clerkship. Society of Teachers of Family Medicine 28th Annual Predoctoral Education Conference, February 2, 2002, Tampa, Florida.
20. Sumner W. Decision support opportunities in off-site clerkships. Society of Teachers of Family Medicine 28th Annual Predoctoral Education Conference, February 2, 2002, Tampa, Florida.
21. Sumner W. Uses of electronic student encounter logs. Society of General Internal Medicine Midwest Regional Meeting, September 27, 2002, Chicago, Illinois.
22. Campbell J, Sumner W. OOPS: A Hand-Held Interface for Recording Medical Errors. AMIA 2005: Biomedical and Health Informatics. October 24, 2005, Washington DC. PMID: 16779197, PMCID: PMC1560645
23. Lee A, Sharkey A, McGann K, Sumner W. Mapping Students' Clinical Experiences to Pediatric Clerkship Goals. AMIA Annu Symp Proc 2006: Biomedical and Health

- Informatics 2006:1003 (November 14, Washington DC) PMID: 17238622, PMCID: PMC1839346
24. Kymes S, Lee BS, McIntosh LD, Nease RF, Sumner W. Preference Based Measurement of Vision-Related Quality of Life: Are We Mixing Apples and Oranges? iHEA 2007 6th World Congress: Explorations in Health Economics Copenhagen, Denmark, June 2007
 25. Sumner W, Hagen MD. Value of information in virtual patients portraying pharyngitis. AMIA Annu Symp Proc 2008 Nov 6:1150. PMID: 18998813
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 27. Sumner W, Hagen MD. Value of information in virtual patient performance evaluations. AMIA Annu Symp Proc 2008 Nov 6:1149. PMID: 18998811
 28. Mittler B, Littenberg B, Sumner W, Brown K, Habrock T, Nease RF, Thompson P, Yusen RD. Validity of a Computer-Based Patient Preference (Utility) Instrument for Assessing Quality of Life in Patients with COPD. Am J Resp Crit Care Med 2008; 177:A574. Presented at the American Thoracic Society meeting, Toronto, Canada, May 20, 2008.
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 30. Sumner W, Asaro P, Hagen MD: Diagnosis switches associated with asthma in emergency claims data. AMIA Annu Symp Proc 2011:1977.
 31. Sumner W, Hagen MD: Survival-Based Quality Of Life Assessments. In: The 33rd Annual Meeting of the Society for Medical Decision Making. Chicago, IL; 2011.
 32. Kapp JM, Sumner W: BMI, Cancer Risk Perception, and Preventive Beliefs. In: The 33rd Annual Meeting of the Society for Medical Decision Making. Chicago, IL; 2011.
 33. Bennett WE, Sumner W: Voice Recognition for a Point-Of-Care History Taking Tool Written for iOS and Implemented on the Apple iPad. AMIA Annu Symp Proc 2011:1689.
 34. Hagen MD, O'Neill T, Owens P, Schootman M, Sumner W. ABFM Examination Asthma Item Performance and Asthma Prevention Quality Indicators in Kentucky. The 13th Annual Kentucky Rural Health Association Conference, Bowling Green, KY, July 21, 2011.
 35. McIntosh LD, Sumner W, George B, Kalantri P, Khot S, Juehne A, Nagarajan R. Information Extraction from Medical Documents to Determine Alcohol, Tobacco, and Illicit Drug Use. AMIA 2013 Annual Symposium, Washington, DC, Nov. 16, 2013.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No.: 14/284,194	)	Examiner: Michael J. FELTON
	)	
Filed: May 21, 2014	)	
	)	
For: COMPOSITIONS, DEVICES, AND	)	Confirmation No.: 4034
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

PETITION FOR EXTENSION OF TIME

Applicant petitions for a one month extension of time to file a reply to the Office
Action of June 19, 2019. A fee of \$200.00 is enclosed.

Please grant any additional extensions of time required to enter the attached
reply and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: October 15, 2019

By: /Huimin Chen/
Huimin Chen
Reg. No. 76,845
(202) 408-4000

Electronic Patent Application Fee Transmittal				
Application Number:		14284194		
Filing Date:		21-May-2014		
Title of Invention:		COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY		
First Named Inventor/Applicant Name:		Joshua RABINOWITZ		
Filer:		Huimin Chen/Dana Lutz		
Attorney Docket Number:		15058.0002-00000		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 1 month with \$0 paid	1251	1	200	200
Miscellaneous:				
Total in USD (\$)				200

Electronic Acknowledgement Receipt

EFS ID:	37454347
Application Number:	14284194
International Application Number:	
Confirmation Number:	4034
Title of Invention:	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY
First Named Inventor/Applicant Name:	Joshua RABINOWITZ
Customer Number:	22852
Filer:	Huimin Chen/Dana Lutz
Filer Authorized By:	Huimin Chen
Attorney Docket Number:	15058.0002-00000
Receipt Date:	15-OCT-2019
Filing Date:	21-MAY-2014
Time Stamp:	10:47:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 200
RAM confirmation Number	E20190EA47284931
Deposit Account	060916
Authorized User	Dana Lutz

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:
37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment Copy Claims/Response to Suggested Claims	15058_0002-00000_FINAL_Amendment.pdf	201370	no	16
			e9ef54a358369eae84f1dce7b4fdb3fe97b6a412		
Warnings:					
Information:					
2	Affidavit-traversing rejectns or objectns rule 132	15058_0002-00000_132_Declaration_Signed.pdf	324379	no	9
			505a79c84d468ba00c28379be105b59c7bae7e4b		
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	Walton_Sumner_II_CV.pdf	285263	no	14
			4c8d071a2b7197591d81e9370e0fa0782b8f80c6		
Warnings:					
Information:					
4	Extension of Time	15058_0002-00000_FINAL_1_EXTENSION.pdf	92977	no	1
			032527a42b063b0fb3fafbc587a91a8b66bd64b		
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30823	no	2
			47523b716ff23041e94be315c341c4163b4de831		
Warnings:					
Information:					
Total Files Size (in bytes):			934812		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No.: 14/284,194	)	Examiner: Michael J. FELTON
	)	
Filed: May 21, 2014	)	
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For: COMPOSITIONS, DEVICES, AND	)	Confirmation No.: 4034
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

AMENDMENT AND REPLY TO OFFICE ACTION

In reply to the Office Action mailed June 19, 2019, the period for response having been extended to October 21, 2019 (October 19, 2019, being a Saturday) by a request for extension of one month and fee payment filed concurrently herewith, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims in this paper.

Remarks/Arguments follow the amendment sections of this paper.

Attachments to this amendment include (1) Declaration by Dr. Walton Sumner II, M.D. and (2) Curriculum vitae of Dr. Walton Sumer II, M.D.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid;

wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1; and

wherein vaporization and condensation of the composition with ~~a vaporizing device~~ an electronic cigarette comprising a battery and a heating element, produces an aerosol having a gas phase and a particulate phase; and

wherein ~~the lactic acid is present in an amount sufficient for~~ at least 85% of the nicotine by weight in the aerosol ~~[[to be]]~~ is partitioned into the particulate phase.

2. (Original) The composition of claim 1, wherein the nicotine is not in free base form.

3. (Original) The composition of claim 1, wherein the at least one solvent comprises at least one alcohol chosen from glycerol, propylene glycol, polyethylene glycol, or any combination thereof.

4-7. (Canceled)

8. (Original) The composition of claim 1, wherein a pH of the composition is within a range of about pH 7 to about pH 8.

9. (Original) The composition of claim 8, wherein a pH of the aerosol is ± 0.3 pH of the pH of the composition.

10. (Previously Presented) The composition of claim 1, further comprising at least one agent chosen from menthol, a tobacco alkaloid compound, a preservative, or a combination thereof, wherein the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2.

11. (Original) The composition of claim 1, comprising from about 1.5% to about 6.0% nicotine, from about 44% to about 48% glycerol, and from about 44% to about 48% propylene glycol, by weight with respect to the total weight of the composition.

12. (Canceled)

13. (Canceled)

14. (Original) The composition of claim 11, further comprising from about 0.1% to about 3.0% of at least one agent chosen from menthol, a tobacco alkaloid

compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.

15-32. (Canceled)

33. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid, wherein the lactic acid has a molar ratio with respect to nicotine of about 5:6, wherein vaporization and condensation of the composition with ~~a vaporizing device~~ an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase, and wherein ~~the lactic acid is present in an amount sufficient for~~ at least 85% of the nicotine by weight in the aerosol ~~[[to be]]~~ is partitioned into the particulate phase.

34. (Canceled)

35. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, at least one ion pairing agent comprising lactic acid, and at least one agent chosen from chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof;

wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1, and the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2;

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase,

and wherein ~~the lactic acid is present in an amount sufficient for~~ at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase.

36-69. (Canceled)

70. (Canceled)

71. (Previously Presented) The composition of claim 1, wherein the composition comprises about 6.0% nicotine by weight with respect to the total weight of the composition.

72. (Withdrawn) The composition of claim 10, wherein the at least one agent comprises a first agent and a second agent, and the molar ratio of the first agent relative to nicotine is greater than the molar ratio of the second agent relative to nicotine.

73. (Previously Presented) The composition of claim 10, wherein the composition comprises less than about 2% by weight of the at least one agent.

74. (Previously Presented) The composition of claim 33, further comprising about 0.1% to about 3.0% of at least one agent chosen from menthol, a

tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.

75. (Previously Presented) The composition of claim 33, wherein the composition comprises about 4.5% or about 6.0% nicotine by weight with respect to the total weight of the composition.

76. (Previously Presented) The composition of claim 33, wherein the composition comprises about 1.0% or about 1.5% nicotine by weight with respect to the total weight of the composition.

77. (Previously Presented) The composition of claim 33, wherein the at least one solvent comprises glycerol and propylene glycol.

78. (Previously Presented) The composition of claim 35, wherein the at least one agent comprises menthol, at least one tobacco alkaloid chosen from nornicotine, myosmine, anabasine, nicotyrine, metanicotine, anatabine, nornicotyrine, or continine, or a combination thereof.

79. (Previously Presented) The composition of claim 35, wherein the at least one agent comprises menthol, and the molar ratio of menthol to nicotine is about 1:100 to about 1:50.

80. (Previously Presented) The composition of claim 35, wherein the molar ratio of lactic acid to nicotine ranges from about 3:4 to about 5:6.

81. (Previously Presented) The composition of claim 35, wherein a pH of the composition is within a range of about pH 7 to about pH 8.

82. (Currently Amended) A composition comprising:
from about 1.5% to about 6.0% nicotine by weight with respect to the total weight of the composition;

lactic acid, wherein a molar ratio of the lactic acid with respect to nicotine ranges from about 2:3 to about 1:1;

at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, the at least one agent having a molar ratio relative to nicotine of about 1:50 to about 1:400; and

at least one solvent;

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element ~~or other vaporizing device~~ produces an aerosol having a gas phase and a particulate phase; and

wherein ~~the lactic acid is present in an amount sufficient for~~ at least 85% of the nicotine by weight in the aerosol ~~[[to be]]~~ is partitioned into the particulate phase.

REMARKS

I. Status of Claims

In the Non-Final Office Action dated September 10, 2018 (“the Office Action”), the Office:

- i. rejected claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 under 35 U.S.C. § 112(a) as allegedly not enabling for a person skilled in the art to which it pertains to form the composition of the invention commensurate in scope with the claims;
- ii. rejected claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 under 35 U.S.C. § 112(b) as allegedly being indefinite and failing to particularly point out and distinctly claim the subject matter regarded as the invention;
- ii. rejected claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 under 35 U.S.C. § 103 as allegedly unpatentable over US Patent Publication No. US2014/000638 (“Sebastian”).

Applicant has amended claims 1, 33, 35, and 82, and canceled claim 70. Upon entry of this amendment, claims 1-3, 8-11, 14, 33, 35, 71, and 73-82 will remain pending and under examination. Support for the amendments to claims 1, 33, 35, and 82 is found in the specification at, for example, [0013], [0062] - [0071], and in Example 1. No new matter is introduced.

II. Rejections under 35 U.S.C. §§ 112(a) and (b)

With regard to claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82, the Office contends that “the specification, while being enabling for lactic acid to nicotine molar ratios of 2:3 to about 1:1, does not reasonably provide enablement for ‘lactic acid is present in an amount sufficient for at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase.’” Office Action at p. 2-3. Specifically, the

Office alleges that “[o]ne of ordinary skill would not be able to make and use the composition over the entire scope of the claimed invention without undue experimentation,” because not only are there “numerous methods of vaporizing,” but also “there are thousands of types of electronic cigarettes (heating coils, tobacco heaters, ink jets, piezoelectric, capillary, pressurized gas, etc.).” *Id.* at 3.

Applicant respectfully disagrees. Without acquiescing to the rejection, and solely to advance prosecution, Applicant has amended claims 1, 35, and 82, to specify that vaporization and condensation of the liquid composition is performed with an electronic cigarette comprising a battery and a heating element. Support for these amendments can be found, for example, at [0013], [0062] - [0071], and in Example 1, of the as-filed specification. Applicant submits that the amendment obviates the rejection.

The Office also contends that claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82, are indefinite for failing to particularly point out and distinctly claim the subject matter. In particular, the Office contends that the claims are “incomplete for omitting essential steps. . . [t]he omitted steps are: how a[n] aerosol is formed with 85% of the nicotine by weight with respect to the total weight of the composition is in a particulate phase of an aerosol.” *Id.* at 4.

Applicant respectfully disagrees. Without acquiescing to the rejection, and solely to advance prosecution, Applicant has amended claims 1, 35, and 82, to specify that “vaporization and condensation of the liquid composition with an electronic cigarette comprising a battery and a heating element, produces an aerosol having a gas phase and a particulate phase.” Support for these amendments can be found, for example, at

[0013], [0062] - [0071], and in Example 1 of the as-filed specification. Applicant submits that the rejection is obviated by these amendments.

III. Rejection under 35 U.S.C. § 103

Applicant respectfully traverses the Office's rejection of claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 under 35 U.S.C. § 103 as allegedly unpatentable over Sebastian.

A. Sebastian does not teach or suggest modifying the lactic acid to nicotine ratio

"The key to supporting any rejection under 35 U.S.C. § 103(a) is the clear articulation of the reason(s) why the claimed invention would have been obvious.... [R]ejections on obviousness cannot be sustained with mere conclusory statements." MPEP § 2142. "[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. § 103(a) is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).... The factual inquiries ... [include determining the scope and content of the prior art and] ... [a]scertaining the differences between the claimed invention and the prior art." MPEP § 2141(II). In rejecting a claim, "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art." MPEP § 2141(III). Here, no *prima facie* case of obviousness has been established for at least the reason that the Office has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claimed invention.

Regarding claims 1, 3, 10, 33, and 80, the Office reasons that while Sebastian does not specifically disclose a lactic acid to nicotine ratio of about 2:3 to 1:1, "this somewhat narrower range is within the range disclosed by Sebastian et al. of about 0.1

to about 0.5 moles of lactic acid per mole of Nicotine (0.1:1 or 1/10, 0.5:1 or 1:2) up to equimolar (1:1).” *Id.* at 7. Applicant respectfully disagrees with the Office’s characterization of Sebastian for at least the reasons of the record, and the following reasons. Specifically, Sebastian teaches that:

“For example, organic acids, such as levulinic acid, lactic acid, and pyruvic acid, can be included in the aerosol precursor with nicotine in amounts up to being equimolar (based on total organic acid content) with the nicotine. Any combination of organic acids can be used. For example, the aerosol precursor can include about 0.1 to about 0.5 moles of levulinic acid per one mole of nicotine, about 0.1 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine, or combinations thereof, up to a concentration wherein the total amount of organic acid present is equimolar to the total amount of nicotine present in the aerosol precursor.” Sebastian at [0059].

Applicant submits that Sebastian does not teach that the amount of lactic acid *alone* can range from about 0.1 to about 0.5 moles per one mole of nicotine up to an equimolar concentration. Rather, Sebastian teaches that the amount of lactic acid can range *only* from about 0.1 to about 0.5 moles per one mole of nicotine, but together in combination with other organic acids (i.e., levulinic acid or pyruvic acid), the total amount of organic acid present can be up to equimolar to the total amount of nicotine. Thus, Sebastian does not teach “the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1,” as required by amended claim 1.

In an effort to advance prosecution, Applicant submits a declaration under 37 C.F.R. § 1.132 by Dr. Walton Sumner II, M.D. (“Sumner Declaration”), discussing what a person of ordinary skill in the art would or would not have understood from reading Sebastian. As explained by Dr. Sumner in his declaration, [0059] is directed to adding combinations of organic acids to aerosol precursors containing a medicament, which

can be nicotine, and states in the plural form that “organic acids ... can be combined with the aerosol precursor” instead of indicating that one or more organic acids may be incorporated. Sumner Declaration at paragraph 13. Dr. Sumner also posits that “[h]ad Sebastian intended to teach equimolar content of lactic acid and nicotine, the passage could have used one or more statements like: (a) “levulinic acid, lactic acid, or pyruvic acid;” (b) “at least one of levulinic acid, lactic acid, and pyruvic acid;” or (c) “... about 0.0 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 1.0 moles of lactic acid per one mole of nicotine, or combinations thereof...” Accordingly, “[t]he absence of any of these constructs in the Sebastian patent is conspicuous, suggesting that it intends to teach something else.” Sumner Declaration at paragraph 14. Thus, a person of ordinary skill in the art would understand [0059] of Sebastian “as teaching one to include in the aerosol precursor a combination of organic acids that may be present in an amount that is equimolar with the amount of nicotine present.” Sumner Declaration at paragraph 16. Since “the combination of organic acids is limited to an equimolar amount, no single organic acid, for example, lactic acid, may be present in an amount that is equimolar with the amount of nicotine,” then logically “Sebastian would not be understood by the person of ordinary skill as teaching that lactic acid may be present in a 1:1 molar ratio with nicotine.” Sumner Declaration at paragraph 16.

Furthermore, Applicant submits that there are no examples or data in Sebastian to support the Office’s interpretation of [0059]. Accordingly, the only guidance regarding the molar ratio of lactic acid to nicotine to one of ordinary skill in the art comes solely from:

“For example, the aerosol precursor can include about 0.1 to about 0.5 moles of levulinic acid per one mole of nicotine, about 0.1 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine, or combinations thereof, up to a concentration wherein the total amount of organic acid present is equimolar to the total amount of nicotine present in the aerosol precursor.” [0059].

As explained above, the only reasonable interpretation of this passage that one of ordinary skill in the art could draw, is that the amount of lactic acid can range *only* from about 0.1 to about 0.5 moles per one mole of nicotine, but together in combination with other organic acids (i.e., levulinic acid or pyruvic acid), the total amount of organic acid present can be up to equimolar to the total amount of nicotine. See, e.g., Sumner Declaration at paragraphs 13-14.

For at least the above reasons, Applicant submits that a person of ordinary skill in the art would understand Sebastian teaches that the amount of lactic acid can range *only* from about 0.1 to about 0.5 moles per one mole of nicotine, and that Sebastian actually teaches away from using lactic acid to nicotine ratio of about 2:3 to 1:1, as required by amended claim 1.

B. Sebastian does not recognize the lactic acid to nicotine ratio as a result-effective variable

Next, Applicant submits that Sebastian does not disclose or suggest that the claimed molar ratio relationship between the lactic acid and nicotine in the composition is a result effective variable. As described in Example 1 of the specification, Applicant demonstrated that lactic acid, when used as an ion pairing agent with nicotine, provides greater partitioning of nicotine particles into the particle phase relative to the gas phase of an aerosol when the composition is vaporized and condensed in a vaporizing device to produce the aerosol. There is no such teaching or suggestion in Sebastian.

“Sebastian primarily teaches separation of components for vaporization at different temperatures by a multiplicity of heating elements, not combination of components in a solution to optimize features of an aerosol produced with a single heating element. By changing nicotine ionization and therefore wicking properties, Sebastian teaches that acidification can change which heating element vaporizes nicotine, maximizing volatilization while minimizing unwanted high temperature reactions.” Sumner Declaration at paragraph 15. Sebastian also focuses solely on the capacity of organic acids to “affect the flavor, sensation, or organoleptic properties of medicaments, such as nicotine....” Sebastian at [0059]. Because “Sebastian emphasizes that the organoleptic effects of the formulations taught are sensory, and does not address nicotine partitioning in aerosols, deposition in the respiratory system, or absorption by users. . . [t]here is little or no chance that a person of ordinary skill would understand from Sebastian that any one or more organic acids in any concentration would favorably affect nicotine partitioning, deposition, or absorption.” Sumner Declaration at paragraph 15.

In *In re Yates*, 663 F.2d 1054, 1056-57 (C.C.P.A. 1981), the court held that the claimed invention was not obvious because there was no teaching of the *claimed relationship* in the prior art and also “no evidence of this relationship in the prior art.” The Office relies on paragraph [0059] of Sebastian as teaching the use of lactic acid with nicotine in a smoking composition. *Id.* at 8. But it is beyond dispute that Sebastian does not disclose or suggest the claimed relationship between the lactic acid to nicotine molar ratio and the “increase [in] the amount of nicotine particles partitioned in the particle phase [of the aerosol] relative to the same liquid composition without the lactic

acid.” For this reason, the rejection is contrary to established case law and should be withdrawn for this reason alone.

In *In re Antoine*, 559 F.2d 618, 620 (C.C.P.A. 1977, the court held that the claimed invention was not obvious even where the general conditions of the claim were disclosed in the prior art because the prior art did not teach or suggest that one of the claimed parameters was a result-effective variable. The prior art cited in *Antoine* did not disclose the claimed ratio, or even recognize that one of the variables in the ratio was relevant to the desired outcome. *Id.* The Office relies on Sebastian’s range of “0.1 to 0.5 moles of lactic per mole of nicotine” as suggesting Applicant’s claimed range. As in the *Antoine* case, Sebastian does not disclose that the claimed ratio is a result-effective variable, or even recognize that one of the variables, in this case lactic acid, in the ratio is relevant to the desired outcome of “increase[ing] the amount of nicotine particles partitioned in the particle phase [of the aerosol] relative to the same liquid composition without the lactic acid”. For this additional reason, the rejection is contrary to established case law and should be withdrawn.

Thus, the rejection of claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 should be withdrawn, for at least the reasons that (1) Sebastian does not provide teaching or suggestion to modify the lactic acid to nicotine ratio to achieve a at least 85% partitioning of nicotine into the particulate phase, and (2) Sebastian does not recognize the lactic acid to nicotine ratio as a result-effective variable.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: October 15, 2019

By: /Huimin Chen/
Huimin Chen
Reg. No. 76,845
(202) 408-4000

Attachments: Declaration by Dr. Walton Sumner II, M.D.
Curriculum Vitae of Dr. Walton Sumner II, M.D.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/284,194	Filing Date 05/21/2014	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 = *		x \$40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		x \$210 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED - PART II

	(Column 1)		(Column 2)	(Column 3)	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	05/12/2020		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	* 20	Minus	** 23	= 0	x \$50 = 0
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 4	= 0	x \$230 = 0
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						0
AMENDMENT			CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/SHAREILL A COLES/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".						
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.						

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	14/284,194
Filing Date	May 21, 2014
First Named Inventor	Joshua RABINOWITZ
Art Unit	1747
Examiner Name	Michael J. FELTON
Attorney Docket Number	15058.0002-00000

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

ii. ☐ Other _____

b. ☒ Enclosed

i. ☒ Amendment/Reply

iii. ☐ Information Disclosure Statement (IDS)

ii. ☐ Affidavit(s)/ Declaration(s)

iv. ☒ Other Three-Month Extension of Time

2. Miscellaneous

a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

b. ☐ Other _____

3. Fees

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

a. ☒ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 06-0916.

i. ☒ RCE fee required under 37 CFR 1.17(e)

ii. ☒ Extension of time fee (37 CFR 1.136 and 1.17)

iii. ☐ Other _____

b. ☐ Check in the amount of \$ _____ enclosed

c. ☐ Payment by credit card (Form PTO-2038 enclosed)

d. ☒ Payment by EFS-Web

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/Steven P. O'Connor/	Date	May 12, 2020
Name (Print/Type)	Steven P. O'Connor	Registration No.	41,225

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being EFS-Web transmitted to the United States Patent and Trademark Office (USPTO), deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the USPTO on the date shown below.

Signature		Date	
Name (Print/Type)		Date	

This collection of information is required by 37 CFR 1.114. 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 1.11 and 1.14. This collection is estimated to take 12 minutes 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: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Instruction Sheet for RCEs

(not to be submitted to the USPTO)

NOTES:

An RCE is not a new application, and filing an RCE will not result in an application being accorded a new filing date.

Filing Qualifications:

The application must be a utility or plant application filed on or after June 8, 1995. The application cannot be a provisional application, a utility or plant application filed before June 8, 1995, a design application, or a patent under reexamination. See 37 CFR 1.114(e).

Filing Requirements:

Prosecution in the application must be closed. Prosecution is closed if the application is under appeal, or the last Office action is a final action, a notice of allowance, or an action that otherwise closes prosecution in the application (e.g., an Office action under *Ex parte Quayle*). See 37 CFR 1.114(b).

A submission and a fee are required at the time the RCE is filed. If reply to an Office action under 35 U.S.C. 132 is outstanding (e.g., the application is under final rejection), the submission must meet the reply requirements of 37 CFR 1.111. If there is no outstanding Office action, the submission can be an information disclosure statement, an amendment, new arguments, or new evidence. See 37 CFR 1.114(c). The submission may be a previously filed amendment (e.g., an amendment after final rejection).

WARNINGS:

Request for Suspension of Action:

All RCE filing requirements must be met before suspension of action is granted. A request for a suspension of action under 37 CFR 1.103(c) does not satisfy the submission requirement and does not permit the filing of the required submission to be suspended.

Improper RCE will NOT toll Any Time Period:

Before Appeal - If the RCE is improper (e.g., prosecution in the application is not closed or the submission or fee has not been filed) and the application is not under appeal, the time period set forth in the last Office action will continue to run and the application will be abandoned after the statutory time period has expired if a reply to the Office action is not timely filed. No additional time will be given to correct the improper RCE.

Under Appeal - If the RCE is improper (e.g., the submission or the fee has not been filed) and the application is under appeal, the improper RCE is effective to withdraw the appeal. Withdrawal of the appeal results in the allowance or abandonment of the application depending on the status of the claims. If there are no allowed claims, the application is abandoned. If there is at least one allowed claim, the application will be passed to issue on the allowed claim(s). See MPEP 1215.01.

See MPEP 706.07(h) for further information on the RCE practice.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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 inspection 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.

Electronic Patent Application Fee Transmittal

Application Number:	14284194			
Filing Date:	21-May-2014			
Title of Invention:	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY			
First Named Inventor/Applicant Name:	Joshua RABINOWITZ			
Filer:	Steven P. OConnor/Jane Brazier			
Attorney Docket Number:	15058.0002-00000			
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 3 months with \$0 paid	1253	1	1400	1400
Miscellaneous:				
RCE- 2ND AND SUBSEQUENT REQUEST	1820	1	1900	1900
Total in USD (\$)				3300

Electronic Acknowledgement Receipt

EFS ID:	39412654
Application Number:	14284194
International Application Number:	
Confirmation Number:	4034
Title of Invention:	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY
First Named Inventor/Applicant Name:	Joshua RABINOWITZ
Customer Number:	22852
Filer:	Steven P. OConnor/Jane Brazier
Filer Authorized By:	Steven P. OConnor
Attorney Docket Number:	15058.0002-00000
Receipt Date:	12-MAY-2020
Filing Date:	21-MAY-2014
Time Stamp:	09:09:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 3300
RAM confirmation Number	E20205B009513321
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Extension of Time	15058_0002_00_EOT3months.pdf	90334	no	1
			0376d95e09cb592bad6878313699b02adc8f2bfe		
Warnings:					
Information:					
2		15058_0002_00_Combined_Amendment_And_Definition_As Filed.pdf	829442	yes	24
			e8da22615008079a606cd38357984319683226d5		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment Submitted/Entered with Filing of CPA/RCE		1	1	
	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		8	24	
Warnings:					
Information:					
3	Request for Continued Examination (RCE)	15058_0002_00_RCE_Transmittal_Final_AsFiled.pdf	210172	no	3
			7f3b097737b557f1a2f0fcc84c494bf763326302		
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	32621	no	2
			bcb1af31c53f010091f5b0254b1e82bb3f58659f		
Warnings:					
Information:					
Total Files Size (in bytes):			1162569		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No.: 14/284,194	)	Examiner: Michael J. FELTON
	)	
Filed: May 21, 2014	)	
	)	
For: COMPOSITIONS, DEVICES, AND	)	Confirmation No.: 4034
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	<u>VIA EFS WEB</u>

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

PETITION FOR EXTENSION OF TIME

Applicant petitions for a three-month extension of time to reply to the final Office Action dated November 13, 2019. A fee of \$1,400.00 is enclosed.

Please grant any additional extensions of time required to enter the attached reply and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 12, 2020

By: /Steven P. O'Connor/
Steven P. O'Connor
Reg. No. 41,225
(202) 251-0870

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No.: 14/284,194	)	Examiner: Michael J. FELTON
	)	
Filed: May 21, 2014	)	
	)	
For: COMPOSITIONS, DEVICES, AND	)	Confirmation No.: 4034
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	<u>VIA EFS WEB</u>

Mail Stop: RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

AMENDMENT WITH REQUEST FOR CONTINUED EXAMINATION

This Amendment accompanies a Request for Continued Examination, fulfills the requirement for submission under 37 C.F.R. § 1.114, and responds to the Final Office Action dated November 13, 2019. The period for response is extended through May 13, 2020, by a petition for a three-month extension of time filed herewith. Applicant respectfully requests reconsideration of the application in view of the following amendments and remarks:

Amendments to the Claims begin at page 2 of this paper.

Remarks/Arguments follow the amendments section of this paper.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid;
wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1; and
wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element, produces an aerosol having a gas phase and a particulate phase; [[and]]
wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase; and
wherein a pH of the composition is within a range of about pH 7 to about pH 8.

2. (Original) The composition of claim 1, wherein the nicotine is not in free base form.

3. (Original) The composition of claim 1, wherein the at least one solvent comprises at least one alcohol chosen from glycerol, propylene glycol, polyethylene glycol, or any combination thereof.

- 4-7. (Canceled)

8. (Canceled)

9. (Currently Amended) The composition of claim ~~[[8]]~~1, wherein a pH of the aerosol is ± 0.3 pH of the pH of the composition.

10. (Previously Presented) The composition of claim 1, further comprising at least one agent chosen from menthol, a tobacco alkaloid compound, a preservative, or a combination thereof, wherein the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2.

11. (Original) The composition of claim 1, comprising from about 1.5% to about 6.0% nicotine, from about 44% to about 48% glycerol, and from about 44% to about 48% propylene glycol, by weight with respect to the total weight of the composition.

12. (Canceled)

13. (Canceled)

14. (Original) The composition of claim 11, further comprising from about 0.1% to about 3.0% of at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.

15-32. (Canceled)

33. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid, wherein the lactic acid has a

molar ratio with respect to nicotine of about 5:6, wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase, ~~[[and]]~~ wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase, and wherein a pH of the composition is within a range of about pH 7 to about pH 8.

34. (Canceled)

35. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, at least one ion pairing agent comprising lactic acid, and at least one agent chosen from chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof;

wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1, and the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2;

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase~~[[,]]~~;

~~[[and]]~~ wherein at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase; and

wherein a pH of the composition is within a range of about pH 7 to about pH 8.

36-70. (Canceled)

71. (Previously Presented) The composition of claim 1, wherein the composition comprises about 6.0% nicotine by weight with respect to the total weight of the composition.

72. (Withdrawn) The composition of claim 10, wherein the at least one agent comprises a first agent and a second agent, and the molar ratio of the first agent relative to nicotine is greater than the molar ratio of the second agent relative to nicotine.

73. (Previously Presented) The composition of claim 10, wherein the composition comprises less than about 2% by weight of the at least one agent.

74. (Previously Presented) The composition of claim 33, further comprising about 0.1% to about 3.0% of at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.

75. (Previously Presented) The composition of claim 33, wherein the composition comprises about 4.5% or about 6.0% nicotine by weight with respect to the total weight of the composition.

76. (Previously Presented) The composition of claim 33, wherein the composition comprises about 1.0% or about 1.5% nicotine by weight with respect to the total weight of the composition.

77. (Previously Presented) The composition of claim 33, wherein the at least one solvent comprises glycerol and propylene glycol.

78. (Previously Presented) The composition of claim 35, wherein the at least one agent comprises menthol, at least one tobacco alkaloid chosen from nornicotine, myosmine, anabasine, nicotyrine, metanicotine, anatabine, nornicotyrine, or continine, or a combination thereof.

79. (Previously Presented) The composition of claim 35, wherein the at least one agent comprises menthol, and the molar ratio of menthol to nicotine is about 1:100 to about 1:50.

80. (Previously Presented) The composition of claim 35, wherein the molar ratio of lactic acid to nicotine ranges from about 3:4 to about 5:6.

81. (Canceled)

82. (Currently Amended) A composition comprising:
from about 1.5% to about 6.0% nicotine by weight with respect to the total weight of the composition;

lactic acid, wherein a molar ratio of the lactic acid with respect to nicotine ranges from about 2:3 to about 1:1;

at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, the at least one agent having a molar ratio relative to nicotine of about 1:50 to about 1:400; and

at least one solvent;

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase; [[and]]

wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase; and

wherein a pH of the composition is within a range of about pH 7 to about pH 8.

REMARKS

I. Status of Claims

With entry of this Amendment, claims 1-3, 9-11, 14, 33, 35, 71-80, and 82 are currently pending. Applicant has amended claims 1, 33, 35, and 82 to incorporate the subject matter recited in claims 8 and 81, which are similar in language. Thus, claims 8 and 81 are now canceled without prejudice or disclaimer. Claim 9 has been amended to depend from claim 1. Claims 4-7, 12, 13, 15-32, 34, and 36-70 were previously canceled. Claim 72 was previously withdrawn. No new matter has been added by this amendment.

II. Rejection under 35 U.S.C. § 103

The Office rejects claims 1-3, 8-11, 14, 33, 35, 70, 71, and 73-82 under 35 U.S.C. § 103 as allegedly unpatentable over US2014/0000638 ("Sebastian"). Office Action at 5. Applicant respectfully traverses the rejection for the reasons explained below.

A. Sebastian Does Not Teach or Suggest "wherein a pH of the composition is within a range of about pH 7 to about pH 8"

Independent claims 1, 33, 35, and 82 have been amended to incorporate the subject matter of previous claims 8 and 81 – "wherein a pH of the composition is within a range of about pH 7 to about pH 8." As to claims 8 and 81 the Office contends that:

Sebastian et al. do not disclose the pH of the composition or the aerosol that is intended to be produced from the composition. However, it would have been obvious to one of ordinary skill in the art at the time of filing that because the acid or basic nature of the solution is not discussed, a pH neutral solution (i.e. around pH 7) would be assumed. Furthermore, the prior art teaches the same ingredients and would inherently produce the same pH as the claimed composition.

Office Action at 7. Applicant disagrees.

Sebastian is silent regarding the pH, as conceded by the Office. Furthermore, Applicant submits that a person of ordinary skill would not simply assume the claimed composition would

have a pH of about 7 to about 8, nor has the Office provided any reasoned basis or evidence supporting this assumption. The composition comprises an acid, thus, if any assumption concerning pH was made by a person of ordinary skill it would be that the composition would have a lower, *i.e.*, acidic pH relative to the pH recited in the claims.

For at least these reasons, Applicant submits that amended claims 1, 33, 35, and 82 would not have been obvious over Sebastian. Moreover, claims 2, 3, 9-11, 14, and 71-80 depend directly or indirectly from claims 1, 33, 35, and 82 and thus, incorporate the subject matter recited therein. Therefore, these claims are also not obvious, at least for the same reasons. Applicant respectfully requests withdrawal of the rejection.

B. The Office Improperly Dismisses the Declaration by Dr. Walton Sumner

In addition to the argument set forth above, Applicant submits the following separate arguments in support of patentability of the pending claims. In response to the previous Office Action, Applicant submitted, under 37 C.F.R. § 1.132, the declaration of Dr. Walton Sumner II, M.D. ("Sumner Declaration") discussing what a person of ordinary skill in the art would have understood from reading Sebastian. In reply to the Sumner Declaration, the Office stated that "the declaration concerns opinions about the language used in the prior art and does not provide evidence that the prior art is limited to combinations of organic acids." Office Action at 2. On this basis the Office presumably found the Sumner Declaration unpersuasive. But as the M.P.E.P explains, "[a]lthough factual evidence is preferable to **opinion testimony, such testimony is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue.**" M.P.E.P., 716.01(c)III (emphasis added). Applicant submits that the Sumner Declaration contains opinion testimony, not on the ultimate legal issue of obviousness, but concerning what a person of ordinary skill in the art would have understood from the teaching of Sebastian, specifically paragraph [059]. Accordingly, the Office should not dismiss the declaration on the basis that it is not evidence.

In a situation where an examiner concludes that a declaration is insufficient to overcome a rejection the M.P.E.P. instructs examiners to “set forth the reasons for the insufficiency; e.g., categories include: --untimely--; --fails to set forth facts--; --facts presented are not germane to the rejection at issue--;--showing is not commensurate in scope with the claims--; etc.”

M.P.E.P., 716 ¶ 7.66. Applicant submits that the Office has not provided any valid reason why the Summer Declaration is insufficient to overcome the rejection. Applicant respectfully requests that the Office reconsider the Summer Declaration.

As explained by Dr. Sumner in his declaration, [0059] of Sebastian is directed to adding combinations of organic acids to aerosol precursors. Sumner Declaration at paragraph 13. Dr. Sumner also states that “[h]ad Sebastian intended to teach equimolar content of lactic acid and nicotine, the passage could have used one or more statements like: (a) ‘levulinic acid, lactic acid, or pyruvic acid;’ (b) ‘at least one of levulinic acid, lactic acid, and pyruvic acid;’ or (c) ‘... about 0.0 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 1.0 moles of lactic acid per one mole of nicotine, or combinations thereof...’” *Id.* at paragraph 14. Accordingly, “[t]he absence of any of these constructs in the Sebastian patent is conspicuous, suggesting that it intends to teach something else.” *Id.* Thus, a person of ordinary skill in the art would understand paragraph [0059] of Sebastian “as teaching one to include in the aerosol precursor a combination of organic acids that may be present in an amount that is equimolar with the amount of nicotine present.” *Id.* at paragraph 16.

C. Sebastian Does Not Teach or Suggest the Lactic Acid to Nicotine Ratios Recited in the Claims

The Office concedes that Sebastian does not specifically disclose a lactic acid to nicotine ratio of about 2:3 to about 1:1 but maintains that this range would have been obvious because it is within the range disclosed by Sebastian, citing to paragraph [0059]. Office Action at 3-6. Applicant respectfully disagrees and submits that Sebastian does not teach or suggest a

molar ratio of lactic acid with respect to nicotine ranging from about 2:3 to about 1:1 (claims 1, 35, 82), or a molar ratio of lactic acid with respect to nicotine of about 5:6 (claim 33).

Paragraph [0059] of Sebastian states (emphasis added):

Organic acids particularly can be incorporated into the aerosol precursor to affect the flavor, sensation, or organoleptic properties of medicaments, such as nicotine, that can be combined with the aerosol precursor. For example, organic acids, such as levulinic acid, lactic acid, and pyruvic acid, can be included in the aerosol precursor with nicotine in amounts up to being equimolar (based on total organic acid content) with the nicotine. **Any combination of organic acids can be used. For example, the aerosol precursor can include about 0.1 to about 0.5 moles of levulinic acid per one mole of nicotine, about 0.1 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine, or combinations thereof, up to a concentration wherein the total amount of organic acid present is equimolar to the total amount of nicotine present in the aerosol precursor.**

Applicant submits, as evidenced by the Sumner Declaration, that this paragraph clearly teaches that lactic acid can be present in the composition only at a ratio of about 0.1 to about 0.5 moles per one mole of nicotine, and that the total amount of acid provided by a combination of levulinic acid, pyruvic acid, and lactic acid can be present in the composition up to a 1:1 ratio with nicotine. This does not mean that lactic acid alone can be present up to an about 1:1 ratio with nicotine.

Moreover, this is consistent with Applicant's Specification, which discloses that:

In current electronic cigarette and vaporizing/vaping e-liquid compositions, it is common for no such acid to be provided and the nicotine resides in free base form, which renders it highly volatile and leads to propensity for vaporized nicotine to remain in or reenter the gas phase, rather than residing in the particulate phase of a condensation aerosol. **Alternatively, the amount of whatever acid is present may be insufficient (e.g., less than about a 1:2 molar ratio with respect to nicotine),** or may fail to co-vaporize with the nicotine, thereby resulting in the propensity for vaporized nicotine to remain in and/or reenter the gas phase of the aerosol.

Specification at par. [044] (emphases added).

The 1:2 molar ratio, *i.e.*, 0.5 moles of acid per one mole of nicotine, described by Applicant in paragraph [044] is consistent with the teaching of Sebastian that each of the acids

listed are only present in a ratio of about 0.1 to about 0.5 moles per one mole of nicotine. Thus, Sebastian teaches compositions comprising a single acid being present in a composition at a ratio of up to 0.5 moles per mole of nicotine.

Additionally, Sebastian discloses that "any **combination** of organic acids can be used[.]" Sebastian at par. [0059] (emphasis added). The Office contends that:

one of ordinary skill would understand that this is a broad statement and that "any combination" would also encompass any one of the acids alone. Alternatively, for sake of argument, if a combination is required "any combination" would also include 99% of one acid and 1 % of another acid, which would still result in the "about 1 :1" ratio claimed

Office Action at 3. Applicant respectfully disagrees and submits that Sebastian does not define how many elements a combination must have, therefore, one must use the regular definition of a "combination." The Cambridge Dictionary defines a "combination" as "a mixture obtained when two or more things are combined." A person of ordinary skill in the art would understand that the disclosure that "any combination of acids s can be used" (emphasis added) in Sebastian means that two or more acids can be used, not that "any combination" encompasses "any one of the acids alone" as asserted by the Office.

Additionally, Applicant disagrees with the Office's assertion that "for sake of argument, if a combination is required 'any combination' would also include 99% of one acid and 1% of another acid, which would still result in the 'about 1:1' ratio claimed." Office Action at 3. Applicant submits that "combination" could not include 99% of one acid and 1% of another acid because as paragraph [0059] of Sebastian explains, within a composition the three acids listed may each be present only within a ratio of about 0.1 to about 0.5 moles per 1 mole of nicotine. Thus, considering the condition provided by Sebastian that any combination should not exceed an equimolar ratio with nicotine if one wished to obtain a composition comprising a combination of organic acids and nicotine at a 1:1 ratio, said composition comprising 1 mole of nicotine, the

most amount any one of the three acids could be present in the composition is at 0.5 moles. Thus, any single acid in the combination could not cover more than 50% of the combination.

Additionally, if one was to interpret Sebastian's reference to "any combination of organic acids" as broadly as the Office interprets it in order to cover a hypothetical combination of acid X at 99% and acid Y at 1%, this broad interpretation would encompass a very large number of combinations and a person of ordinary skill in the art would have no guidance as to how to arrive at the combination the Office posits, *i.e.*, acid X at 99% and acid Y at 1%, much less to a combination that would result in the specific ratio range recited in the present claims, *i.e.*, "lactic acid to nicotine ratio of about 2:3 to about 1:1." Thus, were the Office to interpret "any combination of organic acids," as disclosed by Sebastian to mean "any acids" at "any ratios," Applicant submits that the teachings of Sebastian would be so broad that the present claimed compositions could not be considered obvious over the large genus of compositions encompassed by the disclosures of Sebastian.

D. Sebastian Does Not Teach or Suggest "Wherein at Least 85% of the Nicotine by Weight in the Aerosol Is Partitioned into the Particulate Phase"

Regarding the "wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase" element of the claims, the Office contends that:

[b]ecause the composition of Sebastian et al. is the same as that which is claimed . . . , the composition would inherently result in, or be capable of producing **under certain conditions**, an aerosol having a gas phase and a particulate phase, and at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase.

Office Action at 6 (emphasis added).

Applicant respectfully disagrees. As the M.P.E.P. explains:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). Also, "[a]n invitation to

investigate is not an inherent disclosure” where a prior art reference “discloses no more than a broad genus of potential applications of its discoveries.” *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that “[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category” but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species).

M.P.E.P., 2112, IV (emphasis in original).

As explained above, Sebastian does not teach or suggest compositions having the lactic acid to nicotine ratios recited in the claims. Nevertheless, Applicant submits that even if Sebastian taught or suggested said ratios, which Applicant does not concede, the Office concedes that only “under certain conditions” would the compositions of Sebastian result in compositions “wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase” as recited in the present claims. This reasoning is not consistent with an allegedly inherent teaching, where “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows from the teachings of the applied prior art.” *Id.* (emphasis added). Here, the Office does not provide a basis in fact and/or technical reasoning to support that the claimed element necessarily flows from the teachings of Sebastian, but instead merely suggests that said element “may occur or be present in [Sebastian].” Additionally, Applicant submits that Sebastian is silent regarding any desired partitioning effect.

Moreover, in *Par Pharmaceutical Inc. v. Twi Pharmaceuticals, Inc.*, the Federal Circuit emphasized the high standard required to rely on the doctrine of inherency in an obviousness context – “the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.” *Par Pharm., Inc. v. Twi Pharm., Inc.*, 773 F.3d 1186 (Fed. Cir. 2014) at 1195-1196. Here, Applicants submits that the “wherein at

least 85% of the nicotine . . .” element is not present or a natural result of the combination of elements explicitly disclosed by Sebastian.

For at least these reasons, Applicant submits that the present claims comprise elements which cannot be considered inherent over the teachings of Sebastian, despite the Office’s contention.

E. Sebastian Does Not Teach or Suggest the Elements of Claim 9

Regarding claim 9, which recites “wherein a pH of the aerosol is ± 0.3 pH of the pH of the composition,” the Specification explains that

As one of ordinary skill in the art would recognize, the pH of a composition and the pH of aerosol particles produced from that composition (e.g., via vaporization and condensation) may not be the same, depending upon the nature of the ingredients or components of the composition. In some embodiments of the present disclosure, the composition ingredients may be chosen to provide for substantially the same pH in the composition as in an aerosol produced from the composition, e.g., pH values that are within ± 0.5 pH of each other, within ± 0.3 pH, within ± 0.2 pH, or within ± 0.1 pH of each other. For example, a composition having a pH of about 7.8 may generate an aerosol having a pH of about 7.7 or vice versa.

Specification at par. [0046].

Thus, a person of ordinary skill would not expect that the pH of an aerosol would be like the pH of the composition originating the aerosol. Thus, claim 9 would not be obvious to a person of ordinary skill. Particularly, Sebastian is silent regarding the pH, as conceded by the Office (“Sebastian et al. do not disclose the pH of the composition or the aerosol that is intended to be produced from the composition.” See section A above (citing Office Action at 7)). It is Applicant’s disclosure which provides the teachings for modifying a composition in such a way as to obtain an aerosol “wherein a pH of the aerosol is ± 0.3 pH of the pH of the composition.”

For at least the reasons presented above, Applicant submits that claims 1-3, 9-11, 14, 33, 35, 71-80, and 82 would not have been obvious over Sebastian. Applicant respectfully requests withdrawal of the rejection.

III. Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims. The Office is invited to contact the undersigned attorney if an interview would serve to advance the prosecution of this application.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 12, 2020

By: /Steven P. O'Connor/
Steven P. O'Connor
Reg. No. 41,225
(202) 251-0870

Attachment: Definition of "combination" from the Cambridge English Dictionary



Meaning of **combination** in English



combination

noun [C/U]

US /ˌkəm.bəˈneɪ.ʃən/



a mixture obtained when two or more things are combined:

- [C] *Green is a combination of blue and yellow.*
- [C] *A combination of tiredness and boredom made me doze off in class.*
- *We'll be working in combination with (= together with) two other departments on this project.*



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(Definition of **combination** from the Cambridge Academic Content Dictionary © Cambridge University Press)

combination | ENGLISH

combination

noun

UK /ˌkɒm.biˈneɪ.ʃən/ US /ˌkɑːm.bəˈneɪ.ʃən/



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- *This drug can be safely used **in combination with** other medicines.*
- *Her experience and energy are a **winning combination** (= a successful mixture) in business.*



[C]

an arrangement in a particular order:

- *From the letters X Y Z, we can get three combinations of two letters: XY, XZ, and YZ.*



[C]

a set of letters or numbers in a particular order that can be used to open some types of locks:

- *He forgot the combination for his bike lock.*

— More examples

- *Champagne and caviar make a wonderful combination.*
- *The school uses a combination of modern and traditional methods for teaching reading.*
- *She wears the most hideous colour combinations you could ever imagine.*
- *The bride's mother was wearing a horrible combination of green and yellow.*
- *That combination of tiredness and alcohol is extremely dangerous.*
- *Only two people know the combination for the safe.*

+ Thesaurus: synonyms and related words

(Definition of **combination** from the [Cambridge Advanced Learner's Dictionary & Thesaurus](#) © Cambridge University Press)

combination | BUSINESS ENGLISH

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[C or U]

a result of two or more things joining together:

- **a combination of sth and sth** *A combination of economic slowdown and tax cuts is having a drastic effect on public finances.*
- *New technologies work particularly well when they are used **in combination with** traditional classroom learning.*

See also

[business combination](#)

[horizontal combination](#)

[vertical combination](#)

(Definition of **combination** from the [Cambridge Business English Dictionary](#) © Cambridge University Press)

EXAMPLES of **combination**

combination

It was designed to facilitate the *combination* of qualitative methods with statistical analysis.

From [Cambridge English Corpus](#)



The generalizations are advanced on the basis of statistical data from the population census of 1897 in *combination* with other quantitative and qualitative sources.

From [Cambridge English Corpus](#)



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COLLOCATIONS WITH "COMBINATION"

combination

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combination chemotherapy

- This result challenges the conventional wisdom not of polychemotherapy, but specifically of combination chemotherapy, as a gold standard.

From *Cambridge English Corpus*



complex combination

- Punishment derived from a complex combination of sociocultural factors and longstanding legal prescriptions, doctrines and traditions.

From *Cambridge English Corpus*



dangerous combination

- Desiring the possibilities but rejecting the responsibilities is a dangerous combination.

From *Cambridge English Corpus*



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combination

combinatorial BETA

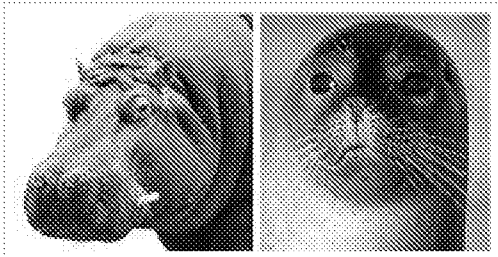
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vertical combination, at [vertical integration](#)

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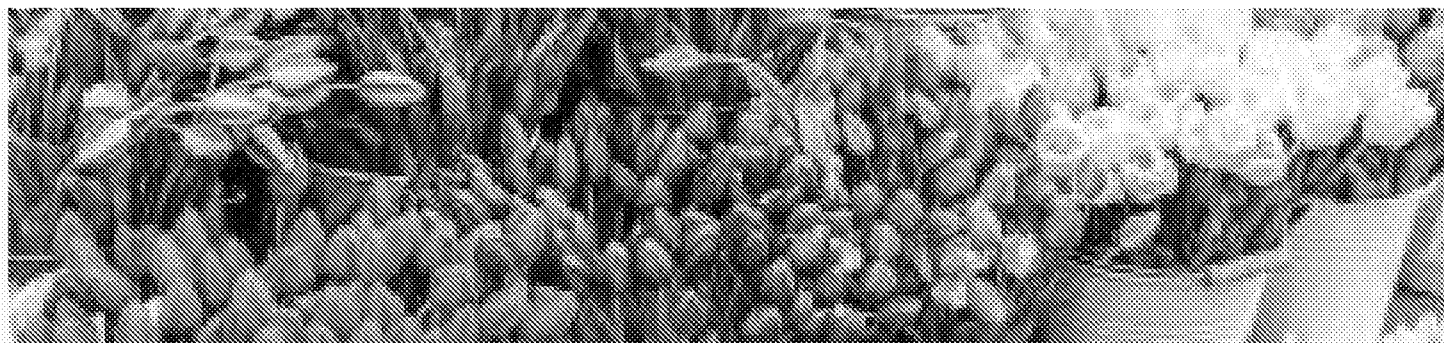
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No.: 14/284,194	)	Examiner: Michael J. FELTON
	)	
Filed: May 21, 2014	)	
	)	
For: COMPOSITIONS, DEVICES, AND	)	Confirmation No.: 4034
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	<u>VIA EFS WEB</u>

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AMENDMENT AND RESPONSE

This Amendment responds to the non-final Office Action dated December 23, 2020. The period for response is extended through June 23, 2021, by a petition for a three-month extension of time filed herewith. Applicant respectfully requests reconsideration of the application in view of the following amendments and remarks:

Amendments to the Claims begin at page 2 of this paper.

Remarks/Arguments follow the amendments section of this paper.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid;

wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1; and

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element, produces an aerosol having a gas phase and a particulate phase;

wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase; [[and]]

wherein a pH of the composition is within a range of about pH 7 to about pH 8;
and

wherein the at least one solvent comprises from about 44% to about 48% glycerol and from about 44% to about 48% propylene glycol by weight with respect to the total weight of the composition.

2. (Original) The composition of claim 1, wherein the nicotine is not in free base form.

3-8. (Canceled)

9. (Previously Presented) The composition of claim 1, wherein a pH of the aerosol is ± 0.3 pH of the pH of the composition.

10. (Previously Presented) The composition of claim 1, further comprising at least one agent chosen from menthol, a tobacco alkaloid compound, a preservative, or a combination thereof, wherein the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2.

11. (Currently Amended) The composition of claim 1, comprising from about 1.5% to about 6.0% nicotine, ~~from about 44% to about 48% glycerol, and from about 44% to about 48% propylene glycol, by weight with respect to the total weight of the composition.~~

12. (Canceled)

13. (Canceled)

14. (Original) The composition of claim 11, further comprising from about 0.1% to about 3.0% of at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.

15-32. (Canceled)

33. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, and at least one ion pairing agent comprising lactic acid,
wherein the lactic acid has a molar ratio with respect to nicotine of about 5:6,
wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase,
wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase, [[and]]
wherein a pH of the composition is within a range of about pH 7 to about pH 8;
and
wherein the at least one solvent comprises from about 44% to about 48% glycerol and from about 44% to about 48% propylene glycol by weight with respect to the total weight of the composition.

34. (Canceled)

35. (Currently Amended) A liquid composition comprising nicotine, at least one solvent, at least one ion pairing agent comprising lactic acid, and at least one agent chosen from chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof;

wherein the lactic acid has a molar ratio with respect to nicotine ranging from about 2:3 to about 1:1, and the at least one agent has a molar ratio with respect to nicotine ranging from about 1:200 to about 1:2;

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase;

wherein at least 85% of the nicotine by weight in the aerosol to be partitioned into the particulate phase; [[and]]

wherein a pH of the composition is within a range of about pH 7 to about pH 8;
and

wherein the at least one solvent comprises from about 44% to about 48% glycerol and from about 44% to about 48% propylene glycol by weight with respect to the total weight of the composition.

36-70. (Canceled)

71. (Previously Presented) The composition of claim 1, wherein the composition comprises about 6.0% nicotine by weight with respect to the total weight of the composition.

72. (Canceled)

73. (Previously Presented) The composition of claim 10, wherein the composition comprises less than about 2% by weight of the at least one agent.

74. (Previously Presented) The composition of claim 33, further comprising about 0.1% to about 3.0% of at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, by weight with respect to the total weight of the composition.

75. (Previously Presented) The composition of claim 33, wherein the composition comprises about 4.5% or about 6.0% nicotine by weight with respect to the total weight of the composition.

76. (Previously Presented) The composition of claim 33, wherein the composition comprises about 1.0% or about 1.5% nicotine by weight with respect to the total weight of the composition.

77. (Canceled) .

78. (Previously Presented) The composition of claim 35, wherein the at least one agent comprises menthol, at least one tobacco alkaloid chosen from nornicotine, myosmine, anabasine, nicotyrine, metan nicotine, anatabine, nornicotyrine, or continine, or a combination thereof.

79. (Previously Presented) The composition of claim 35, wherein the at least one agent comprises menthol, and the molar ratio of menthol to nicotine is about 1:100 to about 1:50.

80. (Previously Presented) The composition of claim 35, wherein the molar ratio of lactic acid to nicotine ranges from about 3:4 to about 5:6.

81. (Canceled)

82. (Currently Amended) A composition comprising:
from about 1.5% to about 6.0% nicotine by weight with respect to the total weight of the composition;

lactic acid, wherein a molar ratio of the lactic acid with respect to nicotine ranges from about 2:3 to about 1:1;

at least one agent chosen from menthol, a tobacco alkaloid compound, a non-tobacco flavor, or a combination thereof, the at least one agent having a molar ratio relative to nicotine of about 1:50 to about 1:400; and

at least one solvent comprising from about 44% to about 48% glycerol and from about 44% to about 48% propylene glycol by weight with respect to the total weight of the composition.

wherein vaporization and condensation of the composition with an electronic cigarette comprising a battery and a heating element produces an aerosol having a gas phase and a particulate phase;

wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase; and

wherein a pH of the composition is within a range of about pH 7 to about pH 8.

83. (New) The method of claim 1, wherein the at least one solvent comprises about 45% glycerol and about 45% polyethylene glycol by weight with respect to the total weight of the composition.

84. (New) The method of claim 33, wherein the at least one solvent comprises about 45% glycerol and about 45% polyethylene glycol by weight with respect to the total weight of the composition.

85. (New) The method of claim 35, wherein the at least one solvent comprises about 45% glycerol and about 45% polyethylene glycol by weight with respect to the total weight of the composition.

86. (New) The method of claim 82, wherein the at least one solvent comprises about 45% glycerol and about 45% polyethylene glycol by weight with respect to the total weight of the composition.

REMARKS

I. Status of Claims

With entry of this Amendment, claims 1-2, 9-11, 14, 33, 35, 71-80, and 82-86 are currently pending. Applicant has amended claims 1, 11, 33, 35, and 82 to incorporate subject matter recited in claims 3 and 11. Claim 3 has been canceled without prejudice or disclaimer. Claims 83-86 are new and incorporate subject matter recited in claims 3 and 11, and depend from claims 1, 33, 35, and 82, respectively. No new matter has been added by this amendment.

II. Rejection under 35 U.S.C. § 103

The Office rejects claims 1-3, 9-11, 14, 33, 35, 71, and 73-82 under 35 U.S.C. § 103 as allegedly unpatentable over US 2014/0000638 ("Sebastian"). Office Action at 3. Applicant respectfully traverses the rejection for the reasons explained below.

A. Sebastian Does Not Teach or Suggest "at least one solvent comprising from about 44% to about 48% glycerol and from about 44% to about 48% propylene glycol by weight with respect to the total weight of the composition."

Independent claims 1, 33, 35, and 82 have been amended to incorporate the subject matter of claims 3 and 11 – "at least one solvent comprising from about 44% to about 48% glycerol and from about 44% to about 48% propylene glycol by weight with respect to the total weight of the composition." In addressing this claim language the Office acknowledges that "[g]lycerol and propylene glycol are both expressly disclose[d in Sebastian] but about 44-48% of each is not expressly disclosed." But the Office contends "it would have been obvious to one of ordinary skill in the art at the time of invention to split the 98% as indicated by Sebastian et al., in half between two polyols,

such as glycerol and propylene glycol as disclosed. This would result in less than 49% of each, which would have been considered to be 'about 44 to about 48%.'" Office Action at 5-6. Applicant disagrees.

Applicant submits that a person of ordinary skill would not have simply assumed the claimed percentages of glycerol and propylene glycol. Nor has the Office provided any reasoned basis or evidence supporting this assumption. Sebastian does not teach or suggest an equal amount of polyols:

For example, a useful aerosol precursor composition can comprise up to about 98% by weight up to about 95% by weight, or up to about 90% by weight of a polyol. This total amount can be split in any combination between two or more different polyols. For example, one polyol can comprise about 50% to about 90%, about 60% to about 90%, or about 75% to about 90% by weight of the aerosol precursor, and a second polyol can comprise about 2% to about 45%, about 2% to about 25%, or about 2% to about 10% by weight of the aerosol precursor.

Sebastian at [0060].

Sebastian teaches that one polyol might comprise the majority of the aerosol precursor composition. whereas the now claimed ranges specify an approximately equal balance of two specific polyols. New claims 83-86 further specify an equal balance of two polyols. For at least these reasons, Applicant submits that amended claims 1, 33, 35, and 82 would not have been obvious over Sebastian. Moreover, claims 2, 9-11, 14, 71-80, and 83-86 depend directly or indirectly from claims 1, 33, 35, and 82. Therefore, these claims would not have been obvious at least for the same reasons. Applicant respectfully requests withdrawal of the rejection.

B. Sebastian Does Not Teach or Suggest the Lactic Acid to Nicotine Ratios Recited in the Claims

The Office concedes that Sebastian does not specifically disclose a lactic acid to nicotine ratio of about 2:3 to about 1:1 but maintains that this range would have been obvious because it is within the range disclosed by Sebastian, citing to paragraph [0059]. Office Action at 4. Applicant respectfully disagrees and submits that Sebastian does not teach or suggest a molar ratio of lactic acid with respect to nicotine ranging from about 2:3 to about 1:1 (claims 1, 35, 82), or a molar ratio of lactic acid with respect to nicotine of about 5:6 (claim 33).

Paragraph [0059] of Sebastian states (emphasis added):

Organic acids particularly can be incorporated into the aerosol precursor to affect the flavor, sensation, or organoleptic properties of medicaments, such as nicotine, that can be combined with the aerosol precursor. For example, organic acids, such as levulinic acid, lactic acid, and pyruvic acid, can be included in the aerosol precursor with nicotine in amounts up to being equimolar (based on total organic acid content) with the nicotine. **Any combination of organic acids can be used. For example, the aerosol precursor can include about 0.1 to about 0.5 moles of levulinic acid per one mole of nicotine, about 0.1 to about 0.5 moles of pyruvic acid per one mole of nicotine, about 0.1 to about 0.5 moles of lactic acid per one mole of nicotine, or combinations thereof, up to a concentration wherein the total amount of organic acid present is equimolar to the total amount of nicotine present in the aerosol precursor.**

Applicant submits, as evidenced by the Sumner Declaration, that this paragraph clearly teaches that lactic acid can be present in the composition only at a ratio of about 0.1 to about 0.5 moles per one mole of nicotine, and that the total amount of acid provided by a combination of levulinic acid, pyruvic acid, and lactic acid can be present in the composition up to a 1:1 ratio with nicotine. This does not mean that lactic acid alone can be present up to an about 1:1 ratio with nicotine.

Moreover, this is consistent with Applicant's Specification, which discloses that:

In current electronic cigarette and vaporizing/vaping e-liquid compositions, it is common for no such acid to be provided and the nicotine resides in free base form, which renders it highly volatile and leads to propensity for vaporized nicotine to remain in or reenter the gas phase, rather than residing in the particulate phase of a condensation aerosol. **Alternatively, the amount of whatever acid is present may be insufficient (e.g., less than about a 1:2 molar ratio with respect to nicotine),** or may fail to co-vaporize with the nicotine, thereby resulting in the propensity for vaporized nicotine to remain in and/or reenter the gas phase of the aerosol.

Specification at par. [044] (emphases added).

The 1:2 molar ratio, *i.e.*, 0.5 moles of acid per one mole of nicotine, described by Applicant in paragraph [044] is consistent with the teaching of Sebastian that each of the acids listed are only present in a ratio of about 0.1 to about 0.5 moles per one mole of nicotine. Thus, Sebastian teaches compositions comprising a single acid being present in a composition at a ratio of up to 0.5 moles per mole of nicotine.

C. Sebastian Does Not Teach or Suggest "Wherein at Least 85% of the Nicotine by Weight in the Aerosol Is Partitioned into the Particulate Phase"

Regarding the "wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase" element of the claims, the Office contends that:

[b]ecause the composition of Sebastian et al. is the same as that which is claimed . . . , the composition would inherently result in, or be capable of producing **under certain conditions**, an aerosol having a gas phase and a particulate phase, and at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase.

Office Action at 6 (emphasis added).

Applicant respectfully disagrees. As the M.P.E.P. explains:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). Also, "[a]n invitation to

investigate is not an inherent disclosure” where a prior art reference “discloses no more than a broad genus of potential applications of its discoveries.” *Metabolite Labs., Inc. v. Lab.Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that “[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category” but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species).

M.P.E.P., 2112, IV (emphasis in original).

As explained above, Sebastian does not teach or suggest compositions having the lactic acid to nicotine ratios recited in the claims. Nevertheless, Applicant submits that even if Sebastian taught or suggested said ratios, which Applicant does not concede, the Office concedes that only “under certain conditions” would the compositions of Sebastian result in compositions “wherein at least 85% of the nicotine by weight in the aerosol is partitioned into the particulate phase” as recited in the present claims. This reasoning is not consistent with an allegedly inherent teaching, where “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows from the teachings of the applied prior art.” *Id.* (emphasis added). Here, the Office does not provide a basis in fact and/or technical reasoning to support that the claimed element necessarily flows from the teachings of Sebastian, but instead merely suggests that said element “may occur or be present in [Sebastian].” Additionally, Applicant submits that Sebastian is silent regarding any desired partitioning effect.

Moreover, in *Par Pharmaceutical Inc. v. Twi Pharmaceuticals, Inc.*, the Federal Circuit emphasized the high standard required to rely on the doctrine of inherency in an

obviousness context – “the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.” *Par Pharm., Inc. v. TWi Pharm., Inc.*, 773 F.3d 1186 (Fed. Cir. 2014) at 1195-1196. Here, Applicants submits that the “wherein at least 85% of the nicotine . . .” element is not present or a natural result of the combination of elements explicitly disclosed by Sebastian.

For at least these reasons, Applicant submits that the present claims comprise elements which cannot be considered inherent over the teachings of Sebastian, despite the Office’s contention.

III. Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims. The Office is invited to contact the undersigned attorney if an interview would serve to advance the prosecution of this application.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 16, 2021

By: /Steven P. O’Connor/
Steven P. O’Connor
Reg. No. 41,225
(571) 203-2718

Electronic Patent Application Fee Transmittal				
Application Number:		14284194		
Filing Date:		21-May-2014		
Title of Invention:		COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY		
First Named Inventor/Applicant Name:		Joshua RABINOWITZ		
Filer:		Steven P. OConnor/Dena Bohannon		
Attorney Docket Number:		15058.0002-00000		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 3 months with \$0 paid	1253	1	1480	1480
Miscellaneous:				
Total in USD (\$)				1480

Electronic Acknowledgement Receipt

EFS ID:	43002438
Application Number:	14284194
International Application Number:	
Confirmation Number:	4034
Title of Invention:	COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY
First Named Inventor/Applicant Name:	Joshua RABINOWITZ
Customer Number:	22852
Filer:	Steven P. OConnor/Dena Bohannon
Filer Authorized By:	Steven P. OConnor
Attorney Docket Number:	15058.0002-00000
Receipt Date:	16-JUN-2021
Filing Date:	21-MAY-2014
Time Stamp:	13:31:57
Application Type:	Utility under 35 USC 111(a)

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Payment Type	CARD
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1	Extension of Time	150580002EOT.pdf	13334	no	1
			b35d4e7d86ab5f2d989c7c7f187581a4a928f37b		
Warnings:					
Information:					
2		150580002Amendment.pdf	67728	yes	14
			c215173297f6b54dfeab242dbe46c505b928fc01		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	8	
	Applicant Arguments/Remarks Made in an Amendment		9	14	
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31055	no	2
			2680e0b2722d77a5e932db265c278737bffdfa8a		
Warnings:					
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Joshua RABINOWITZ et al.	)	Group Art Unit: 1747
	)	
Application No.: 14/284,194	)	Examiner: Michael J. FELTON
	)	
Filed: May 21, 2014	)	
	)	
For: COMPOSITIONS, DEVICES, AND	)	Confirmation No.: 4034
METHODS FOR NICOTINE	)	
AEROSOL DELIVERY	)	<u>VIA EFS WEB</u>

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

PETITION FOR EXTENSION OF TIME

Applicant petitions for a three-month extension of time to file a reply to the Office
Action of December 23, 2020. A fee of \$1,480.00 is enclosed.

Please grant any additional extensions of time required to enter the attached
reply and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 16, 2021

By: /Steven P. O'Connor/
Steven P. O'Connor
Reg. No. 41,225
(571) 203-2718

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/284,194	Filing Date 05/21/2014	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 = *		x \$40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		x \$210 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED - PART II

	(Column 1)		(Column 2)	(Column 3)	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	06/16/2021		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	* 21	Minus	** 23	= 0	x \$50 = 0
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 4	= 0	x \$240 = 0
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						0
AMENDMENT			CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/PAMELA V THERATT/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".						
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.						

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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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NOTICE OF ALLOWANCE AND FEE(S) DUE

22852 7590 09/09/2021
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

FELTON, MICHAEL J

ART UNIT

PAPER NUMBER

1747

DATE MAILED: 09/09/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/284,194	05/21/2014	Joshua RABINOWITZ	15058.0002-00000	4034

TITLE OF INVENTION: COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	12/09/2021

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

22852 7590 09/09/2021

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

Certificate of Mailing or Transmission

Hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/284,194	05/21/2014	Joshua RABINOWITZ	15058.0002-00000	4034

TITLE OF INVENTION: COMPOSITIONS, DEVICES, AND METHODS FOR NICOTINE AEROSOL DELIVERY

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	12/09/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
FELTON, MICHAEL J	1747	131-352000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/284,194	05/21/2014	Joshua RABINOWITZ	15058.0002-00000	4034
22852	7590	09/09/2021	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP			FELTON, MICHAEL J	
901 NEW YORK AVENUE, NW			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20001-4413			1747	

DATE MAILED: 09/09/2021

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. 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 30 minutes 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b) (2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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 inspection 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.

Notice of Allowability	Application No. 14/284,194		Applicant(s) RABINOWITZ et al.	
	Examiner MICHAEL J FELTON		Art Unit 1747	AIA (FITF) Status Yes

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to claim amendments received 6/16/2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ 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.

3. ☒ The allowed claim(s) is/are See Continuation Sheet. As a result of the allowed claim(s), 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**.

4. ☐ 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)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.	

/Michael J Felton/ Primary Examiner, Art Unit 1747	
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Continuation of 3. The allowed claim(s) is/are: 1-2,9-11,14,33,35,71,73-76,78-80 and 82-86

Notice of Pre-AIA or AIA Status

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

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance:
3. The applicant's arguments concerning the disclosure in Sabastian of the amounts of glycerol to propylene glycol are persuasive. In particular, Sabastian discloses that the less propylene glycol is used than glycerol, thus teaching away from using a 50:50 ratio (or the narrow range of 44-48% of each of the two compounds.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J FELTON whose telephone number is (571)272-4805. The examiner can normally be reached on Monday, Thursday-Friday 7:00-4:30, Wednesday 7:00-1:00.

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, Michael H Wilson can be reached on 571-270-3882. 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.

/Michael J Felton/
Primary Examiner, Art Unit 1747